

An hourglass is the central visual element, with dark sand falling from the top bulb to the bottom bulb. The background is a dark, textured grey.

2017
DSCSA
Update
enforcement
delayed

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Editor's Note

Some of the key milestones contained in the Drug Supply Chain Security Act (DSCSA) are behind us, but the industry has many more to come. In fact, the industry has successfully prepared for only the first major milestone: serialization of packages and homogeneous cases. Yet to come are major milestones for repackagers (2018), wholesale distributors (2019) and dispensers (2020), and then the biggest milestone will occur for the entire industry on November 27, 2023. That may sound like a distant point in time, but when you look at the important decisions the industry and FDA must make—and then the solutions that must be designed, developed, tested and deployed between now and then—you can only conclude that we are behind where the industry should be today.

This version of the PMMI Serialization Playbook contains updates that focus on the issues and challenges associated with the future milestones, while keeping some of the content related to the 2017 serialization milestone. Serialization is the foundation for every one of the future milestones and even the DSCSA deadlines that are aimed at downstream trading partners will cause a big impact on pharma manufacturers related to aggregation, verification and suspect product investigations.

Manufacturers must not take their eyes off the ball just because serialization is “done”. Serialization is only the beginning of the process that will transform this industry into something that the original authors of the DSCSA could not comprehend. This future is filled with risks and potential rewards. The only way to navigate your way from here to there safely is to stay informed and ready to act.

We will continue to refine the contents of the Serialization Playbook as new milestones are met and new issues arise, so check for those updates in the future.



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Section One: The Drug Supply Chain Security Act



Define your role in DSCSA: November 2017 Update

How to read the regs to be sure you're in compliance come December 2018, and how to know which rules will apply to you in different circumstances.

The FDA's June issuance of a draft guidance on product identifier requirements for the Drug Supply Chain Security Act (DSCSA) [\[available here\]](#) has drug manufacturers scratching their heads on how and when to comply.

At a Global Track & Trace event held last week in New Jersey, Gordon Glass, Vice President, Consulting, Excellis Health Solutions, updated attendees with key insights and important lenses through which to view and interpret the likely-to-be-postponed regulations.

DSCSA non-enforcement draft guidance

The full compliance policy still hasn't been published, as it's going through review as a draft to accept challenges, recommendations and a critique. The primary reason for seeking further guidance dealt with enforcement of DSCSA, specifically with regards to manufacturers applying serialization to products. The deadline for compliance here remains Nov. 27 of 2017, but in the draft the FDA states they will not enforce the manufacturers' product identifier requirements under the DSCSA for another full year. While this buys some manufacturers, wholesalers, and repackagers some

more time, there are different ways to interpret the text as it currently exists.

Consider lines 37-41 of the draft guidance:

"In brief, FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogeneous case of products intended to be introduced in a transaction into commerce before Nov. 26, 2018. This represents a one year delay in enforcement of the requirement for manufacturers to affix or imprint product identifiers."

What does this mean? Is the date of introduction of the product into commerce the guiding deadline here? The language remains up to interpretation. A less conservative approach might assume that as long as the batch is released before Nov. 27, 2018, then there is no requirement for compliance, even if shipping that product after the deadline. The more conservative approach is to consider each and every product individually. Which begs the question- what does 'product' might mean batch, unit of product, or unit of sale? It is written into federal regulations, but there is still room for interpretation.



Define your role in DSCSA: November 2017 Update | continued

Importantly the draft guidance for DSCSA distinguishes between compliance policy for manufactures from compliance policy for repackagers, wholesale distributors, and dispensers. So as product travels through the supply chain and is repackaged in altered units, it needs to be re-serialized.

“So, for any product that a manufacturer is going to introduce into commerce – if anything happens to it after Nov. 26 2018, such as repackaging, wholesaling, or dispensing on a different unit level, it should be serialized,” Glass said. “Therefore, the more careful and conservative approach is to consider the individual unit of sale as the product.”

DSCSA Roles

The roles used throughout DSCSA— Manufactures, wholesalers, repackagers, and dispensaries—aren’t necessarily mutually exclusive. Many companies may be acting in multiple roles at a given time, so it’s key to understand what your role is when and where you perform a certain function.

Consider the following: In some circumstances, a company may manufacturer a product and sell that downstream, making it a

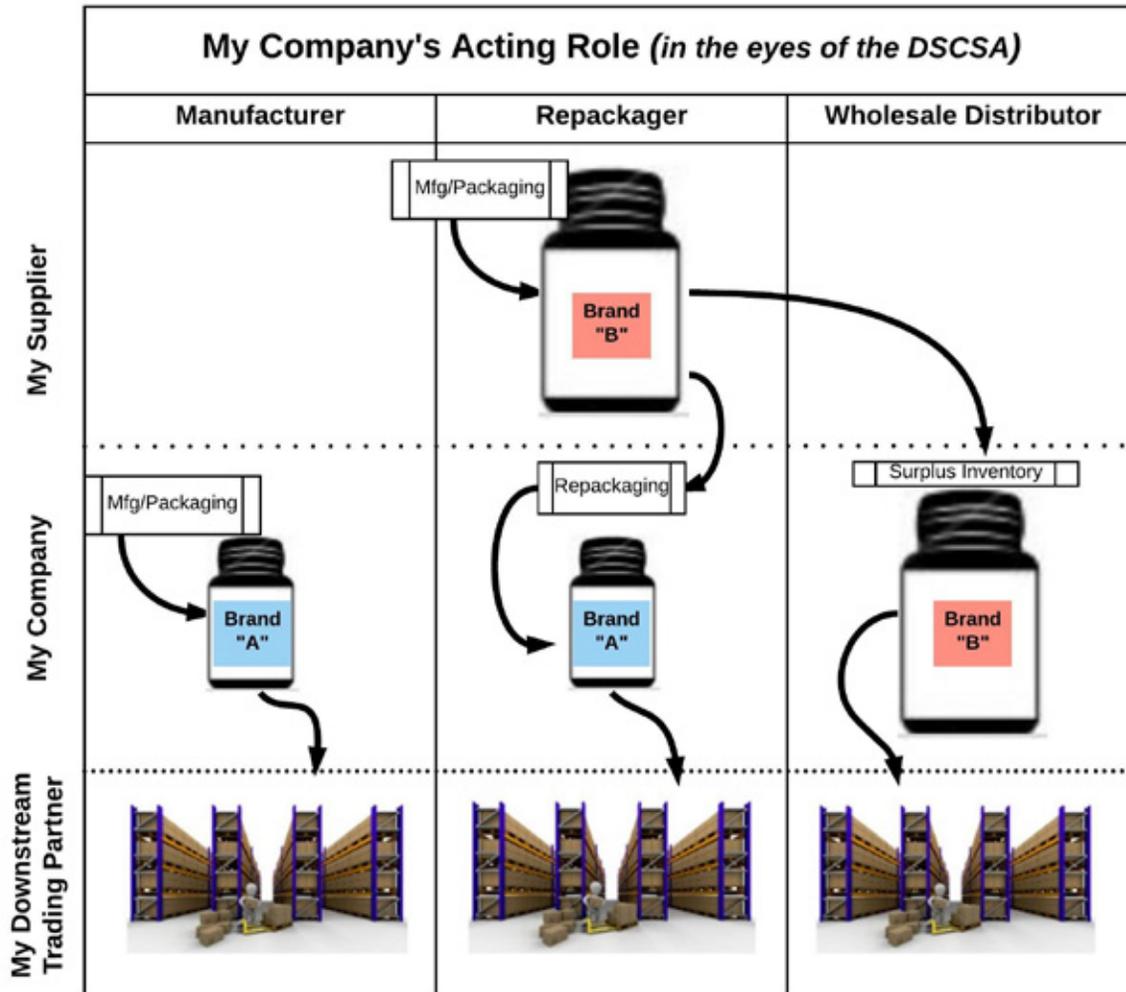
manufacturer. But other times, that same company may purchase product from another manufacturer and repackage it in such a way to make it more convenient for downstream partners, making the company a repackager in that circumstance. But perhaps that company only repackaged half that product, and due to lack of demand, decides to avoid keeping inventory of the product or letting it go to waste by selling it straight through to downstream entities. In that case, the company becomes a wholesale distributor. It’s important to understand what a company’s role might be in each one of those circumstances to know which regulation applies to it.

Consider this key repackager requirement with regards to product identifiers from the DSCSA

‘(2) PRODUCT IDENTIFIER.— “(A) IN GENERAL.—Beginning not later than 5 years after the date of enactment of the Drug Supply Chain Security Act, a repackager described in section 581(16)(A)—“(iv) **shall maintain records for not less than 6 years to allow the repackager to associate the product identifier the repackager affixes or imprints with the product identifier assigned by the original manufacturer of the product.**

The bolded portion above indicates that if a company acts as a

Define your role in DSCSA: November 2017 Update | continued



repackager, it will naturally have been purchasing product. That product, if it's a finished drug product, will be coming in serialized, with a product identifier and serial number on it. If the company then repackages that product, the regulations state that the company must capture the original product identifier on those packages, maintain the information, and associate it with the product identifiers it is putting on its repackaged product.

“This entails capturing the original product identifier on the package, perhaps a Global Trade Item Number (GTIN) or serialized (s)GTIN to initially identify the product as the SNI, capturing that for the product that the company will be consuming (or breaking down for repackaging – once the package is broken, the SNI is broken),” Glass said. “It will then become a new product with new packaging, requiring a new sGTIN.”

How does a company accomplish this? This would require an EPCIS data repository-type model to store the data of the product. In this model the repackager would create an EPCIS standard “Transformation Event”



Define your role in DSCSA: November 2017 Update | continued

that captures the “Product Identifiers” (SNI/sGTINs, expiration date and lot) from the consumed drug, “Product Identifiers” from the newly repackaged drug, marry them together and store them for at least 6 years. This data relationship could be accessed by querying the EPCIS repository through a search of any product identifier involved in the transformation; thus, satisfying the DSCSA requirement for records associating repackaged product. The concept of “Transformation Event” was first introduced in EPCIS version 1.1.

Verification component

Verification is key to various aspects of the DSCSA and is seen throughout the regulations regardless of the supply chain role as manufacturer, repackager, wholesaler, or dispenser.

Below is language considering verification of suspect products, returns requirements, and general requests for verification. This bolded area is similar to language you will see throughout the DSCSA. For wholesalers and wholesale distributors, there’s even simpler language.

Consider the **Manufacturer** Verification Requirements

*“(C) Requests for verification.--Beginning **4 years** after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be manufactured by such manufacturer, a manufacturer shall, **not later than 24 hours after receiving the request** for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request **whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer.***

Consider the **Wholesaler** Verification Requirements

“(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the wholesale distributor and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 6 years after the date of enactment of the Drug Supply



Define your role in DSCSA: November 2017 Update | continued

*Chain Security Act (except as provided pursuant to subsection (a)(5)), **verifying the product at the package level**, including the standardized numerical identifier.*

Consider the **Wholesale Distributor** Verification Requirements

*“(2) **PRODUCT IDENTIFIER**. — Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).*

“Throughout DSCSA, we find similar language linked to product identifiers and standardized numerical identifiers,” Glass said. “The essential point here is that in the case of requiring verification, the verification will always be linked to the product identifier, specifically the serial number, and the Global Trade Item Number (GTIN) and lot and expiry, to make sure what you’re being asked to verify agrees with your records.”

Consider these definitions in DSCSA to better understand relationships between recurring language

*“(28) **VERIFICATION OR VERIFY**. — The term ‘verification’ or ‘verify’ means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.*

*“(14) **PRODUCT IDENTIFIER**. — The term ‘product identifier’ means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.*

*“(20) **STANDARDIZED NUMERICAL IDENTIFIER**. — The term ‘standardized numerical identifier’ means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters. +*

DSCSA overview - The Drug Quality and Security Act

The Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013 as Public Law 113-54. Title II of the DQSA is referred to as the

Drug Supply Chain Security Act (DSCSA) and it establishes new federal requirements for drug serialization, transaction documentation and verification, among other things.

The DSCSA mandates a 10-year long series of milestones for each of the major segments of the U.S. drug supply chain. The first milestone occurred on January 1, 2015 when all participants in the supply chain were required to be licensed, only trade with trading



Figure 2. DSCSA Repackager Timeline

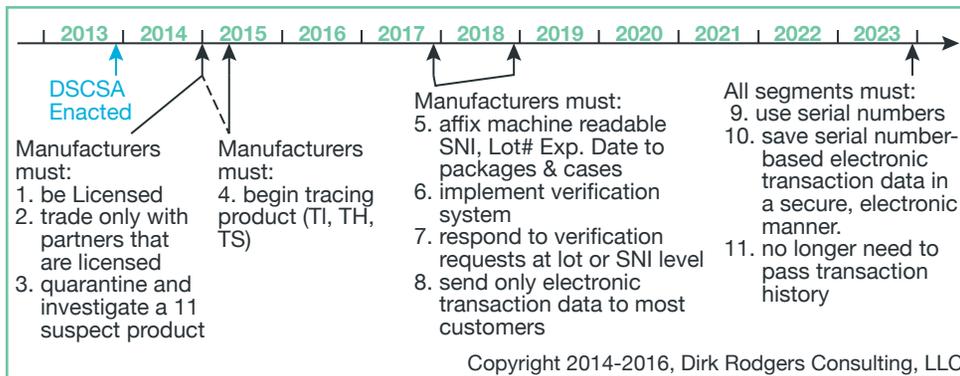


Figure 1. DSCSA Manufacturer Timeline

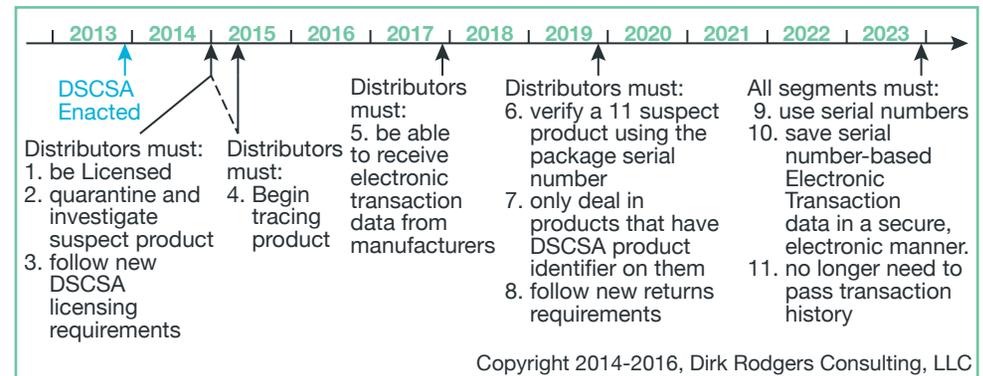


Figure 3. DSCSA Wholesale Distributor Timeline

DSCSA overview - The Drug Quality and Security Act | continued

partners who were licensed, and were to quarantine and conduct investigations into suspect product whenever it was found. On that same date manufacturers, wholesale distributors and repackagers were to begin passing specific sets of transaction documentation in paper or electronic form along with their shipments. That requirement was not enforced by the FDA until May 1, 2015. By July 1, 2015 dispensers were to begin saving the transaction documents they received. That requirement was not enforced by the FDA until March 1, 2016. See figures 1, 2, 3 and 4 for all major DSCSA deadlines for manufacturers, repackagers, wholesale distributors and dispensers. +

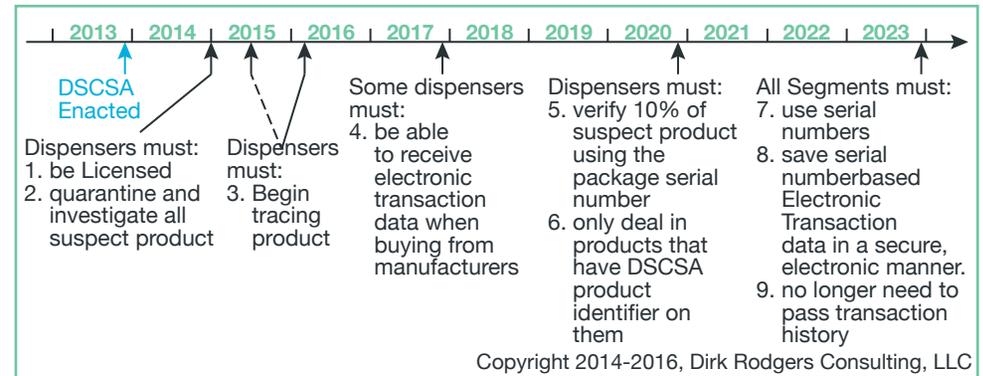


Figure 4. DSCSA Dispenser Timeline

FDA Delays Enforcement of DSCSA November 2017 Deadline: What It Means

On August 3, 2017 the FDA published a draft guidance document announcing that they intend to not enforce the DSCSA's November 27, 2017 deadline for manufacturers to apply the new serialized product identifier on drug packages and verification requirements for one year, but it also contains cascading enforcement delays. This was a major move by the FDA and it has important consequences for the industry.

SERIALIZATION AND VERIFICATION DELAYED

The main purpose of this draft guidance is to announce a delay in enforcement of the requirement to apply the new DSCSA product identifier on drug packages and homogeneous cases. But once the FDA does that, they must also delay enforcement of a number of other manufacturer requirements, including the need to begin verifying drug packages and homogeneous cases using the Standardized Numerical Identifier (SNI) contained in the new product identifier, rather than just the lot number. The SNI contains the serial number.

In fact, almost all of the manufacturer requirements set to go into effect on November 27, 2017 would not be enforced for the proposed one year delay. It is easier to list the requirements that will still go

into effect on that date than to list those that are affected by the delay. Here are all of the new DSCSA manufacturer requirements that would still go into effect on that date and be fully enforced:

- Manufacturers must begin to provide the transaction information, transaction history and transaction statement in electronic format only, except when selling directly to a licensed healthcare practitioner who is authorized to prescribe medication under State law, or to other licensed individuals who are under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice. [see Section 582(b)(1)(C)]

That's it.

CASCADING ENFORCEMENT DELAYS

By not enforcing the manufacturer's requirement to apply the new DSCSA product identifier on all drug packages by this November the FDA is forced to soften some of the deadlines for other segments of the supply chain. And here is where things get a little complex. Repackagers, wholesale distributors and dispensers each have their own DSCSA requirement not to engage in transactions

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FDA Delays Enforcement of DSCSA November 2017 Deadline: What It Means | continued

that involve products that do not have the DSCSA product identifier on them. And each segment also has enhanced requirements for verification of suspect product and saleable returns. Those requirements all kick in on November 27 of 2018, 2019 and 2020 respectively.

Rather than not enforce these deadlines for a comparable one year delay, the new draft guidance makes it clear that these deadlines will still be enforced for product that the manufacturer introduced into commerce with the new DSCSA product identifier before November 27, 2017. For example, as the FDA puts it for the enhanced verification requirements, *“If a product has a product identifier, FDA expects manufacturers, and downstream trading partners to use it in verification”*.

Interestingly, this draft guidance would not affect the requirement for repackagers to apply a DSCSA product identifier to repackaged products by November 27, 2018. That deadline would still stand (for now at least).

So now, according to the draft, enforcement or non-enforcement of subsequent deadlines on downstream trading partners will depend



FDA Delays Enforcement of DSCSA November 2017 Deadline: What It Means | continued

on whether or not the product without a DSCSA product identifier was first introduced into commerce by the manufacturer between November 27, 2017 and November 26, 2018. If it was, then the FDA will not enforce those specific downstream requirements. If the product was introduced into commerce after November 26, 2018 (or if the product has a DSCSA product identifier on it) then the full DSCSA requirements would be enforced. That means we need a way to identify exactly when a given product was first introduced into commerce by the manufacturer.

FDA proposes two ways to do that. One is to use the Transaction Information documents contained within the Transaction History to determine the date of first introduction into commerce by the manufacturer. The other is to use non-DSCSA documentation that clearly describes the products and indicates when the manufacturer introduced them into commerce. These may include things like bills of lading, commercial invoices and shipping invoices, but could include other types not listed. Companies buying drugs after their DSCSA deadline would need to study these documents to determine if products that do not have a DSCSA product identifier on them would be in compliance. You might want to ask ahead of time so you don't receive shipments containing non-compliant drugs.

How will all this impact “grandfathering”? Hard to say, but at least the FDA recognizes that things will now be more complex. The last section of the draft guidance indicates that the FDA intends to address that impact someday when they finally publish the mandated grandfathering guidance document. That will be interesting.

Why doesn't the FDA just announce new deadlines for these sections of the DSCSA? Because the DSCSA is a law and the dates of each deadline contained within it were set by Congress. Only Congress can change the dates, but because the FDA is the agency that enforces this law, they can choose to enforce it selectively—particularly “[t]o minimize possible disruptions in the distribution of prescription drugs in the United States”.

More on the cascading delays

So what is the likely impact on downstream trading partners, including repackagers, wholesale distributors and dispensers?

Under the Drug Supply Chain Security Act (DSCSA), these organizations have specific obligations to only engage in transactions with product that has the DSCSA-mandated product identifier

FDA Delays Enforcement of DSCSA November 2017 Deadline: What It Means | continued

(serial number) on it. And when investigating suspect product or receiving saleable returns, they must verify those drugs with the manufacturer using the standardized numerical identifier (SNI). These obligations kick-in on November 27, 2018 for repackagers, 2019 for wholesale distributors and 2020 for dispensers. These are the “cascading” deadlines.

But now, when the draft compliance policy becomes final, the manufacturer’s one year serialization delay will result in cascading delays at each of these downstream trading partners. The manufacturer’s enforcement delay will cause non-serialized product to legally enter the supply chain between November 27, 2017 and November 26, 2018. Because the FDA would not enforce the manufacturer’s deadline for one year, it would be unfair for them to enforce these cascading deadlines on downstream trading partners.

The manufacturer’s delay is for exactly one year, but notice how the delay in enforcement for downstream trading partners does not have a specific end date. The reason is that no one can predict how long it will take all of the those non-serialized drugs that enter the supply chain from the manufacturers between November 27, 2017 to November 26, 2018, to exit the supply chain. As long as

they are still in the supply chain, they would continue to get a pass on the serialization requirements.

Instead of a specific end-date, the FDA expects downstream trading partners to determine for themselves if the non-serialized product they are dealing with (buying, selling, returning, investigating) entered the supply chain from the manufacturer during that magical year when the FDA used enforcement discretion to allow that to occur.

After your original cascading deadline, if the product does not have the DSCSA product identifier on it, and it originally entered the supply chain from a manufacturer before November 27, 2017 or after November 26, 2018, you should not buy it, you should not return it to saleable inventory (for returns) and if you are conducting an investigation into suspect product, you should strongly consider labeling it illegitimate product. But if it originally entered the supply chain between November 27, 2017 and November 26, 2018, you can treat it as you treat non-serialized product today.

The compliance policy leaves it up to you to “...take steps to determine that the product was introduced in a transaction into commerce by the manufacturer in this timeframe.” But don’t despair.

FDA Delays Enforcement of DSCSA November 2017 Deadline: What It Means | continued

The FDA recommends two ways of doing it:

“At least one of the transaction information documents that compose the transaction history for the product describes an initial transaction date from the manufacturer that occurs between November 27, 2017, and November 26, 2018; or

“There is other documentary evidence created by a trading partner in the ordinary course of business and containing a product description that matches the package or homogenous case of product that is not labeled with a product identifier. In addition, this other documentary evidence should contain a date from which it can be determined that the product was introduced in a transaction into commerce by the manufacturer between November 27, 2017, and November 26, 2018. Examples of such documents may include,

but are not limited to, bills of lading, commercial invoices, and shipping invoices.”

The draft compliance policy makes it clear that, if the drug has a DSCSA product identifier on it, you should follow the un-modified DSCSA when acting on it.

There is one more thing to say about the impact of this compliance policy on repackagers. Repackagers will not get a delay in their November 27, 2018 requirement to apply the DSCSA product identifier to their own packages—at least not from this guidance document. That means the first date that 100% of drugs entering the supply chain will be serialized, will not change. It will still be November 27, 2018 as it would have been before the compliance policy. +



Definitions of key terms

The DSCSA defines 29 key terms that are used within the law. Figure 4 is a list of those terms. This list includes many terms whose DSCSA-specific definitions are different than their typical dictionary definitions. This means that a casual reading of the DSCSA—one that does not include a rigorous studying of these DSCSA definitions—will lead to misinterpretation and misunderstanding. To understand the meaning of any section of the DSCSA the reader must repeatedly recall these DSCSA-specific definitions and apply them appropriately. When interpreting any section in isolation it is important to refer back to the DSCSA definitions of any words used there.

Who is a DSCSA dispenser?

“Dispenser” is one of the terms the DSCSA defines so that the rest of the text does not need to repeat the full list of organizations the authors are referring to. Its definition is only applicable within the text of the law and so it is one of the terms you cannot simply look up in a dictionary to figure out if it applies to you. You must apply the definition contained within the law itself. From Section 581(3), that definition is (bullets added):

Figure 4. Key Terms defined within the DSCSA

- Affiliate
- Authorized
- Dispenser
- Disposition
- Distribute or Distribution
- Exclusive Distributor
- Homogeneous Case
- Illegitimate Product
- Licensed
- Manufacturer
- Package
- Prescription Drug
- Product
- Product Identifier
- Quarantine
- Repackager
- Return
- Returns Processor or Reverse Logistics Provider
- Specific Patient Need
- Standardized Numerical Identifier
- Suspect Product
- Third-Party Logistics Provider
- Trading Partner
- Transaction
- Transaction History
- Transaction Information
- Transaction Statement
- Verification or Verify
- Wholesale Distributor



Definitions of key terms | continued

“ ‘dispenser’—

(A) means

- a retail pharmacy,
- hospital pharmacy,
- a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor,
- or any other person authorized by law to dispense or administer prescription drugs,
- and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).”

This definition covers a lot of companies as well as individuals in our healthcare system. In fact, it covers more companies, more

locations and more people than those covered by the DSCSA definitions of “manufacturer”, “wholesale distributor” and “repackager” combined. Essentially, a “DSCSA dispenser” is any company or individual that is authorized to dispense or administer prescription drugs to a patient. This not only covers the obvious companies, like CVS Health, Walgreens, Rite-Aid, Kroger, WalMart, Target, hospitals, clinics and your corner mom-and-pop pharmacy, but it also includes individual pharmacists, physicians and dentists. If there is a State or Federal law that authorizes a company or individual to dispense or administer prescription drugs to a person, that company or individual is covered in the DSCSA definition of “dispenser” and they are obligated to follow the dispenser provisions of the DSCSA.

Who Is A DSCSA “Repackager”?

The DSCSA defines the term “Repackager” as:

“...a person who owns or operates an establishment that repacks and relabels a product or package for—

(A) further sale; or



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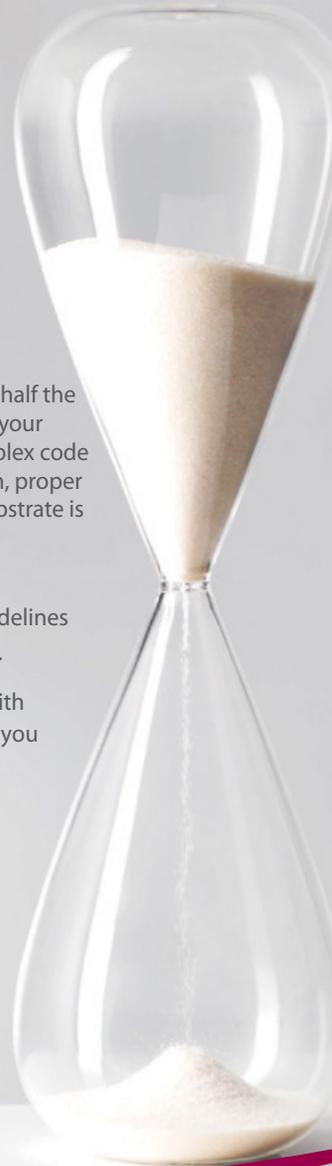


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Definitions of key terms | continued

(B) distribution without a further transaction.”

To really understand this definition you have to apply the DSCSA definitions of the terms “distribution” and “transaction” as well as those of “product” and “package”. These last two definitions are obvious enough that we won't show them, but here are the first two:

“The term ‘distribute’ or ‘distribution’ means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).”

“The term ‘transaction’ means the transfer of product between persons in which a change of ownership occurs. ...”

The many exemptions to “transaction” have been left out here because they are not important to the analysis below.

A “DSCSA Repackager” includes any company that does the typical repackaging of drugs that they buy, repackage and then sell. This is clear by clause (A) in the DSCSA definition of “repackager” where it says the repackaged drugs are for “further sale”. But it

Definitions of key terms | continued

also appears to include contract repackagers as well as in-house repackaging departments, such as those found in a hospital setting. This comes from the inclusion of companies that repackage drugs for “*distribution without a further transaction*”.

As you can see, the definition of “distribution” includes receipt, handling, storage and delivery of a product and it does not require a sale, purchase or trade, although those are also part of the definition. Notice the use of the word “or” in that definition. The term “transaction” means a change of ownership. Since a repackager includes companies who repackage drugs that are for distribution without a further change of ownership, that means the term likely includes contract repackaging and in-house repackaging, because ownership, or the lack thereof, does not affect the repackaging operation.

Transaction documentation

Any change of ownership of drugs in the supply chain after January 1, 2015 must be accompanied by three new documents:

- Transaction Information (TI)
Data describing the product (including the lot number and

expiration date), the transaction and the parties (buyer, seller and recipient) of the current transaction. Until November 27, 2023 the Standardized Numerical Identifier (SNI) is not required. The first wholesale distributor who buys directly from the manufacturer, the manufacturer’s exclusive distributor, or a repackager who purchases directly from the manufacturer, is exempt from including the lot number and the transaction or shipping dates of their purchase.

- Transaction History (TH)
Composed of all TI information for all previous supply chain transactions of the drug going back to the original manufacturer. After November 27, 2023 TH as defined here will no longer necessary in the data passed from seller to buyer.
- Transaction Statement (TS)
Composed of a series of assertions about the authenticity of the seller, the transaction, the product and the contents of the transaction documents.

Until November 27, 2017, these documents may be passed and stored in paper or electronic form. After that date, they must be

Definitions of key terms | continued

exchange in electronic form only. Each trading partner must save these documents for six years after the transaction. The FDA or appropriate Federal or State agency may request to review these documents from certain transactions as part of an investigation into suspect or illegitimate product at any time during those six years. Document owners must be able to retrieve the requested document(s) within one business day (not to exceed 48 hours in case of a weekend or holiday). Dispensers must respond within 2 business days.

DSCSA “Serial Numbers”

Articles written about U.S. pharma serialization are often about the fact that drug manufacturers and repackagers that sell into the U.S. market must put “serial numbers”, or “serialize” their drug packages and homogeneous cases before November 27, 2017, but what exactly does that mean?

Let’s break it down. The Drug Supply Chain Security Act (DSCSA) defines the term “Product identifier” this way:

“PRODUCT IDENTIFIER. —

The term ‘product identifier’ means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.” (Section 581[14])

Back in March of 2010—3 ½ years before Congress passed the DSCSA—the FDA published final guidance called “Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages”, which defined the term “standardized numerical identifier (SNI)” this way:

“The SNI for most prescription drug packages should be a serialized National Drug Code (sNDC). The sNDC is composed of the National Drug Code (NDC) (as set forth in 21 CFR Part 207) that corresponds to the specific drug product (including the particular package configuration) combined with a unique serial number, generated by the manufacturer or repackager for each individual package. Serial numbers should be numeric (numbers) or alphanumeric (include letters and/or numbers) and should have no more than 20 characters (letters and/or numbers).” (See “FDA Aligns with GS1 SGTIN For SNDC”.)

Definitions of key terms | continued

So the DSCSA product identifier is composed of:

- the drug’s 10-digit NDC,
- a unique serial number,
- the lot number and
- the expiration date of the product.

According to the SNI guidance, the “*serial number*” portion of the SNI should be up to 20 characters that can be letters and/or numbers. (Notice that symbols are not allowed.)

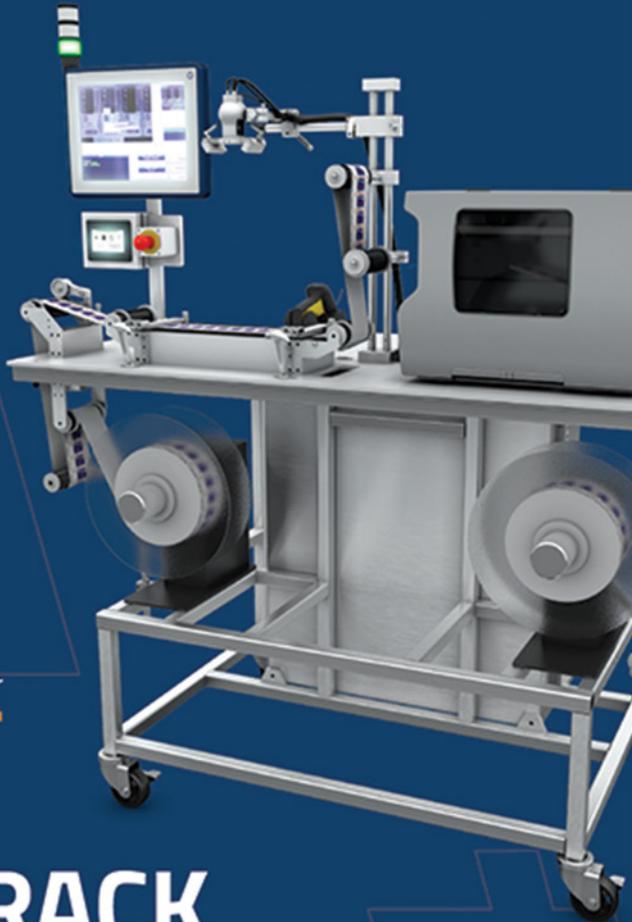
So whenever people talk about “pharma serialization”, or “putting a serial number on a drug package”, or even a “serial number-based repository”, it’s all just shorthand for the DSCSA product identifier. The serial number is actually just one part of that identifier, but people focus in on that part because that’s the part that is new and hard to implement correctly. So please don’t get confused when you hear people using the terms “*serial number*” and “*serialization*” loosely.

“...A machine-readable data carrier that conforms to...”

Congress did not want the FDA to go off and create their own machine-readable data carrier, but they also did not want to prescribe exactly which existing standard should be used. However, they described it in a way that there really is not any question about which standards development organization will be used: the same widely recognized international standards development organization that is used to barcode drugs in the U.S. market today: GS1. From that, we can infer that the most common implementation of the DSCSA product identifier will be a GS1 Global Trade Identification Number (GTIN) (a GTIN-14 to be exact) that encodes an NDC combined with a serial number that conforms to the specification that Congress provided (above) in the format of a GS1 serial number element string that is associated with that GTIN.

The only difference between the serial number specification that Congress provided and the specification of a GS1 serial number is that GS1 would allow some symbols to be used (see table 7.11 of the latest GS1 General Specification), but Congress does not. That is not a big difference and is probably a good idea anyway.

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Definitions of key terms | continued

In Section 582(a)(9) of the DSCSA, “PRODUCT IDENTIFIERS”, includes the requirement:

“...the applicable data—

“(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; and

“(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case...”

This means that the “*machine-readable data carrier*” that carries the DSCSA product identifier must be a 2-dimensional “data matrix” (otherwise known as a “GS1 DataMatrix”, see “GS1 DataMatrix: An Introduction and Implementation Guideline”) barcode. That is pretty specific, although they really did not say it had to be the “GS1” version of the data matrix symbology.

Identification of pharma cases In The U.S.

A case product identification label is the label a manufacturer usually places on each homogeneous case at case-packing time to identify what is inside the corrugated box. A “homogenous



Definitions of key terms | continued

case” is a case that contains units from a single NDC and all units are from a single packaging lot. The product identification label should not be confused with a shipping/logistics label, which, if it exists, is applied at the time of shipment and contains information about the destination.

Typically, cases that are shipped from a higher-volume manufacturer to a larger wholesale distributor will be placed onto a pallet. The pallet often has cases of multiple products, and even different homogeneous cases of the same product can contain different lot numbers. You can sometimes even find a Non-homogeneous case mixed in with the homogeneous cases. Further, cases on the same pallet can actually be fulfilling different purchase orders submitted by the buyer. All of these variations complicate the job of the receiving clerk.

Before the DSCSA was enacted, cases were rarely serialized by the manufacturer. That is, for most products, neither the typical case product identification label nor the typical shipping/logistics label contained a serial number, unless perhaps one was applied for internal purposes by UPS, Federal Express or other courier. But a few manufacturers did apply a Serial Shipping Container Code (SSCC)—which contains a serial number—to some of their

shipping/logistics labels. Scheduled drugs were a likely candidate for an SSCC because the Drug Enforcement Administration (DEA) recommends not printing any kind of product identification on the outside of their shipping containers.

In the DEA’s Controlled Substances Security Manual, under the heading “Common or Contract Carriers” it says:

“Although not required, precautions such as securely wrapping and sealing packages containing controlled substances and using unmarked or coded boxes or shipping containers are strongly recommended for guarding against in-transit losses.”

It’s kind of hard to ship and “unmarked” box to a customer these days, but an SSCC is a nice way to keep track of which shipping case contains which product when it is referenced in an Electronic Data Interchange (EDI) Advance Ship Notice (ASN). That way, those who have access to the ASN will know what it inside, but others will not. The SSCC is composed of only a company identifier and a serial number that is unique to that company and that case.

The DSCSA contains new, specific language about how manufacturers must mark cases after November of 2017 (2018 for

Definitions of key terms | continued

Repackagers). The FDA has since announced that they will not enforce this requirement until November of 2018. After those dates, all homogeneous cases packed by manufacturers and repackagers in the supply chain must have a DSCSA “Product Identifier” on them. After November of 2019 wholesale distributors may not buy or sell products that do not have a DSCSA Product Identifier on them, and the same goes for dispensers after November of 2020 (with exceptions introduced by the FDA announcement that they will not enforce parts of this requirement).

A DSCSA “Product Identifier” on a homogeneous case is the NDC and serial number (together known as a Standardized Numerical Identifier), the lot number and expiration date of the product contained inside. These data elements must be presented on the case in human readable form as well as in a 2-dimensional Datamatrix or linear barcode.

Congress made no provision in the DSCSA for the DEA’s recommendation to not mark the outside of cases containing controlled substances, so after these deadlines, companies who were previously using an SSCC to provide some level of concealment of the contents of their cases may be forced to expose those contents. To continue that practice, packing one or more properly marked

homogeneous case(s) inside an overpack box marked with an SSCC is probably the best solution. But with this approach you might find that wholesale distributors expect you to provide accurate aggregation data (a.k.a., serial number-based packaging hierarchy data) in your ASN so they can tell exactly what is inside before they open the overpack box.

The DSCSA product identifier on drug packages

According to the Drug Supply Chain Security Act (DSCSA), manufacturers must apply a new “Product Identifier” on all of their prescription drug products by November 27, 2017 (Repackagers by that date in 2018) (to see how these dates were impacted by the announcement that they would not enforce this requirement until November of 2018, see “FDA Delays Enforcement of DSCSA November Deadline: What It Means”).

The DSCSA Product Identifier is defined this way:

“PRODUCT IDENTIFIER.—

The term ‘product identifier’ means a standardized graphic that includes, in both human-readable form and on a machine-readable

Definitions of key terms | continued

data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.” (Section 581[14]

Section 582(a)(9) of the DSCSA, “PRODUCT IDENTIFIERS”, in part says:

“...the applicable data—

“(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; ...”

So we know that the drug’s NDC and serial number (known as a Standardized Numerical Identifier, or SNI) must be presented on the label of every drug package along with its packaging lot number and expiration date in two ways:

- Encoded within a 2-dimensional (2D) Datamatrix barcode, and
- Printed in human-readable form

In the DSCSA, Congress allows the FDA to decide which technologies

beyond a Datamatrix barcode can be used to carry the DSCSA product identifier.

If the Datamatrix turns out to be too slow for certain high-volume drug products or runs into other problems, companies can petition the FDA to allow them to use something else, like, perhaps Radio Frequency Identification (RFID).

The Standardized Numerical Identifier (SNI)

In January of 2010 the FDA published guidance on their Standardized Numerical Identifier (SNI) for prescription drug packages. This was right on time since the FDA Amendments Act of 2007 gave the agency 30 months to develop a standard for SNI and they published, almost to the day, 30 months later.

The SNI guidance establishes the way companies wishing or needing to add a serial number to their drug packages or homogeneous cases should do it. For most prescription drugs, it described a serialized National Drug Code (sNDC). An sNDC is just what it sounds like, a serial number combined with the drug’s existing 10-digit NDC, including the particular package configuration.

Definitions of key terms | continued

The serial number “...*should be numeric (numbers) or alphanumeric (include letters and/or numbers) and should have no more than 20 characters (letters and/or numbers).*”

The final guidance was not radically different from the draft guidance that the agency published under the same name in January of 2009. In fact, the only really important difference is how the serial number portion of the sNDC was defined. The obvious difference is an increase in length from 8 to 20 characters, but more subtle and significant changes are that the serial number was changed from a proposed fixed length to a variable length field, and from numeric-only to optionally alphanumeric.

These are important changes because, taken together, they resulted in bringing the FDA sNDC into full alignment with the GS1 definition of a product serial number using Application Identifier (AI) 21, and an SGTIN in RFID tags. This change also technically resulted in a mis-alignment in the name “Standardized Numeric Identifier” since the serial number would no longer have to be numeric.

This alignment with SGTIN was a common recommendation in the many comments submitted in response to the FDA’s Request for Comments that was issued at the same time the draft SNI guidance

was published. The FDA no doubt appreciated these comments and they retained a reference to the GS1 SGTIN as their justification for fulfilling the FDA Amendments Act (FDAAA) requirement that the SNI “...*be harmonized...with internationally recognized standards for such an identifier.*” The final guidance points out that “...*use of an sNDC is compatible with, and may be presented within,...a serialized GTIN (sGTIN).*...”. Clearly this was just an example and not necessarily the only FDA-sanctioned way to represent an NDC-based sNDC. That is the FDA did not mandate the use of GS1’s SGTIN. On the other hand, it is likely to be the only one we’ll see in actual use within the supply chain.

It’s important to mention here another characteristic of the final SNI guidance, for no other reason than to remind everyone that the sNDC is not the only SNI that the supply chain will need to deal with. The FDA officially refers to “*other recognized standards, such as ISBT 128*”, the standard of the ICCBBA for the uniform container labeling and identification of blood and blood components (blood, tissue and organ products), as the SNI for those products. These products are specifically exempt from the Drug Supply Chain Security Act (DSCSA). But this is really the only reason we still need the term “SNI”. “sNDC” is only one of the two primary forms of SNI.



Definitions of key terms | continued

The SNI Guidance itself was not a mandate that all drugs be serialized. At the top of each page the FDA included the header “Contains Nonbinding Recommendations”. It was just a standard that could be used in subsequent regulations, which it was in 2013 in the DSCSA where serialization was mandated. +



Is your drug exempt from the DSCSA?

In truth, no one can answer that question for you. Even the FDA can't answer that question for you. We can't answer that question for you. Only YOU can answer that question based on your knowledge of your product's characteristics and a careful reading of certain provisions of the DSCSA. We can help you with that part.

Application of the DSCSA

In general, many of the provisions of the DSCSA that are related to the movement of product in the supply chain apply only to prescription drugs “...in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution)”. So if the FDA does not consider your drug to be a prescription drug (“Rx Only”), then it does not need to comply with the DSCSA.

Formally, a “prescription drug” is defined by the law to as a drug for human use that is subject to the Food, Drug and Cosmetics Act, Section 503(b)(1). This apparently exempts drugs that are strictly for use only in animals.

Further, if your drug must be sold “behind the pharmacy counter” in some States, that does not make it a prescription drug. Those

are State laws and the FDA does not pay attention to State laws when regulating drugs nationally. Even if some States require your drug to be dispensed by a pharmacist only to those who have a physician-issued prescription, if the FDA has not classified it as a prescription drug, then you are off the hook when it comes to following the DSCSA. In these cases, the FDA considers your drug to be Over-The-Counter (OTC), and therefore exempt.

If your product is a device—even if the FDA requires your device to be dispensed only with a physician-issued prescription (“Rx Only”)—then it is not a prescription drug and therefore it is not covered by the DSCSA.

But be careful here. Some devices are classified by the FDA as drug-device or biologic-device Combination Products (CPs). In that case, if the FDA has determined that the Primary Mode of Action (PMOA) of your product is as a drug or a biologic, then your CP is not exempt from the DSCSA (unless the FDA has already informed you that your CP must be labeled with a Unique Device Identifier, UDI). If your device has a drug or biologic built into it or in combination with it, you should check with the FDA office of Combination Products to make sure you understand how they would classify it before deciding to ignore the DSCSA.



Is your drug exempt from the DSCSA? | continued

Other exemptions

The elimination of drugs that are only for use in animals, OTC products, and devices narrows the application of the DSCSA nicely. But we can go further. Here is a list of products that are explicitly exempt from the DSCSA. That is, they are not considered DSCSA “products” and are therefore not required to follow the DSCSA regulations:

- Blood or blood components intended for transfusion;
- Radioactive drugs or radioactive biological products that are already regulated by the Nuclear Regulatory Commission (NRC) or by a State under an agreement with the NRC;
- Imaging drugs;
- Medical gases;
- Appropriately marked homeopathic drugs;
- Compounded drugs (Compounded drugs are now regulated by the Compounding Quality Act, which is Title I of the DQSA);

- Intravenous products that are intended for the replenishment of fluids and electrolytes or calories;
- Intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
- Products intended for irrigation, or sterile water, whether intended for such purposes or for injection.

Special cases

Any product that is recognized by the FDA as a product that requires humans to obtain a prescription before they may receive it, and as long as it is not on the list above, you can be reasonably sure it must follow the DSCSA.

In this case, you should already have a National Drug Code (NDC) assigned to your product, which is necessary to properly identify your product under the DSCSA. If you don't have an NDC for your product, then there is a disconnect somewhere. Either you are mistaken that your product is licensed by the FDA as a drug or biologic, or you have not yet registered your product with the FDA. In either case, maybe your product is not a drug or biologic. If not,



Is your drug exempt from the DSCSA? | continued

then you don't have to follow the DSCSA. Check with the FDA.

Exempt transactions

Even if your product is not exempt, you may still be exempt from following many of the provisions of the DSCSA under certain types of transactions. In most cases, these are products that would need to follow the DSCSA (not exempt) under other types of transactions, but in these transactions, they are exempt. Here is a short list of transactions that manufacturers might be involved in and that are not considered "DSCSA transactions" and are therefore exempt from following the DSCSA, but only while in these specific transactions:

- Intracompany distribution of any product between members of an affiliate or within a manufacturer;
- The distribution of product samples by a manufacturer or a licensed wholesale distributor;
- The distribution of "medical convenience kits", a collection of finished medical devices, which may include a drug product or biological product, assembled in kit form strictly for the

convenience of the purchaser or user, if:

- the kit is assembled in an establishment that is registered by the FDA as a device manufacturer;
- the kit does not contain any controlled substance; and
- the kit manufacturer purchased the drug or biologic product contained in the kit directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased it directly from the pharmaceutical manufacturer, and the primary container label of the drug or biologic product contained in the kit is not altered;
- and the drug or biologic product contained in the kit is:
 - An intravenous solution intended for the replenishment of fluids and electrolytes;
 - A product intended to maintain the equilibrium of water and minerals in the body;
 - A product intended for irrigation or reconstitution;

Is your drug exempt from the DSCSA? | continued

- An anesthetic;
- An anticoagulant;
- A vasopressor; or
- A sympathomimetic;

As soon as you determine that your product is exempt from the DSCSA make sure you notify all trading partners who will receive that product to provide them with your rationale. Wholesale distributors, 3PLs, repackagers and dispensers will all need to decide if they agree with you, or they may expect you to provide them

with the DSCSA transaction documentation when they receive your product.

If they do not agree with your determination, they may not be willing to accept it because they would feel obligated to follow the DSCSA, even if you do not, and you would not be able to give them the documentation they need to comply. That would be a disaster for you. Interpretations will vary, especially early on, and the FDA may not be willing to fill the role as an arbiter in these cases.

Only you can make the final determination if your product is exempt from the DSCSA. You need to fully understand the DSCSA to do that. +



What is a product identifier?

- A unique identity for individual prescription drug packages and cases, which will allow trading partners to easily trace drug packages as they move through the supply chain.
- Includes the product's lot number, expiration date, national drug code (or NDC), and a serial number. The serial number is different for each package or case. This creates a unique identifier – human and machine readable – to enable product tracing throughout the supply chain and enable all trading partners to better detect illegitimate products within the supply chain.

The compliance policy outlined in the draft guidance applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017 and November 26, 2018.

While manufacturers work to meet product identifier requirements, they must comply with other DSCSA requirements. +



July 2017 UPDATE: DSCSA enforcement delay information for you to weigh in on *FDA Issues Draft Guidance Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*

On June 30, 2017, FDA issued a draft guidance for industry, Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy. This guidance informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, the FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. +

[Access the June 30, 2017 Draft Guidance here](#)



DSCSA's one-year delay, and what it means to pharma manufacturers

Adapted from articles published in July, 2017 *Healthcare Packaging* and *Automation World* magazines

The FDA's recent draft guidance document pushes back enforcement for the Drug Supply Chain Security Act's product identifier deadline. But experts warn that nothing has really changed. Here's what pharma companies need to know.

The FDA's latest draft guidance on the Drug Supply Chain Security Act's (DSCSA) product identifier requirements gives pharmaceutical manufacturers a little breathing room, as enforcement of the original November 2017 deadline gets pushed back a year.

The FDA issued a June 30 draft guidance document saying, "FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of products intended to be introduced in a transaction into commerce before **November 26, 2018**. **This represents a one year delay in enforcement of the requirement** for manufacturers to affix or imprint product identifiers. For the products that manufacturers introduce in a transaction into commerce before November 26, 2018, without a product identifier, FDA also does not intend to take action against manufacturers who do not use a product identifier to verify such product at the package level."

But this news should not inject indolence into the industry because, the reality is, nothing has changed except that companies won't be facing enforcement of the requirements—until November of 2018.

To be clear: the law remains intact and this should not be seen as a sign that the FDA is easing off the industry—at all. In fact, I asked a few industry experts what this change means, and it seems to be a "friendly gesture" by the FDA to give the companies that are way behind in compliance some more time. But there are no free rides here. In fact, it just means stricter enforcements in the future.

"It is more than likely that this suspension of enforcement for 12 months will entail a complete zero-tolerance approach in 2018 as anyone not in compliance would technically have been in violation of the law for a full year," said Dave Harty, vice president of professional services at Adents, a maker of unit identification serialization and traceability software.

"In short, pharmaceutical companies and CMOs producing prescription medicines will not be penalized if they do not meet the upcoming serialization deadline of November 2017," Harty explained. "But, and this is very important, the original deadline remains unchanged. **You still are legally required to serialize prescription medicines**

DSCSA's one-year delay, and what it means to pharma manufacturers | continued

intended for distribution to the American market before the end of the year.”

Adents official statement on the DSCSA's delay:

“Though the law itself remains unchanged (a formal amendment would require an act of Congress), news recently broke that penalization for the law’s key facets – most crucially, the necessity of printing a unique product identification code on all Rx units of sale and homogenous cases distributed domestically – will be put off until November 2018. Leading up to the announcement, however, an alarmingly high number of pharmaceutical manufacturers and CMOs did not have serialization solutions in place sufficient to meet the initial November 2017 deadline.”

“With the postponement, companies who have not yet completed the serialization process stand to gain the most,” said Christophe Devins, Adents’ CEO.

compliant with the law or not?’ The FDA announcement means it will not enforce any penalties on manufacturers for non-compliance of the serialization requirement, but it still makes good business sense for manufacturers to continue to prepare their production lines for serialization.”

“This law enforcement waiver will allow all pharmaceutical companies in the U.S. to become compliant with the opportunity to install custom serialization systems that do not compromise line efficiency. OPTEL has been involved in the FDA’s public hearings since November 2016. We stood in front of the FDA commissioner to explain the reality of all solution providers: November 2017 compliance represented an unprecedented challenge that was technically unachievable.” - Jean-Pierre Allard, Chief Technology Officer — Traceability with Optel Group.

Peter Sturtevant, senior director of industry engagement for GS1 US, agrees. “Even though it may seem like manufacturers have the luxury of an additional year, the FDA’s enforcement delay has no direct impact on the Act itself. It would require an act of Congress to change DSCSA,” he said. “The question for manufacturers now becomes, when November 27th approaches, ‘do we want to be

Indeed, the law is not expected to change, even though there’s been industry speculation that the Trump administration is angling to eliminate regulations that burden businesses unnecessarily. But this law is not about creating problems for pharma companies. Rather, it is meant to protect the consumer by keeping counterfeit products out of the supply chain.



DSCSA's one-year delay, and what it means to pharma manufacturers | continued

The next obvious observation, however, is how this will impact the downstream deadlines for repackagers (November 2018), distributors (November 2019) and dispensers (November 2020), which must comply with the same serialization mandates.

“There is a strong possibility downstream trading partners will experience cascading discretionary delays as a result of this announcement, as we saw this happen the last time there were discretionary enforcement delays on two different occasions for phase one of DSCSA for the lot-based requirement,” Sturtevant said.

The bottom line here is that nothing has changed, because, as noted, Congress set the deadlines and only Congress can change

the deadlines. Rodgers pointed out that since the FDA is the agency that enforces the law, “they can choose to enforce it selectively—particularly to minimize possible disruptions in the distribution of prescription drugs in the United States.”

For now, the FDA—and hopefully the industry—is still on track to meet the 2023 deadline for full serialization interoperability with track and trace for all supply chain trading partners.

So, while pharma manufacturers now may be able to afford to take a breath... it's in their best interest to keeping moving forward on this—quickly. +



Here are 10 reasons to serialize now:

Brand protection—shine a light on cargo theft, pharmacy theft, counterfeiting, and diversion.

Chargeback or discount reconciliation—the specific sale price can be identified, and duplicate requests for discount or chargeback discovered.

Reverse logistics—aid recalls, returns, withdrawals, and shrink/loss recovery.

Inventory control—better insight into raw materials ordering and process scheduling.

Workflow processes—increased productivity through reduced physical handling and decreased errors.

Marketing—ability to build consumer trust through verification (authentication) via online portal or 800 number. It's not part of the U.S. law, though it could be part of the legal framework in other countries.

Asset visibility—opens the door to the possibility of logistics transparency, including cold chain monitoring.

Order-to-cash—increasing visibility of exactly what items were delivered to a specific customer and where the goods traveled, for proof of delivery and authorization of payment.

Perfect order fulfillment—improving visibility of the exact item and quantities delivered and catching incorrect orders (caught when an attempt to authenticate an item shipped in error is made).

Returns—ability to detect returns that were not originally sold to the customer.

Recalls—with the addition of the expiration date and serial number in the barcode, companies can more readily determine if they

Wider implications:

With an estimated 60% to 80% of raw ingredients for drug manufacturing coming from foreign shores, serialization can be coupled with track-and-trace of raw materials from receiving to finished product delivered to end user (hospital, pharmacy, patient). This helps batch recall by tracing back to original ingredients, and providing day and work shift identification.

Here are 10 reasons to serialize now: | continued

have, or have had, a particular lot of a product in their inventory.

Consignment inventory—reporting the explicit serial number of an item that is held in consignment inventory can increase trust levels between trading partners in terms of tracking accuracy.

Competitive readiness—as mergers/acquisitions open new markets, or Marketing seeks to expand to another region of the world, your organization will be able to react faster and more efficiently by being able to meet local regulations anywhere.

Design flexibility

Serialization should deliver organizational flexibility to respond to any global business opportunity. If properly implemented, it should allow manufacturers to prepare a correctly labeled package to meet country rules and regulations, now and in the future, with as little customization as possible.

The key is flexibility. Don't design and build a system that complies with only U.S. federal regulations, but can't handle requirements in other countries from the start.

STANDARDS AT THE CORE OF TRACK-AND-TRACE		
	EXAMPLE	STANDARD
EPCIS	WHO Ship-From, Ship-To, Buyer, Seller	GLN
	WHAT Products, Logistics Units, Assets, Relationships	GTIN, SSCC, GRAI, GIAI, GSRN
	WHERE Postal Locations, Warehouses, Floors, Rooms	GLN
	WHEN Time and Date	
	WHY Commissioning, Packing, Shipping, Receiving, Dispensing	Business Step

Source: GS1 US

 THE GLOBAL LANGUAGE OF BUSINESS

GS1 standards at the core of track-and-trace

Here are 10 reasons to serialize now: | continued

Key questions to consider at this stage.

- Which lines produce which drugs, and where are these drugs sold?
- How are the drugs shipped today? And how long is product left sitting in storage versus immediate delivery?
- Are there any current plans to expand distribution to other regions of the world or relocate manufacturing?

Bake in flexibility-- leverage local resources to deliver enterprise-wide compliance, layer encoding, local serial number management, enterprise systems, and country regulatory reporting.

Beyond compliance with U.S. law, the business case for a global serialization program is strong, and has already proven to be successful in many other industries, including apparel, auto parts, and consumer electronics. +



Industry collaboration

“For almost a decade, members of the pharmaceutical supply chain industry have been working together to enhance track-and-trace initiatives, address policy, and improve patient safety and security in the supply chain through the use of standards. With the passage of H.R. 3204, these efforts have come to fruition in a national policy that will ensure a consistent, standardized approach is taken by the pharmaceutical industry to further combat counterfeiting, theft, and diversion, and to share critical information across the supply chain. The federal law will replace a potential patchwork of 50 state regulations, which is critical for manufacturers, wholesalers, and dispensers as they can leverage their hard work that culminated in the publication of the industry guideline earlier this year (“Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes to Support Serialization, Pedigree and Track & Trace”). GS1 Healthcare US and our industry partners are ready to further the collaboration to now align the guideline to comply at the federal level, along with supporting industry education and workshops.”

—Bob Celeste, Senior Director, Pharmaceutical Sector Lead, GS1 US, rceleste@gs1us.org

With so many players in the supply chain poised to exchange data, it's important that the industry coalesce around a common set of standards to ensure interoperability and scalability of integrations.

Through GS1 standards, companies have the ability to build solutions with real value and without having to go through a whole lot of data transformation, remapping, and reformatting. GS1 standards enable companies to drive out the uncertainty and cost associated with developing solutions.

At the end of the day, the goal is to make sure that the information everyone publishes across the supply chain is reliable and consumable by everyone else. The only way to accomplish that is to have a common set of standards to which everyone adheres.

What are GS1 standards?

GS1 is an international, nonprofit organization that publishes a system of supply chain standards, now in use by more than 2 million companies operating in 145 countries, designed to work together in concert. Companies who plan to use GS1 standards must contact their local GS1 organization and discuss their needs.

GS1 standards are truly global and are applied across multiple industries, including the grocery supply chain and the general merchandise supply chain. This is a bonus for pharmacies and wholesalers that participate in these supply chains.



Industry collaboration | continued

Here is a partial listing of GS1 standards that you may benefit from adopting if you haven't already:

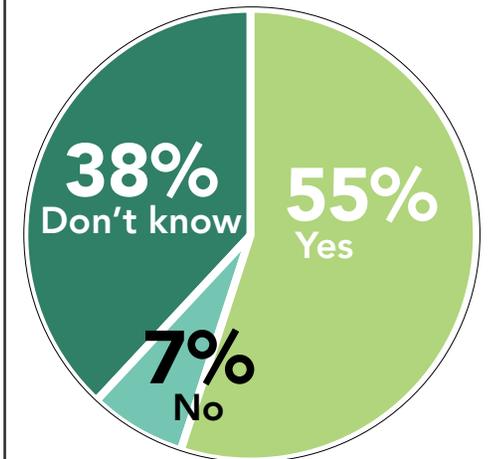
- GS1 GLN Global Location Number
- GS1 GTIN Global Trade Item Number
- GS1 UPC barcode symbology
- GS1 element strings encoded in a barcode symbology such as GS1-128, GS1 DataMatrix, GS1 DataBar
- GS1 EANCOM EDI standard (Not used in the U.S. pharma supply chain)
- GS1 EPC RFID in frequencies including UHF and HF
- GS1 Electronic Product Code Information Services (EPCIS)
- GS1 Drug Transaction Messaging Standard (DPMS)
- GS1 Global Data Synchronization Network (GDSN)

Any company wishing to make use of GS1 standards— including barcodes, identifiers, and data exchange standards— must first obtain a GS1 Company Prefix or “GCP.”

Normally a company obtains a GCP by applying for GS1 membership in the country where your company headquarters resides. But if your company makes drugs for the U.S. market, regardless of where you are located, you will need to obtain a special GCP from GS1 US (the local affiliate, or Member Organization, M.O., of GS1).

Currently, drugs sold into the U.S. must contain a linear barcode that encodes your U.S. Food and Drug Administration (FDA) National Drug Code (NDC).

PLAN TO USE GS1 AT THE PACKAGE LEVEL



Source: 105 pharmaceutical manufacturers and contract packagers surveyed October 2012 by *Healthcare Packaging*.

GS1 is clearly going to be the standard at the package coding level, and from all evidence, at the information exchange layer as well.

Industry collaboration | continued

To encode that NDC into a GS1 barcode symbol, you must register with GS1 US so your GS1 GCP matches the FDA-assigned Labeler Code that is a part of every NDC. Only GS1 US can assign/register a GCP that matches your FDA-assigned Labeler Code.

It's important to note that a company could easily end up with more than one GCP. For example, if a drug company from Switzerland merged with a company in France that sells globally, one GCP could come from Swiss GS1 member organization, and one issued by the France GS1 member organization. Another GCP could be issued by GS1 US for use in identifying drugs sold into the U.S. that use the NDC.

The parent company should view these GCPs as enterprise resources and manage them centrally rather than in silos. Companies should establish governance for their GS1 registration and use.

What is a GCP used for?

The GS1 Company Prefix (GCP) is at the core of the GS1 System, the set of standards used globally for identification of products, services, assets, relationships, and even documents.

Building your serialization strategy using GS1 standards will help you

comply in as many countries around the world as possible.

Brazil, India, and South Korea have explicitly named GS1 identification standards in their regulations or in their guidance.

The GCP can vary between six and 10 digits in length, and may have a different variation depending on the number of SKUs the manufacturer wants to track. The GCP includes a country code and a unique ID for the company. When the U.S. NDC is used, the 12-digit GTIN will begin with a 3.

Here is a list of GS1 keys that are based on the GCP:

GTIN (Global Trade Item Number)—available in 8-, 12-, 13-, and 14-digit formats, and the serial numbers associated with them when forming a serialized GTIN (sGTIN)

GLN (Global Location Number)—13 digits

SSCC (Serial Shipping Container Code)—18 digits

GRAI (Global Returnable Asset Identifier)—14 digits, first digit is always a zero plus optional serial number up to 16 additional characters



Industry collaboration | continued

GIAI (Global Individual Asset Identifier)—up to 30 characters
GSRN (Global Service Relation Number)—18 digits

GDTI (Global Document Type Identifier)—13 digits plus optional serial number up to 17 additional digits

GINC (Global Identification Number for Consignment)—up to 30 characters

GSIN (Global Shipment Identification Number) — 17 digits

GS1 SSCC (Serial Shipping Container Code) used to track pallets, totes, and other non-homogenous logistic units.

GS1 Core Business Vocabulary (Standard which specifies Business Steps and Dispositions).

Each type of GS1 key includes a numeric value that is combined with the GCP to form a specific instance of the key. It is the assignment of these numeric values that must be managed in some way. The total length of the key minus the length of the GCP determines how many digits are available to the owner to assign specific instances of the key. These digits represent the “key space” for a given key. The shorter the GCP, the larger the key spaces of each key type will be. +

Serialization readiness: What about partial containers?

Often forgotten among all the issues addressed when preparing the serialization of a first packaging line is how to handle partial containers. Frequently, the partial container is that very last packaged case for which there is not enough product to completely fill it. When this case is added to a pallet, it will end up being partial as well. This also applies to other packaging inside a case, such as bundles or trays. For the purpose of this article, we will use the case as our example.

The GS1 “GTIN and Serial Number” (widely referred to as the sGTIN or Serialized Global Trade Item Number) is the serial number format required by most regulations. For most manufacturers, the introduction of the GTIN on their labels coincides with their serialization effort. It is precisely the GTIN introduction that is the issue with partial containers.

In the GTIN structure, the first digit (called the Indicator Digit) must be different for each packaging level. This means that, for a particular product, each packaging level is labeled with a different GTIN. Also, GS1 clearly states that a GTIN must refer to a specific product type, concentration, size, and package configuration (which includes the quantity of items).

Another standard, which logically follows the GTIN implementation, is the GDSN (Global Data Synchronization Network). In a nutshell, the GDSN is the standard way to store and display all the attributes of each GTIN a company manufactures, distributes, or sells. The number of children items is one of those attributes.

To summarize, the sGTIN for the case is an indication that the case is filled with the full quantity that the GTIN is intended to identify. For this reason, a GTIN—whether serialized or not— should not appear on the outside of a partial (or mixed) case. This is to ensure that a partial case is not inadvertently shipped to a trade partner (and confused or charged as a full one).

How is the industry handling this?

At the moment, there is guidance from the GS1 General Specification version 14 and Healthcare Distribution Management Association (www.healthcaredistribution.org) on how to handle partial containers in a serialized environment. Here is a list of some methods that have been deployed or that are possible:

Serialization readiness: What about partial containers? | continued

A. SSCC Identification

An SSCC (Serial Shipping Container Code) is used to track logistics items and link the container to additional information, in electronic or paper form, regarding the contents. The SSCC contains a company's global company prefix (GCP), followed by a unique serial number to identify the specific package.

SSCC are fully EPCIS-compatible (for the aggregation record) and, once in the warehouse, it becomes 100% clear that the partial container is “different” from the others. An SSCC allows the case and its contents to be indicated within an Advanced Shipping Notice (ASN), transaction document or Advanced Shipping Notices (ASN), and/or EPCIS events, which is where the recipient can identify the details, including quantity.

The use of SSCC for partial cases is recommended by GS1 in their General Specification and by HDMA in guidance for barcoding and serialization.

B. SGTIN with a “Partial” mention

This method consists of manually adding a mention, using a label

or even a marker, over or adjacent to the case label. If the Packaging Execution Solution (PES) is not able to print a different label template for a partial container, this is the least that can be done.

This method is not GS1-compliant (as the same GTIN is utilized for different package sizes). However, the “Partial” mention is meant to avoid confusion in the warehouse, where the container (as is, or split into smaller ones) will eventually get an SSCC before being shipped out. Hence, trade partners will never see the SGTIN.

C. SGTIN with Accurate Printed Quantity

This method is identical to the last one but with the accurate quantity printed on the case label.

Since a case label normally states the quantity (both in a barcode and in human-readable text), using the same label template for both complete and partial containers poses another problem. In this case, instead of only adding a “Partial” mention, printing the accurate quantity on the partial container (if the PES allows it) is a step in the right direction toward accurate printed information.

Serialization readiness: What about partial containers? | continued

D. Different GTIN with the “9” as the indicator digit

In the GS1 rules, the GTIN Indicator Digit (left most of a 14-digit GTIN) can be assigned any digit from “1” to “8”. The “9” is reserved to identify a container that has a variable quantity, such as a partial container and zero is reserved for saleable units. GTIN for saleable units may include point-of-sale data carriers that drop the indicator digit and use a 13-digit or shorter GTIN.

The use of indicator digit number 9 is used for variable unregularly sized items, such as a case of apples. When the “9” digit is used in a GTIN, GS1 specifies that the quantity, if encoded in a barcode, uses the Application Identifier number 30 with the actual quantity.

E. No Serial Number

This method consists of simply not applying a case label on the partial containers and treating them as a tote. Only the label of an item level (e.g., a bottle label) is applied to the case in order to indicate the product type.

This is a way to remain GS1-compliant if the PES is unable to print dedicated label schemes for partial containers. An SSCC will eventually be applied before shipment.

The trouble with this approach is that all of the full cases will have a serial number (sGTIN) established at case packing time, but the partial will not have one until shipment from the distribution center. That might cause problems with internal track-and-trace.

Recommendation

Until all manufacturers align their methods so that downstream trading partners can expect consistency, methods for dealing with partial containers should be evaluated on the following criteria:

- Compliance with standards
- Avoiding wrong picking in the warehouse
- Avoiding wrong handling by the other trading partner
- Allowing track-and-trace from the packaging line to the warehouse.

Both methods a) and d) fulfill these criteria.



Serialization readiness: What about partial containers? | continued

When a regulation agency decides to address partial containers in their guidelines, they will most likely choose the method that is most widely used. Because of this, method A or SSCC Identification is advised. It consists of applying a dedicated label carrying an SSCC on the partial container. This method is widely utilized by manufacturers that were early adopters of serialization.

The following figure shows an example of what a partial container label could look like:

Case label examples: The label above on the left illustrates a typical case label for a completely full case. When the case is complete and contains the established quantity it may be uniquely identified using a GTIN and serial number. When a case is partially filled but contains items with the same GTIN, packaging LOT and expiration, as illustrated on the right, it may be identified using a Serial Shipping Container Code (SSCC) code instead of GTIN and serial number. +



Serialization readiness: What about partial containers? | continued

<p>Fletcher Pharmaceuticals, LLC 1122 Some Avenue Somewhere, PA USA</p> <p>Rx ONLY</p>  <p>US NDC 1234-5678-90 Happimed(TM) (Laetans-auxilium) 30 mg capsule, 100 capsules in bottle. STORE AT: 15-30 C</p> <p>GTIN: 40312345678904 SN: 9876543210 EXP: JAN 2017 LOT:ABC1234 QTY IN CASE: 48</p>  <p>(17)170100(10)ABC1234(30)00048</p>  <p>(01)40312345678904(21)9876543210</p>	<p>Fletcher Pharmaceuticals, LLC 1122 Some Avenue Somewhere, PA USA</p> <p>Rx ONLY</p>  <p>US NDC 1234-5678-90 Happimed(TM) (Laetans-auxilium), 30 mg capsule, 100 capsules in bottle. STORE AT: 15-30 C</p> <p>SSCC: 003123498765432104 ***PARTIAL CASE*** EXP: JAN 2017 LOT:ABC1234 QTY IN CASE: 27</p>  <p>(17)170100(10)ABC1234(30)00027</p>  <p>(00)003123498765432104</p>
--	---

Courtesy of Pharma Logic Solutions, LLC



Serial number management, certifications, and transaction reporting

Serial number management is a set of functions that will allow you to securely and accurately control and keep track of the serial numbers you apply to your pharmaceutical or biologic products.

Flexibility is crucial. You will need a single, centralized place where serial numbers of all types will be allocated and then distributed to the remote facilities where the actual commissioning (associating the serial number with the physical product) occurs.

When complying with GS1 standards, this includes sGTINs (Serialized Global Trade Item Numbers), SSCCs (Serial Shipping Container Codes), GIAIs (Global Individual Asset Identifiers), and GRAIs (Global Returnable Asset Identifiers).

All of these standard GS1 identifiers should be managed by the serial number management module of your enterprise resource planning (ERP) or track-and-trace solution.

Some countries define and provide serial numbers to you. These can come in the form of data (as is the case with China) or as pre-printed labels (Italy). Because these numbers may not conform to GS1 standards, your solution will need the flexibility to deal with non-GS1 identifiers and serial numbers.

Certifications

A certification is nothing more than a corporate assertion of truthfulness of the track-and-trace data, incorporated into the transaction documents as statements. This feature is intended to make it easier to prosecute criminals—one of the important components of track-and-trace regulations. Those receiving drug products where traceability is required will require transaction history or records in a central database before accepting the goods.

Not all country regulations require you to include this within your track-and-trace data, but your track-and-trace solution must be able to include this assertion if you expect to meet future transaction requirements.

Some tend to confuse a digital certificate with what U.S. requires, which is simply that you provide transaction facts and statements. Under the U.S. law the transaction document (TD) itself could be counterfeit, although the provisions that trade be conducted with only licensed authorized distributors of record (ADR) helps to reduce the risk. In other countries where a central database is used the credentials to access the system reduce the risk, although any online system may be hacked.

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Serial number management,
certifications, and transaction
reporting | continued

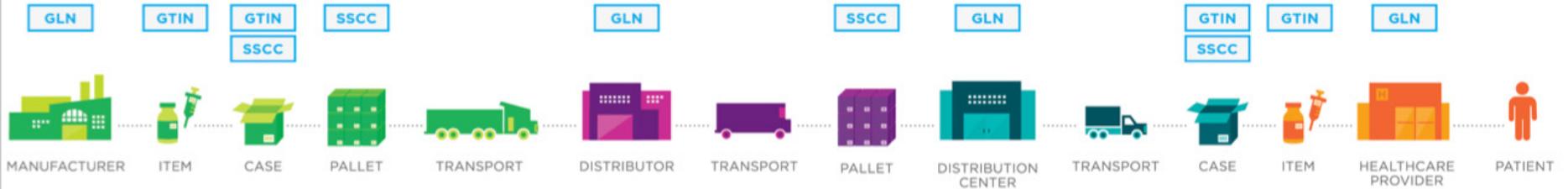
Transaction reporting

If a country regulation requires transaction reporting, your solution needs to supply it. The problem here is that many of the global requirements are not well defined at the time of this writing. You or your technology partner must monitor all government agencies in order to be alerted early to new requirements so that you have enough time to work on a compliant implementation. Layering transaction onto serial number management and design flexibility allows new requirements to be met without substantial changes to the underlying serial number management system. +



IDENTIFY: GS1 IDENTIFICATION NUMBERS

GLN Global Location Number **GTIN®** Global Trade Item Number® **SSCC** Serial Shipping Container Code **EPC®** Serialized Global Trade Item Number



CAPTURE: GS1 SYSTEM DATA CARRIERS

BARCODES

EAN/UPC



GS1-128



ITF-14



GS1 DataBar™



GS1 DataMatrix



EPC-ENABLED RFID

HF RFID



UHF RFID



SHARE: GS1 INTERFACE STANDARDS FOR ELECTRONIC COMMERCE

MASTER DATA GLN Registry for Healthcare®, Global Data Synchronization Network™ (GDSN®) **TRANSACTIONAL DATA** EDI **PHYSICAL EVENT DATA** EPC Information Services



Source: GS1 US

The mission of GS1: Identify, Capture, and Share—identification numbers, data carriers, and standards for electronic commerce.

RFID and barcode data capture interoperability

The track-and-trace solution you select should be capable of handling item identification and serialization data capture from both RFID and imprinted barcode symbol data carriers. Even if you don't plan to make use of RFID today, you may find that certain jurisdictions mandate it in the future. That means even though you may be standardizing on DataMatrix symbols for your item-level serialization, in certain markets you might need to apply linear barcodes or RFID tags at the item level.

There is a valuable resource available for anyone who needs to make use of both GS1 RFID and GS1 barcodes—or even just one or the other—on any product or shipping container and in any supply chain. It is called [“RFID Barcode Interoperability, GS1 Guideline”](#) and can be downloaded from GS1.

This is a guidance document, which means that it isn't a standard itself but draws contents from GS1 standards documents to better explain the subject. In this particular case, it draws primarily from the GS1 General Specifications and the GS1 RFID Tag Data Standard.

Even if you are already familiar with GS1's RFID and barcode standards, intermingling them so that they are

fully interoperable in a single application isn't always intuitive. This guideline starts out by explaining the concept of “data carrier independence,” which lies at the foundation of the GS1 System. It then explains the data carrier-specific forms that are built on top



KEY
CONCEPT

INTEROPERABILITY

Generically, this refers to the ability of data or information created by one computer system to be read by another. In terms of serialization, it can be applied in multiple ways.

At the level of the physical flow of packages and cases, it can mean the ability of a trading partner's scanning systems to scan a barcode (or RFID tag) generated by the manufacturer or contract packager. At the transaction or data-sharing level, it typically refers to the ability of a trading partner to be able to read (or query) another trading partner's data via a common protocol—typically Electronic Product Code Information Services (EPCIS).





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RFID and barcode data capture interoperability | continued

of that foundation, including:

- Barcode scanner output
- EPC Tag URI
- EPC Binary Encoding
- RFID User Memory Encoding (“packed objects”)

From there it explains various translations from various barcodes and RFID tags into and out of a business application. Following that is a number of example scenarios that show how to apply the guidance. An appendix provides illustrations for how to encode and decode SGTIN, SSCC, and GRAI in GS1 Element String form into and from the 96-bit RFID carrier-dependent forms.

Now that we have established that GS1 standards are most likely to prepare you for global flexibility, let’s take a look at the all-encompassing team needed to implement your serialization/track-and-trace/transaction solution. +



Serialization around the world

In 2015, South Korea will join Turkey and Argentina by requiring serialized drug items to be sold in their country. Existing laws at the time of this writing require saleable prescription drug products to include:

- human readable and machine readable symbols, such as a DataMatrix,
- the item's national drug code (often part of a GS1 Global Trade Item Number or GTIN),
- a unique serial number for each item,
- the packaging LOT number, and
- expiration date.

Most existing and emerging laws require the information to be posted into state-controlled databases where the movement of the items through the supply chain may be tracked, and where dispensers seeking reimbursement must confirm the item originated from the manufacturer.

China

In China, a system has been established to track each movement of goods from the manufacturer, through each storage location in the supply chain, to dispensing and the final recipient. Full implementation of the Chinese system is expected in March 2015, extended from an earlier 2013 requirement.



On April 9, 2008, the Chinese State Food and Drug Administration (CFDA) made serialization mandatory on individual saleable pharmaceutical product units for 275 therapeutic classes by December 2011. By May 1, 2013, China's Ministry of Health had released the essential drug list (EDL) of products requiring serialization. This new list expanded the EDL from 307 to 502 products and the list includes traditional drug products and holistic Chinese remedies.

The Chinese National Drug Code (NDC) plus serial number is required to be printed on primary and secondary packages up to the pallet with hierarchy information for the products listed on the

Serialization around the world | continued

EDL. Likewise, the China Drug Identification, Authentication and Tracking System, a division of the China Product Authentication and Tracking System, provides an online portal for drug manufacturers and other enterprises that involve drug supply chain activities to register their products and serial numbers. Saleable items are encoded with a linear ISO-128 barcode containing a 20-digit code comprised of the NDC, serial number and check digits.



Brazil

In Brazil, Resolution No. 54, by the Joint Board of the National Health Surveillance Agency (ANVISA — Agência Nacional de Vigilância Sanitária), established rules and provisions for implementation of a national system of drug

product identification and tracking throughout the pharmaceutical supply chain. The provisions were adopted following a public comment period on December 10, 2013.

The new Brazilian law will require brand owners or importers to collect specific trade data about their products as they move through the supply chain in Brazil after December 10, 2016. Manufacturers and importers must apply the Brazilian Unique Medicine Identifier (IUM) to saleable package and bundles (shelf packs). The law requires the collection of trade data, including ANVISA Drug Registry Number (13 digits), Serial Number (13 digits, unique to all products from manufacturer, random), expiration date (YY/MM format), packaging LOT number in human readable form, and a DataMatrix symbol. Shipper cases (transportation) packages must have a unique identifier (not UDI). GS1 standards support the encoding of the IUM as application identifier (AI) 713 for country reimbursement. The law also requires manufacturers or importers to test their capabilities and provide data from three separate LOTs by December 10, 2015.

Likewise, the Brazilian law requires the brand owner or importer to track and maintain the IUM, CNPJ (Cadastro Nacional de Pessoas Jurídicas) business registration number for the company shipping the item, CNPJ for receiving company, date of transaction, and type of transaction (e.g. shipment). Moreover, the law requires the system to ensure confidentiality, security and integrity of data, accessibility and secure access, and availability of the information.



Serialization around the world | continued



South Korea

In South Korea, the Ministry of Health and Welfare notification 2011- 58, amending “Controlling and indicating barcodes of pharmaceutical products,” establishes new regulations relating to drug traceability. Pharma-

ceutical barcode or RFID tags must be adhered to primary, secondary and external containers (shipper cases) as well as each saleable item.

After January 1, 2015, packages in South Korea must include the item’s identity as a GTIN, a unique serial number for each item, packaging LOT, and expiration date in human readable form and a DataMatrix symbol. Manufacturer must include a barcode or RFID tag on distributed pharmaceuticals that are domestically manufactured or imported (excluding high pressure gas for medical use, drug substances manufactured just for other manufacturing processes, herbal medicines, and products for clinical trials). Likewise, cases must include the same information in linear, GS1-128 barcodes.

Turkey

In Turkey, the Turkish Ministry of Health (MOH) established the ITS system (İlaç Takip Sistemi, or Pharmaceutical Track and Trace System) in 2012 to track prescription drug products and their shipping cases. The law requires serializing and tracking using GS1 encoded DataMatrix symbols for all unit-level items that are reimbursed by MOH, including promotional samples, hospital packaged products, prescription drugs, and non-prescription drugs.



Manufacturers or their packaging agents imprint the item’s identity using a GS1 GTIN, a unique serial number, the packaging lot number, and expiration date in both human readable form and a machine readable GS1-encoded DataMatrix symbol. Information is posted into the ITS database from the manufacturer, and as goods move through the supply chain. As goods are dispensed they are checked to determine if an item with the imprinted information originated



Serialization around the world | continued

from the manufacturer before the dispensed item is submitted for reimbursement.

Many manufacturers employ the services of local, in-country labelers to add the necessary labeling and submit data to ITS. As manufacturers expand their serialization operations, they are increasingly including compliance with Turkish requirements in their internal enterprise serial number management systems.

Argentina

In Argentina, prescription drug products and their shipping cases require serialization. Argentine law requires serializing and tracking using GS1 encoded DataMatrix symbols for all unit-level items that are reimbursed.



Manufacturers or their packaging agents imprint the item's identity using a GS1 GTIN, a unique serial number, the packaging lot number and expiration date in both human readable

form and a machine readable GS1-encoded DataMatrix symbol. Many manufacturers employ the services of local, in-country labelers, to add the necessary labeling. As manufacturers expand their serialization operations they are increasingly including compliance with Argentinian requirements in their internal enterprise serial number management systems.

India

In India, products exported to countries without drug traceability require serialization beginning in 2015, delayed from the earlier implementation date of July 2014.



The Indian Directorate General of Foreign Trade (DGFT) requires GS1-GTIN, serialization and barcodes on tertiary (cases), secondary and primary packaging for all pharmaceuticals exported from the country. The law also requires GS1 DataMatrix symbols on medicines at the unit of sale (i.e., strip/bottle/ vial level) as well as encoding GTIN and Unique Serial Numbers.



Serialization around the world | continued

Exported items requiring serialization require the item's identity (usually as a GS1 GTIN), a unique serial number, the packaging lot and expiration date in human readable and a machine readable symbol. Saleable units include a DataMatrix symbol and shipping cases include a linear GS1-128 barcode.



Saudi Arabia

In Saudi Arabia, beginning March 23, 2015, the outer package of prescription drug products must contain both a human readable, and a DataMatrix, symbol encoded with GS1 GTIN to identify the item,

the packaging lot number, expiration date and pack size.

Beginning on March 12, 2017, each prescription drug item must contain a unique serial number with the information listed above, and the number must be encoded in the DataMatrix symbol.

Jordan

In Jordan, after January 1, 2017, all prescription drug products must



contain both human readable text, and a DataMatrix symbol encoded with GS1 GTIN to identify the item, the packaging lot number, expiration date and pack size.

European Union Countries

In Europe, several countries have established requirements or plans for serializing and tracking prescription drug products domestically. The European Union Directive 2011/62/EU on falsified medicines drives requirements across Europe for tamper evidence, serialization and tracking. Compliance begins in 2017, and for countries with existing serialization, in 2023.

Under the EU directive, manufacturers may choose the appropriate technical solution for the serialization number and its carrier. In order to allow identification of a pack of medicinal products, a serial number must contain, at a minimum, a manufacturer product code



Serialization around the world | continued

and the pack number. The serial number may be combined with other product related information such as (a) packaging batch or lot number (b) expiration date (c) national reimbursement number.

At the time of this writing, several organizations are drafting or have piloted solutions to comply with the EU Directive. The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) have each presented solutions. The EFPIA model encodes products, similar to Turkey, and records the trade of prescription drugs in a central database where items can be checked at the point of dispensing to confirm they originated at the manufacturer.

Developing country compliance

Companies who trade products around the world, or who are expecting to expand their trade operations, may wish to seek expert services from those who have helped other organizations navigate the requirements for traceability and serialization in life sciences around the world. This may allow them to capitalize on lessons learned from other projects and avoid costly mistakes in identifying specific requirements. +



Global compliance: Flexibility is the key

To accomplish the successful deployment of a global serialization program, flexibility is the key. The system you ultimately put together should not be targeted at a single regulation but should be designed to provide building blocks of functionality, which can be applied differently to the same products shipped into many different regulatory environments around the globe.

Waiting for new, nonbinding guidance from the FDA is less important than recognizing the increasing number of binding regulations emerging around the world.

A key to baking in flexibility is to maintain a global regulatory “knowledge base.” GS1 Healthcare maintains an up-to-date database for access by its members. One benefit of their database is that most of the documents have already been translated into English by a professional translator.

You also have the option of selecting a vendor to maintain this library of up-to-date regulations for every country, or you can choose to set this up as part of an in-house quality compliance team.

This library of country-specific regulations should be reviewed and refreshed regularly. Look at each country, your trading partner or customer in that country, and any product-specific requirements there may be. Information on global regulations should be maintained in a user-friendly format that standardizes the required core data, and it must be shared with the entire team.

This will assure the selection of the right code and label (DataMatrix, stacked linear code, even human-readable where dictated).

A best practice is to track regulations in all countries, even those in which you do not currently operate. This will allow a smoother and more efficient transition to serialized production should the opportunity arise to expand into another region. +



Section Two: Staffing and Project Management



The Open Serialization Communication Standard (Open-SCS)

There is a new communications standard being developed that could become very important to drug manufacturers and their contract partners who are implementing pharma serialization systems. The standard being developed is called the Open Serialization Communication Standard, or “OPEN-SCS”.

OPEN-SCS is intended to standardize the communications between the layers of functionality necessary to implement a serialization solution following the ISA-95 model for an automation interface between an enterprise and its control systems. The ISA-95 model defines a set of “layers of functionality” necessary for a properly constructed solution to any kind of manufacturing system. A layered approach to solution design offers benefits to both the solution developer and the end-user, like:

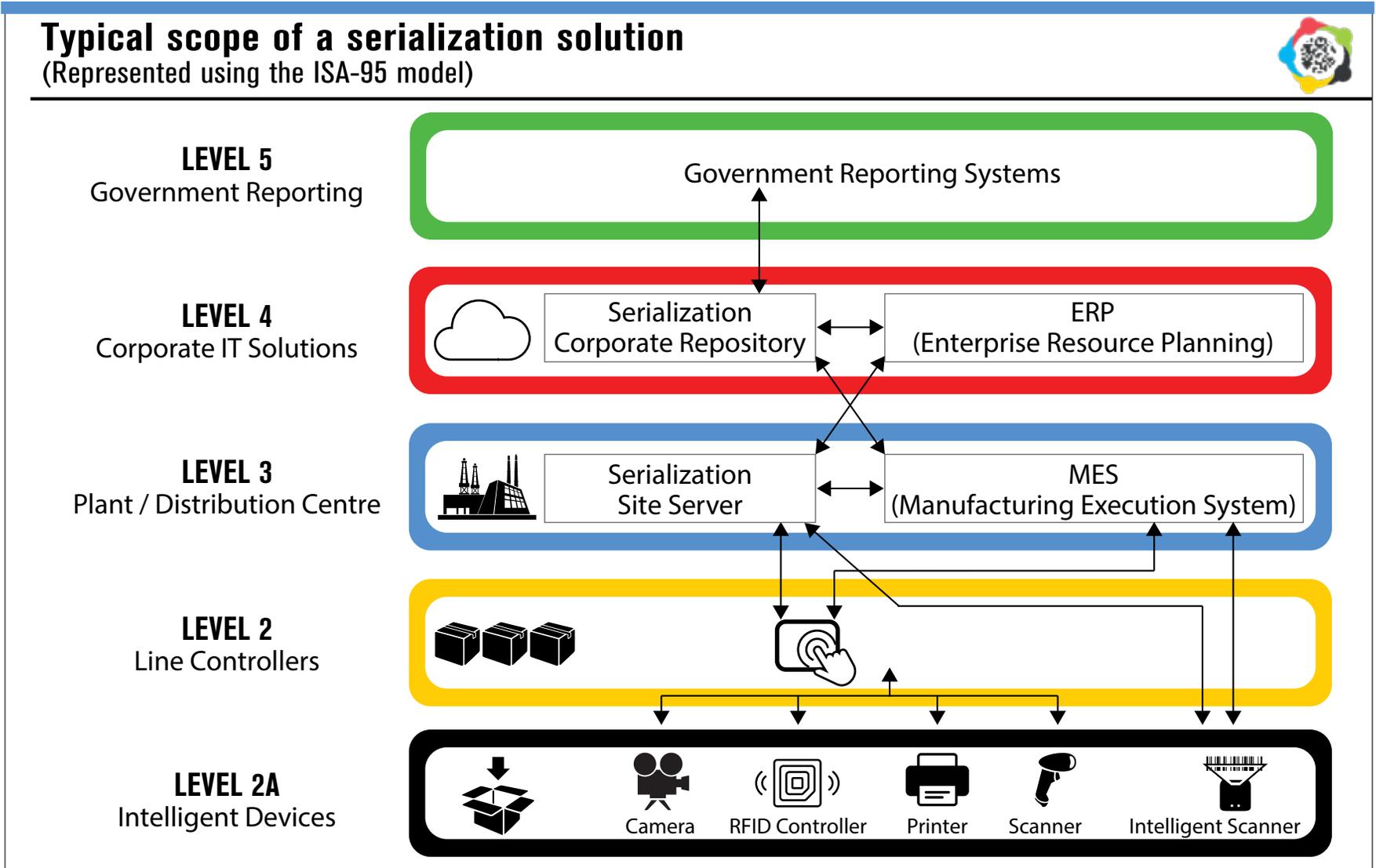
- Flexibility
- Durability
- Reliability
- Faster implementation

This is all well-established. In general, for manufacturing systems, ISA-95 establishes a set of functional layers that should be included in the typical solution. Within a pharma packaging serialization solution, these can be generalized as (from top down):

- Level 4 (L4): Enterprise (this is your corporation)
- Level 3 (L3): Site (this is a single site within your corporation or a CMO/CPO)
- Level 2 (L2): Line (this is a one or more production or packaging lines within a given site)
- Level 1 (L1): Devices (printers, scales, conveyors, scanners, vision components, etc.)

Existing pharma serialization solutions out there today already implement functions like this, but to get the benefits listed above, the functional layers must be able to communicate with the other layers *in a standard way*. This is the goal of OPEN-SCS. The communications that go on between layers L2 and L3, and L3 and L4 will be standardized by OPEN-SCS.





The Open Serialization Communication Standard (Open-SCS) | continued

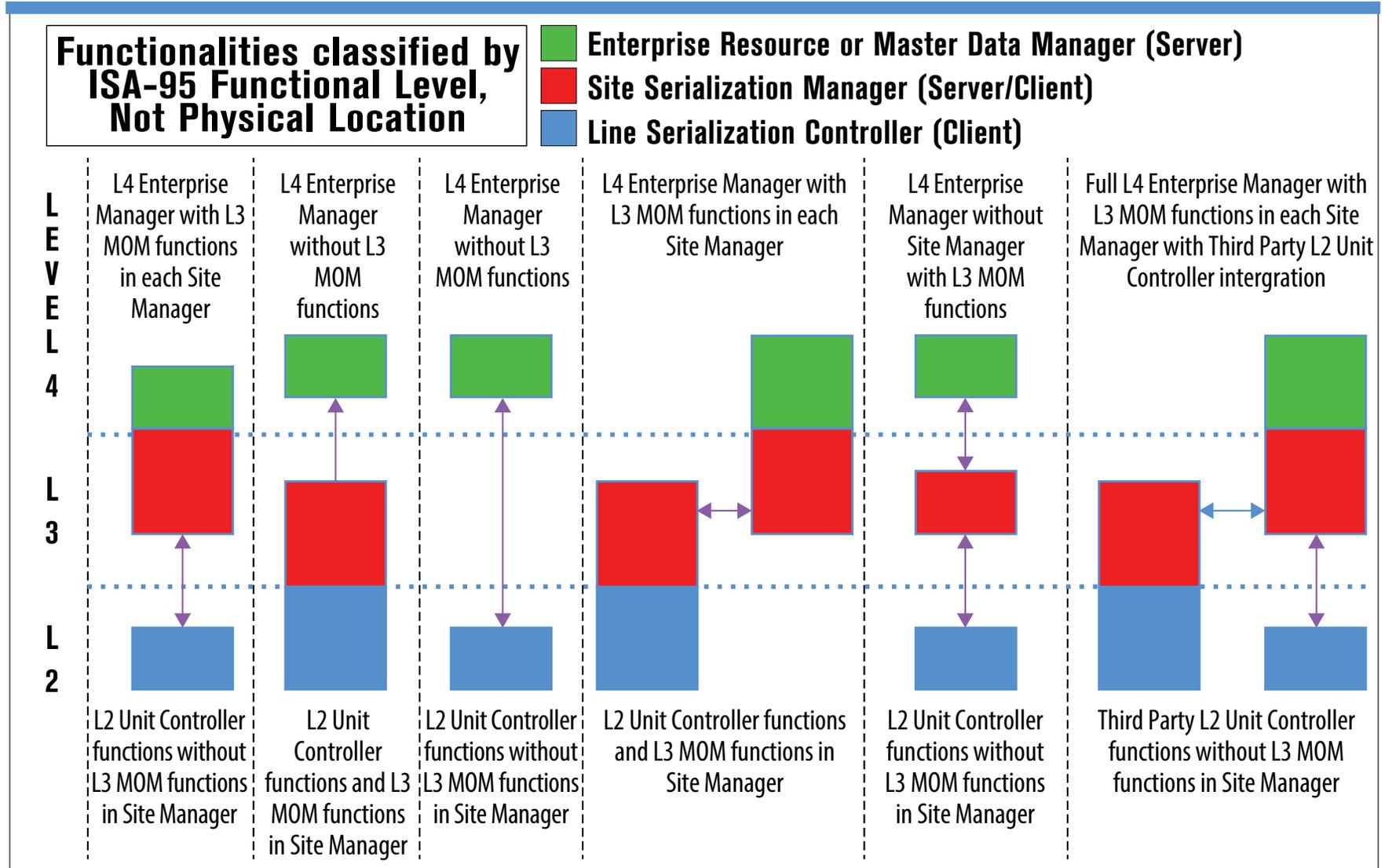
Large-scale systems will usually implement these functional levels in separate executable applications. Once the OPEN-SCS standard is complete and incorporated into the solutions offered by multiple solution providers, these systems could be composed of components from multiple vendors. For example, a given end-user company might incorporate line-level solutions (L2) supplied by Vendor A, B, C and D, site-level components (L3) from Vendors B and C, and an enterprise component L4 from Vendor C. Today this would require custom and proprietary interface software which results in higher costs and brittle implementations. In fact, over time considering mergers and acquisitions, it could become a real mess.

For smaller-scale systems, these functional layers will still exist but they may be combined within fewer executable applications. For example, for a small site with only a single packaging line, the line- and site-level functions might be implemented within a single executable provided by a single vendor. Or, the line-level functions might be in a separate executable, but if the enterprise is composed of a single site, the site- and enterprise-level components might be combined into a single executable provided by a single vendor, and so on.

As a communications standard, won't OPEN-SCS compete with GS1's EPCIS interface standard?

The group of drug manufacturers and solution providers who began the effort to create a new standard first approached GS1, but they apparently declined to get involved since the resulting standard is not intended for use between trading partners. That means the OPEN-SCS standard will fall outside of GS1's normal territory. And don't worry, OPEN-SCS will not compete with any GS1 standard. In fact, it will complement and make use of GS1 standards whenever appropriate.

The OPEN-SCS group has documented six different ways a single end-user solution might be implemented. Colors show functionality from the various "levels". When two colored rectangles are touching, that means they are in the same executable application. Purple arrows indicate communication paths that are the targets for standardization. The acronym "MOM" refers to "Manufacturing Operations Management", also known as "Manufacturing Execution System".



WHAT EXACTLY WILL OPEN-SCS DO FOR YOU (WHY YOU SHOULD CARE)?

Today's global pharma manufacturing landscape is very complex and it changes all the time through mergers and acquisitions, the use of contract manufacturers (CMOs) and contract packages (CPOs) and changing regulations in multiple markets around the world. No drug manufacturer or CMO can expect to end up using a single vendor's components in their serialization solution for very long. OPEN-SCS will make it much easier to retain investments in existing components and allow the overall solution to evolve naturally as the business changes. Components may not become true

Benefits of OPEN-SCS for Pharmaceutical Companies

- Faster implementation
- Validation and other documents template available
- No Vendor Locking = Better prices
- Integration of new supplier
- Integration with CMO / Customers
- Integration in case of mergers /acquisitions

Benefits of OPEN-SCS for Software Vendor

- More robust and stable development
- Lower documentation and validation efforts
- Higher availability of resources
- Business can focus on core competencies
- Seamless integration with existing equipment and systems
- More trust of the regulators, industry and patients
- Global market expansion

“plug-and-play”, but they should be much more “pluggable” than they were before. End-user drug manufacturers should be able to combine the assets from multiple acquisitions, and interface with existing systems owned by different CMO/CPOs easily, efficiently, and predictably. This flexibility will be possible through the magic of standard interfaces offered by multiple vendors.

The organization facilitating this development is the OPC Foundation. Anyone can join the effort and help contribute to the design of the standard by contacting Michael Bryant, Admin Director of the OPC Foundation. +



Staffing for success: Building a proper serialization team

Serialization requires input both at the planning stage and during execution from multiple departments as well as external trading partners.

Internal team members should include someone representing the following departments within the organization:

- Regulatory
- Information Technology
- Label/Package Design
- Packaging Engineering
- Warehousing
- Distribution
- Quality
- Validation
- Operations
- Scheduling
- Supply Chain/Logistics
- Client Services
- Sourcing
- Legal

Cross-functional involvement is critical during the development of a strategy and requirements. It is also beneficial during vendor selection. As a project moves into specific functional designs based on requirements and the selected solution, the related stakeholders are generally grouped accordingly.

Touch points that did not exist in the traditional packaging paradigm extend beyond the packaging line, crossing over to other functional areas. For example, packaging engineers may not be aware of the added risks or may assume that they are someone else's problem, including, but not limited to, Information Technology (IT).

Conversely, IT and network groups often don't realize the impact of imposing IT policies and requirements down to the packaging line. It's critical that the two groups talk, from the beginning.

IT should not be operating in a silo, while plant floor engineers are acquiring new equipment without total visibility into the strategy and plan.

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Staffing for success: Building a proper serialization team | continued

No one department should hand down edicts to the other, or internal politics will be a major roadblock. Standard Operating Procedures (SOP) are often adapted as new points of interaction in the business are exposed during the serialization and traceability project.

Packaging and IT alone do not constitute a team! If your team has fewer than five people, chances are you are not properly staffed to take on serialization as a company-wide initiative, and you could wind up with a stunted or incomplete solution. Teams may be structured with a smaller, tactical core team and a larger, full team. The core team may meet much more frequently than the full team and may be able to call for ad hoc meetings of the full team when issues are encountered.

It is vitally important to form a senior cross-functional governance team to steer, make decisions, and champion the implementation of your serialization strategy across the entire organization.

Experienced consultants stress the importance of total team buy-in from the beginning. Everyone wants to rush through the planning process to get going. You have to take your time up front with requirements, training, design, and layout. Invariably,



Staffing for success: Building a proper serialization team | continued

it is not the technology that will fail; people not fully invested may inadvertently sabotage the project.

It is also critical to establish an information-sharing platform. Not only for the pilot team, but also for future teams as the plan is rolled out.

While it may appear to make sense, at first, to put IT or Regulatory in charge, experts argue they should not lead the project. Instead, having the right executive leadership from the business organization is vital. Experienced consultants may help avoid delays by leveraging their lessons learned and bridging gaps between team members.

The cross-functional team, with core members from each department affected (some of whom may not be used to working with each other) should take ownership of tasks and timelines, but be encouraged to be flexible and think outside the box so they can identify potential problems early on. An independent, experienced subject-matter expert can help to ensure that issues that may fall between functional areas are addressed and can provide valuable input. Clear lines of communication and regular meetings are imperative. +



Secrets to serialization project management

Serialization involves multiple, complex technology components—package execution system (PES) controllers, Supervisory Control and Data Acquisition (SCADA), Programmable Logic Controllers (PLC), machine vision, sensors, scanners, encoding, inspection and verification systems—all feeding information to complex IT layers—device-level, line-level, plant-level, enterprise, and networked to outside trading partners.

Project stewardship must include standardized policies and procedures—even standardized dashboards—to clearly communicate goals and measure progress.

Experts stress flexibility and accommodating change when necessary. Project managers must balance resource allocation internally, define Return on Investment (ROI), manage procurement and contracts, define scope of the project, and schedule events throughout the life cycle of the project.

The serialization project has to be viewed as a single program project in scope, not as a series of independent projects.

Project leaders must have access to the entire network, comprehend all areas of change, develop reusable elements that can be

shared across other lines and plants, and prove the solution for all possible formats and use cases.

Get early input and buy-in from all stakeholders and prepare them for the long haul. Pilot tests can take up to a full year!

Experienced consulting resources are growing scarce. Beware of consulting resources who profess to be experienced only to find out they have been involved in only one or two projects. They must also be a good communicator and understand the technology. You must encourage your team to start now.

Begin by assessing where you are today. Experts warn NOT to start at the equipment layer because data solution choices may then be unintentionally constrained.

Define business and user requirements specifications (URS) first, without respect to specific solutions or vendors, and map vendor solutions into the requirements to compare and score the solutions. Leverage a non-vendor resource to develop the URS tailored to your business practices. This technique helps identify gaps, and the URS can form the basis for future regulatory validation.

Need a Packaging Partner that is

SERIALIZATION READY?

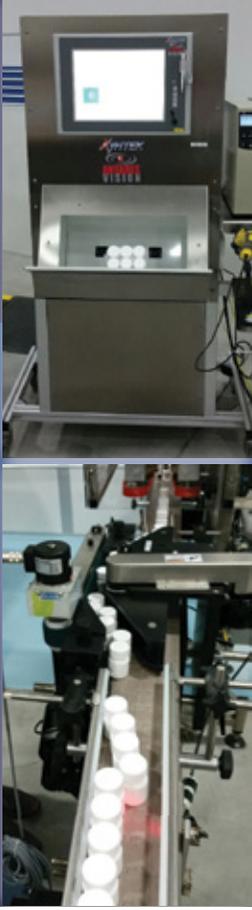


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Secrets to serialization project management | continued

Start at the enterprise level to determine what information will be required from each machine, line, and plant. Leverage standards to ensure compatibility between the needed systems and with your contracted partners.

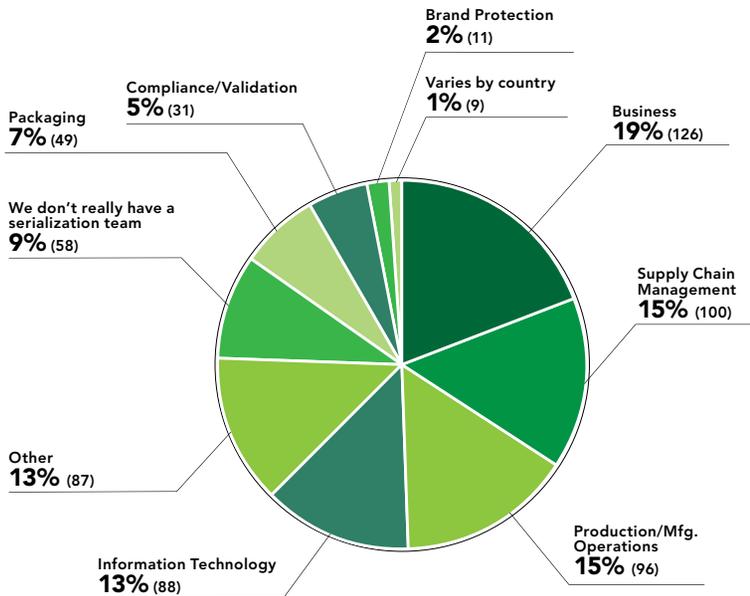
It is generally accepted that the machine layer conversion is easier to execute than setting up the data sharing portion of the project.

Be realistic with timelines. From a risk management perspective, unless you have already locked in contracts and have signed commitments, you may not be able to meet current deadlines.

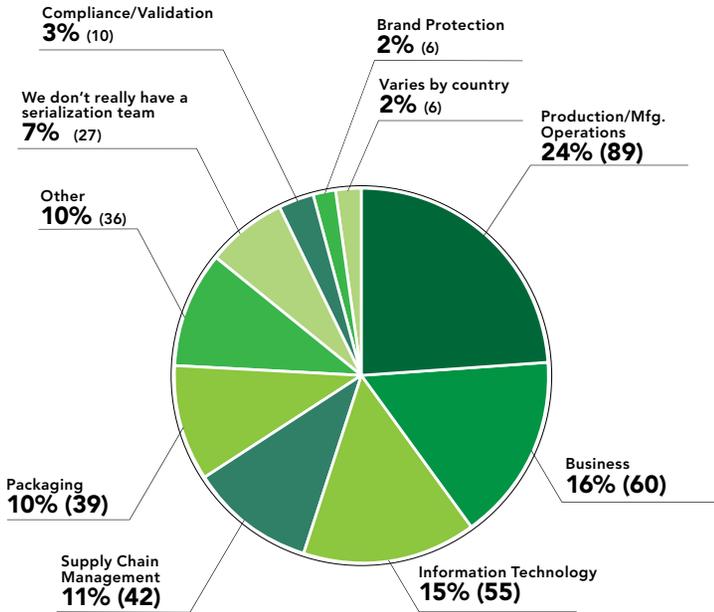
With literally hundreds of manufacturers gearing up to comply with U.S. transaction and serialization requirements, there may very well be a shortage of partners who can help you with information architecture to manage both internal and external information flows, packaging line upgrades, line software, interfacing with enterprise resource planning (ERP), etc.

Consider that solution providers will tend to focus on their systems and may not identify gaps between their system and other needed systems. It may be prudent to have solutions and workflows created by the solution provider reviewed by independent subject-matter

WHICH DEPARTMENT LEADS THE SERIALIZATION TEAM?



U.S. respondents



Non-U.S. respondents

Business managers are the most likely to spearhead the serialization effort in the U.S., whereas for non-U.S. respondents, production/operations is most likely to head up the team.

Secrets to serialization project management | continued

experts with serialization project experience. Use caution when selecting consultants who cater to specific solutions as they may bias the requirements and introduce unwanted gaps into the design or require extensive changes to procedures that might not otherwise be required with other solutions. Research their previous projects to determine their independence by demonstrating projects with different solutions.

Your initial pilot can take up to one year. And while the process will get more efficient on successive deployments, you may still run into

unforeseen circumstances at the next line or plant—often caused by older equipment, outdated software, or a reluctant team. Refer to the timing requirements in the U.S. and other countries found earlier in this document to establish key milestones and back into when your project must start. Include time for unexpected delays and flushing inventory.

Let's begin by learning from those pioneers who have already cut the long trail to implementing serialization. +



11 steps to getting started with serialization

Ready to begin? Here's a roadmap of how to get started.

1. Identify the specific regulations you are complying with, keeping in mind that this is somewhat of a moving target. Consider all global requirements to avoid restrictive designs.

2. Define your current processes. By conducting a thorough review of your current processes and systems, you will be in a better position to start hammering out your roadmap. Consider leveraging experienced subject-matter experts to define requirements independent of vendor solutions and to share lessons learned.

3. Review technology implications. Does the technology team understand the standards they need to support (such as GS1)? Can multiple standards be supported before and after they are merged? Has the technology team identified and coded internal and external product movement events for EPCIS? Before you integrate, are any legacy systems due for replacement in the next three to five years (ERP, Warehouse, and Manufacturing)? How will you respond to transaction and supply chain queries?

4. Map out how your processes will change. Will each aggregation hierarchy be handled by the same data carrier, or will it vary

by item, case, and pallet? How will exceptions be managed internally and externally (e.g., rework, returns, recalls)? Will it be necessary to support randomized serial numbers? How will serial numbers be commissioned and aggregated? How will disaggregation, decommissioning, and reporting work?

5. Understand how trading partners fit in. Have you identified all the parties with whom you need to exchange serialized data? Have you decided how you would like to receive serialized data from trading partners? Have your trading partners decided how they would like to receive data from you? Do you have business systems that will support the exchange of serialization information? Do your trading partners have systems to support new standards such as EPCIS, or should more time-tested standards be used, such as EDI? How will differing customer and country-specific requirements be accommodated?

6. Map out your adoption of GS1 standards. The industry is moving toward adoption of GS1 standards for serialization. Ensure your company is registered with GS1 and you have governance in place. If that's the track you're taking, are your FDA Labeler Codes registered with GS1? Identify what resources will be available to assign sGTIN and SSCC. How many will be required? What resources



11 steps to getting started with serialization | continued

SERIALIZATION PROJECT PLAN		
1. Know where you're starting from	<ul style="list-style-type: none"> Assemble your serialization team and get stakeholder buy-in Map existing internal business processes affected by serialization 	<ul style="list-style-type: none"> Survey capabilities of trading partners Perform an impact analysis Leverage industry groups to learn standards and influence the approach (PhRMA, EFPIA, GS1)
2. Know where you're going	<ul style="list-style-type: none"> Analyze country and state regulatory requirements Determine your core requirements 	<ul style="list-style-type: none"> Talk with your trading partners Create user requirement specifications Develop use cases
3. Design your solution	<ul style="list-style-type: none"> Define your architecture, core components, and system interfaces Determine data carriers, codes, and label designs 	<ul style="list-style-type: none"> Conduct vendor assessments Identify sites, lines, SKUs for pilot testing Pick internal and external event data capture and sharing model
4. Pilot testing	<ul style="list-style-type: none"> Build and install the solution Standards conversion Conduct training Perform internal test & validation Test CMO/CPO integration and validation 	<ul style="list-style-type: none"> Test wholesaler/distributor integration and validation Determine if serialization solution scales with multiple sites, trading partners Build serialization competencies throughout the company
5. Rollout	<ul style="list-style-type: none"> Create your own serialization playbooks Finalize master plan for compliance by market 	<ul style="list-style-type: none"> Develop rollout plan by site, line, and trading partner



DROWNING IN SERIALIZATION? WE ARE HERE TO HELP.

The current waits for no one...and neither does the upcoming serialization mandate. Whether you are still debating between vendors (or you've chosen a vendor who's letting you down), don't worry. The Antares team is here to help.

Antares is very proud to introduce, through a large stock of ready-to-go modules, the Antares Vision "Quick Compliance Program", which implements serialization in less than 10 weeks from the project start. The looming November DSCSA deadline makes this new program particularly important, as Antares is the first to guarantee a fully integrated, validated, and complete serialization program in so short a time frame.

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SERIALIZATION
LINES INSTALLED

170+
PLANTS EQUIPPED
WORLDWIDE

5 BILLION+
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11 steps to getting started with serialization | continued

are available to track down the physical and accurate addresses for every trading partner, supplier, and customer to assign GS1 Global Location Number (GLN), which is required with Electronic Product Code Information Services (EPCIS)? Determine whether internal GLNs will be utilized for tracking of product movement from ingredients through shipping of finished product. What's the timeline to completion of adopting GS1 in the context of the larger serialization project? What dependencies are there?

7. From a regulatory standpoint, decide what will be handled in-house vs. outsourced. Some companies maintain in-house resources to keep up with regulatory changes with regard to serialization. Others subscribe to third-party subscription services or use independent subject-matter experts who may be advising multiple companies. Consider augmenting the global regulatory team with representatives in key regions who speak local languages and who can develop relationships with local regulators and GS1 member offices. Share what kind of data will be managed and archived with your regulatory and risk management departments. As with all new systems, additional data may bring along with it additional responsibility in the areas of validation, authorization, and response to data changes in transactions.



11 steps to getting started with serialization | continued

8. Identify factors that will influence technical architecture. Look closely at the impact of data volume, especially from the packaging-line level all the way up through the enterprise and supply chain. Tabulate the GTIN and Stock-keeping Unit (SKU), lines, plants, and the total volume of items, cases, and pallets. Serialization generates an enormous amount of data, and with it, the task of managing it properly. Cases and pallets may not have GTIN or SSCC now, but may need them for serialization. Look at the regulatory requirements: What are the processes, reporting formats, and consolidation requirements? Decide whether to handle the connectivity to different parties internally or by relying on third-party data connectivity vendors such as Tracelink.

9. Determine when to start serializing for real production. When you outfit a line for serialization, you need to determine when you will want to start producing actual serialized product in order to comply with regulations. Due to product shelf-life considerations and distribution cycles, you may not need to start producing serialized product until well after the line is ready. As a rule of thumb, a good time to start serializing is

when your downstream partner is ready to start receiving the data. Consider earlier serialization on cold chain and small items.

10. Create your own serialization playbook or strategy. Create a strategy for implementing serialization that is specific not only to your own company, but also to specific types of manufacturing sites or trading partners. The initial strategy will take the longest to construct because you are starting from scratch. But then you have a document you can take with you to the next site or partner, which spells out all the process changes, and specifies the validation scripts, training requirements, etc. Any of these can be modified for that subsequent site.

11. Don't shoot from the hip. There are horror stories in the industry of companies that have picked vendors, bought technology, and then started hemorrhaging cash because they didn't have an end-to-end plan. In one example, the IT folks were fashioning IT strategy in a vacuum without talking to packaging and regulatory departments. Meanwhile the packaging engineering team was out buying equipment without talking to IT. Without a team in place and a plan to follow, internal politics sunk the project, and the equipment had to be completely discarded. +



11 steps to getting started with serialization | continued

MAJOR CONSIDERATIONS WHEN IMPLEMENTING SERIALIZATION			
ENTERPRISE LEVEL (ERP/MES)	How is number format conversion between the plant and the enterprise managed?	How are network interruptions minimized to ensure packaging throughput?	Is a third party responsible to provide the tools necessary to maintain data integrity?
PLANT LEVEL (MES)	How are new country requirements managed?	How are evolving changes to existing legislation managed?	Is a third party responsible for code changes?
LINE LEVEL (SCADA)	Are packaging lines isolated or insulated from plant and enterprise level changes?	How does the serialization solution impact line efficiency?	Does the serialization solution manage the line or just the serialization devices?
MACHINE LEVEL (PLCs & Devices)	What impact will changes to the devices have on the line management system?	How many unique HMI displays does the serialization solution require?	Does the serialization solution positively track the status of the item throughout the line processes?

Source: Siemens & Systech Intl.

Some questions to ask as you contemplate each level of your serialization architecture.



11 routinely underestimated aspects of serialization

While there are untold gotchas in any project, here are the areas that are most overlooked or shortchanged, based on feedback from those who've been there:

1. Investing in skills and resources of operators and technicians. A mistake many companies make is not to build up the skills required for serialization on the part of the operators and technicians responsible for day-to-day running and maintenance of the packaging lines. Instead the tendency is to develop dependencies on vendors for support. By not empowering plant personnel with the resources and skill sets necessary to troubleshoot the technology, the people running these lines will be at a huge disadvantage when it comes to troubleshooting problems and taking corrective action.

2. Ensuring that aggregation can be counted on 100% of the time. It might be extra work and extra cost, with a potential hit on line performance, but the method of aggregation you choose must yield reliable aggregation data every time. Consequences are dire at the manufacturer level— where extensive rework can result from aggregation errors— and at the wholesaler/distributor level.

3. Integration challenges with manufacturing or site and enterprise layers. In the last four years, companies have been

so focused on testing serial number management that they haven't focused on integrating the serialization solution into their core business systems (see "software implications").

4. Business process changes. Serialization brings dramatic changes not only to the jobs of operators, mechanics, and technicians, but also to the paperwork that goes along with those job changes—work procedures, SOPs, etc. Many people overlook these changes, which can result in delays and problems. Serialization is more than just serial number management. Think about how serialization is going to run 24/7 across most or all of your packaging lines, and think about what disciplines within your company it will touch.

5. Consultants and vendors may not be available when you want them. Finding qualified partners to help implement your solution will become more difficult the longer you wait. There are a finite number of vendors, consultants, and integrators that have actually implemented a serialization project. Their dance cards are filling up fast, leaving open the possibility that less qualified or experienced consultants may be presented in their place. Securing access to the proper vendor resources is key to a successful project. This risk is particularly acute for smaller companies, which may be put off by the



11 routinely underestimated aspects of serialization | continued

vendor in favor of bigger customers that may receive priority treatment.

6. Look beyond the pilot. Ensure that you are doing more than the “perfect pilot.” Make sure that you really understand a day in the life of your products from the time that they are manufactured through the entire distribution process, including all of the shipping variants that may be used in getting your product to the end customer. This will allow you to exercise the system based on how you manage and ship products in your supply network. Make sure that you take a top-down approach to serialization, focusing on the benefits beyond compliance. Ask yourself how you can use the data to better understand how your supply chain works and how you can provide better service to your customers. When you do perform a pilot, develop tests for exceptions and system failures and test SOPs during the pilot. Avoid dumbing down the pilot just to tell leadership a pilot was conducted.

7. Data transmission lines aren’t fat enough. Having been designed for simpler times, the networks connecting line-level systems to higher-level systems in the enterprise may not be able to receive the sheer volume of data that will emanate from the packaging line once serialization begins. In many cases they use inefficient slow network hubs rather than routers. Consider hierarchical

system models and redundancy to ensure higher availability, such as site and enterprise serial number management. Also beware of packaging control systems with older slower network cards.

8. Multiple vendors increase risk. Simply stated, the more vendors involved in your project, the more integration is required, increasing the amount of risk you’re undertaking. Leverage standards to simplify integration between systems and determine a vendor’s capabilities during selection. Then contractually bind them to their stated capabilities.

9. Understand the standards and roll with the changes. A solid understanding of the standards, even if they’re not fully developed yet, will mitigate errors and design flaws in your serialization systems. Accept the fact that the standards will continue to evolve, so you need to be flexible.

10. Serialization projects take longer and are more complicated than you think. The entire effort is often underestimated simply because we are all heading into uncharted waters. Large global pharmaceutical companies report a pilot test from start to finish can easily take a year, and it’s often a case of two steps forward, one step back. Then there’s the scale issue: Each line takes



11 routinely underestimated aspects of serialization | continued

extensive time, work, and meetings. Multiply that by 10, 20, 30, or 60 lines, however many you have. It's a lot of work.

11. Don't wait for uncertainty to be resolved in order to start.

Companies that have already begun piloting with serialization caution against waiting for regulations and standards to be “finalized” before

beginning your serialization project. Both regulations and standards are undergoing constant evolution. Don't wait any longer. You just need to dive in!

The rest of this Playbook shows you how. +



Section Three: Line and Plant Strategies



Packaging line modifications for serialization

Line serialization, while a significant investment in time and money, is less strategically taxing than sharing the data internally from each line and plant up through the enterprise, and with your trading partners.

Regardless, there are many things that have to happen at the plant and packaging line level to succeed. Accurate serial number commissioning and aggregation are the realm of the plant manager. This means every machine on every packaging line has to be able to communicate the same standardized information to plant IT and through to the enterprise.

WARNING: If you start your project at the packaging-line level, you will get bogged down when it comes to moving data.

Establish package coding requirements independent of hardware or software. This way, teams at plants located in other parts of the world can tap into local resources better equipped to meet their specific local needs.

There are two types of equipment necessary to physically place serial numbers on the package and then verify accuracy:

Printing equipment — This includes ink-jet, laser, or other technologies to mark directly on the package or label web to apply the serial number and DataMatrix symbol.

Vision systems — These systems examine the package label and imprinted code to verify the marking is legible and correct before clearing the serialization line and plant system to signal back to the central database that the serial number has been commissioned.

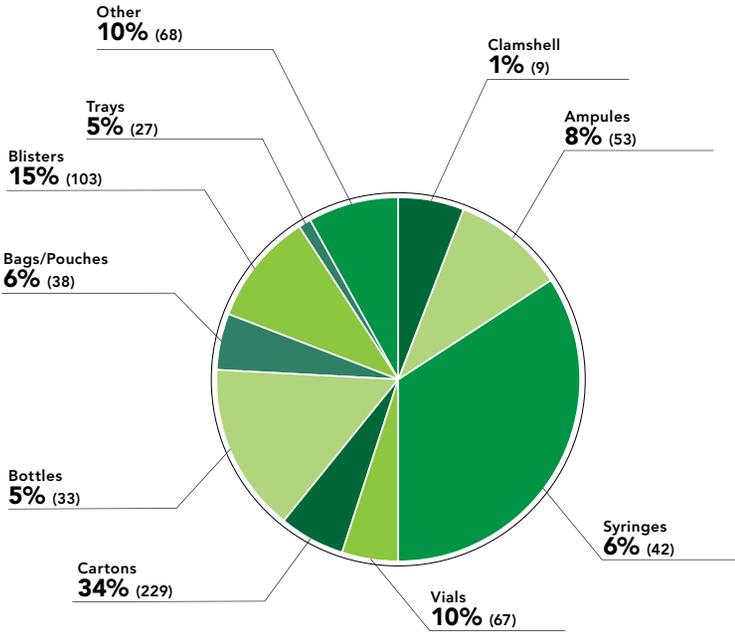
There is much debate about installing new equipment ideally suited to serialization (“rip and replace”) or making do with current machinery by upgrading control modules to accommodate the serialization requirements.

Plant-level engineers would prefer to keep as many existing machines as possible—especially important to avoid getting bogged down in regulatory revalidation.

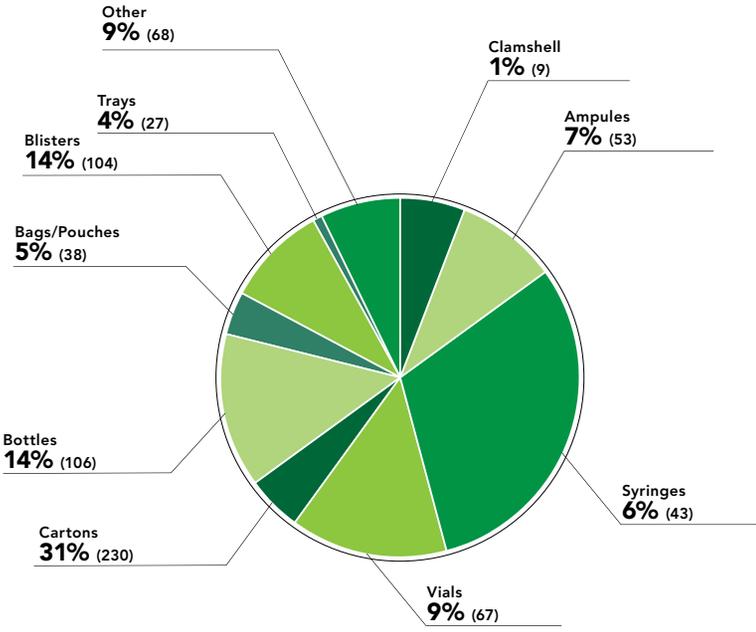
Consider adding two parallel conveyers or stations outfitted with two inspection systems to perform the same label inspection and/or scan tasks while manual case packing. This technique doubles case-packing time and helps gain back loss of overall equipment effectiveness (OEE) due to unit serialization.

Packaging line modifications for serialization | continued

WHAT PACKAGE FORMATS WILL YOU SERIALIZE?



U.S. respondents



Non-U.S. respondents

Cartons and bottles lead the packaging formats that pharma companies intend to serialize as they implement a serialization scheme. For non-U.S. companies, blister packaging draws even with bottles.



Packaging line modifications for serialization | continued

Manpower requirements are a special consideration. Initially, just pulling the CAD files for all machinery affected could take weeks. Who is going to do this? A current employee may be pulled away from regular duties, or a new manpower budget may need to be established.

According to experienced consultants, you might have to add six feet of conveyor to fit inspection cameras, a reject station, even a print-and-apply station for packaging levels that were not even labeled prior to serialization, such as a shrink bundle. You might consider a robotic solution to reduce the footprint to fit into the existing plant layout or add a 90-degree flow-direction change if space is tight.

Consider adding parallel conveyers to maintain line speed and reduce risk by performing the same inspection tasks on two parallel conveyers. In this scenario, two conveyers perform the same label inspection and/or label scan. This allows half of the items to travel down each path and maintain a high overall output. It also ensures that if a system fails, the other lane can continue, and the entire line does not stop.

Consider updates to risk evaluation and mitigation strategies

(REMS) and use previous REMS as use cases and the development of requirement documents.

Experts say that in about half the situations they've encountered, packaging lines typically don't have enough room to expand. In those cases, companies are choosing from these alternatives:

- Knock down walls and expand rooms and/or buildings.
- Jam coding systems and cameras into existing machine footprints.
- Build a standalone serialization system that can be wheeled to different lines as needed.
- Change packaging processes (e.g., bright stocking with separate offline serialization).
- Offload some SKUs to contract packagers.
- Creative solutions include pre-encoding labels or cartons offline the day before packaging, with serial numbers, and using existing label application or cartoning systems.

Packaging line modifications for serialization | continued

Cameras may then be installed at case packing to commission item serial numbers and record aggregation.

Plan for power and equipment failures, such as hard drives in control systems. How do you account for data loss in various modes of equipment failure or loss of power?

Integrating your serialization strategy into existing lines, especially complex machinery like cartoners or case packers, requires involvement from your original equipment partners. Tap into their experience with other customers to save time and money.

Many early adopters of serialization did not perform all of the updates to equipment and systems necessary to ensure the accurate collection of serialization information, especially content to shipper case aggregation. This resulted in rumors that serialization was more complicated or that aggregation could not be accurately collected. The life sciences industry relies on tightly controlled systems and validation to ensure accuracy and repeatability. The same techniques that ensure the correct pill is in the correct bottle with the correct label may be used to ensure the accuracy and repeatability of recording content-to-container serialization relationships or aggregation.

Warehouse and distribution center impacts

There is a separate class of solution providers that focus on warehouse aspects of serialized material handling, so be sure to engage them. These systems are often referred to as edge-of-network or simply EDGE systems.

Most enterprise resource planning (ERP) vendors have very basic solutions for warehousing and shipping with regard to serialization. Likewise, very few packaging-centric serialization solutions support a fully serialized material handling or distribution packing, lacking access to master data, pick orders, and packing and sales order information. There are many issues to deal with moving serialized product through the warehouse. Be sure to engage the appropriate vendors.

The challenge is dealing with a mixed environment where some product is serialized and some is not, managing multiple hierarchies for shipping. This must all be balanced with the need to limit slowdowns in velocity of product through the distribution center.

Finally, don't forget to conduct a full assessment of the scanning capabilities at the warehouse and distribution center levels. Oftentimes entirely new scanner guns may have to be purchased to read a 2-D DataMatrix symbol. Ensure that your purchasing

Packaging line modifications for serialization | continued

organization knows the type of equipment that will be required in the future. This helps avoid situations where purchasing may acquire new scanners or label printers that will not support future needs, such as DataMatrix. +



Inference: The importance of aggregation accuracy



KEY
CONCEPT

INFERENCE

Refers to the ability of a downstream trading partner to read the serial number of a case (or pallet), and “infer” that the individual unit package-level serial numbers match the information supplied by the upstream trading partner, without having to physically open the case and rescan each item.

Most laws mandate unit-level serialization, including the U.S. federal DSCSA law. Most laws also require members of the supply chain to certify shipment and receipt using unit-level serial numbers. For a drug manufacturer, those unit serial numbers are known on the packaging line, but the drug packages are typically packed into multi-unit shipper cases and then stored in their distribution center, or that of a contract third-party logistics provider (3PL).

At some point, the distribution center must fulfill an order, typically

to a wholesaler/distributor. Before the shipment can be made, the manufacturer is responsible for constructing a transaction for all of the unit-level serial numbers of the units in the customer shipment.

While not required under the U.S. law, many supply chain traders may demand to know which specific serial numbers are sealed into a case. Trade relations and industry demands may drive aggregation even without a specific regulatory requirement. Many industries who ship serialized goods, including machine parts and consumer electronics, routinely record the serial numbers within a shipping case and transmit the information in Advanced Shipping Notices (ASN).

So how will the manufacturer or trader know exactly which units have been collected for the shipment? They are sealed inside of cases, and the unit-level serial numbers are not visible. One option would be for the distribution center staff to cut open each case in the shipment, pull the units out, and scan each unit-level serial number on the drug packages, then put them all back into the cases and reseal them. That’s obviously impractical.

A better option would be to use inference to “infer” which unit-level serial numbers are included in the shipment. For that to work, the



Inference: The importance of aggregation accuracy | continued

case-packing operation would need to include unique serial numbers on each case and then capture the unit-level serial numbers as they are being packed into the cases. The unit-level serial numbers would then be associated with the case-level serial number. This is known as unit-to-case “aggregation” information, and it may include unit-to-bundle and then bundle-to-case aggregation, and/or case-to-pallet aggregation as well.

Now, when the distribution center needs to know exactly which unit-level serial numbers to include on their customer’s transaction, all they need to do is read the serial numbers on the cases included in the shipment, and then use the unit-to-case aggregation information in reverse. That is, they would “infer” the units from the case serial numbers.

Further, when the manufacturer’s customer receives their shipment in the U.S. after January 27, 2017, they may wish to confirm that they received a valid transaction document (TD) for all of the units included. Likewise, many countries around the world require that the relationship of serialized contents to the serialized container is recorded—so aggregation may be required irrespective of the U.S. law.

To do that, they too could open every case and scan every unit-level serial number. But the better way is to use the same unit-to-case aggregation information in the same way that the manufacturer’s distribution center did, by simply reading the case-level serial numbers (or the pallet-level serial numbers) and inferring the serialization of the units from electronic documents, such as an Electronic Data Interchange (EDI) Advanced Shipping Notice (ASN). To enable this approach, the manufacturer must pass the unit-to-case aggregation information for the shipment to their customer along with the transaction documents.

Avoiding inaccurate information

However, if the aggregation information is not accurate, due to inaccurate data capture, both the manufacturer and their customers who use inference will have inaccurate information. This puts them both in violation of various country laws. The number of units in the error will depend on what went wrong in the case-packing aggregation capture operation.

In other industries, when the serialized contents are not correct with respect to their shipping documents, the items are returned or trade information is updated to record the correct serial numbers.

Inference: The importance of aggregation accuracy | continued



PHARMACY IMPLICATIONS

Inference is critical not only for wholesaler/distributors, but also for the end pharmacy, hospital, or clinic. What retail pharmacies are nervous about is that if they open up a case or tote and find a problem with mismatching serial numbers, they are stuck solving a supply chain problem, tracing any discrepancy all the way back to the manufacturer. This represents a new headache that they didn't have before. It represents a potentially significant increase in processing overhead that they don't have to worry about today.

Similar practices may be used in life sciences. These errors are usually detected once the serialized items are removed from the case. Those purchasing the serialized goods will not accept them if the serial number does not match their documentation. Manufacturers are encouraged to accurately collect aggregation or they will experience supply chain issues and potential shortages as goods are returned.

Inference saves time and physical system operations for manufacturers and downstream trading partners—especially if the serial numbers attached to each unit package are printed via DataMatrix, which appears to be the direction most pharma manufacturers are going for serialization for U.S. law.

With the massive volume of drugs that pass through the large companies in the U.S. supply chain today, the use of inference by all parties in the supply chain will help prevent costs from skyrocketing, not to mention eliminate the introduction of new errors and theft (thus actually lowering the security of drugs in the supply chain).

Even if wholesalers do not process aggregation information, the manufacture may still benefit by knowing which specific serial numbers were distributed to a specific wholesaler at a specific price.

What happens at the distributor?

After drug distributors receive the cases from the manufacturer's distribution center, they open most cases and fulfill their customer orders by packing small quantities of unit packages in totes for delivery. Once the manufacturer's case is opened by the distributor and individual packages are removed, the unit-to-case aggregation

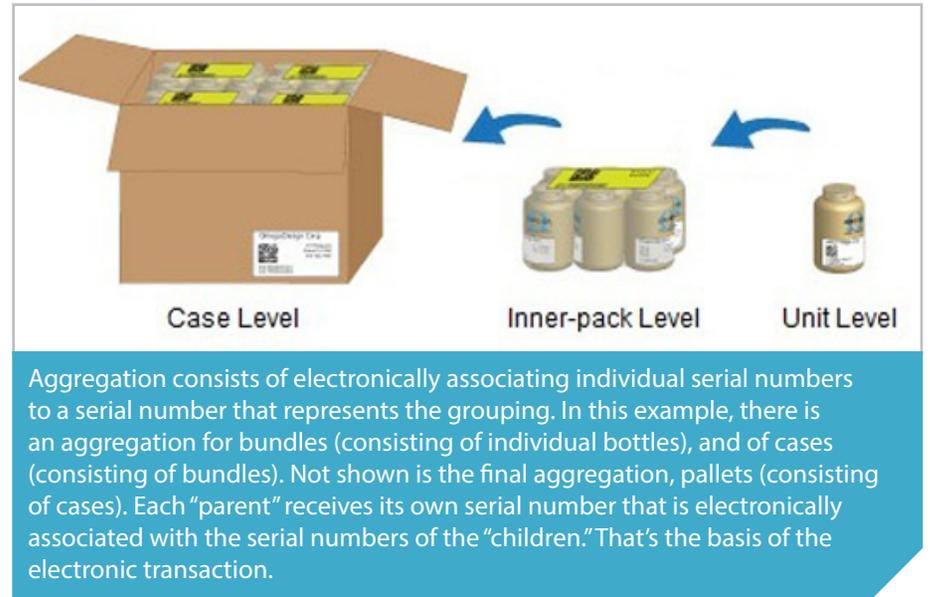


Inference: The importance of aggregation accuracy | continued

information is no longer needed. The distributor would typically read the unit-level serial numbers on each package as they are fulfilling customer orders and update the corresponding transactions to reflect the shipment to their customer.

However, some customers order in quantities large enough for the distributor to simply deliver one or more entire cases of a drug. In that instance, the distributor doesn't need to open the manufacturer's case, so they would rely on the manufacturer's aggregation information to know exactly which unit-package serial numbers are being shipped to their customer, so they can update and pass the correct unit-level transactions to their customer. The distributor would pass on the manufacturer-supplied aggregation information to their customer for the cases that were shipped, along with the transactions for the packages contained within them.

Since the distributor's customer will also want to receive their shipment as efficiently as possible, they will likely make use of the aggregation information to update the transactions that they received from the distributor so that they do not have to open every case and read the serial numbers on every package inside them.



Notice that in this scenario, the manufacturer distribution center, the distributor, and the distributor's customer are all relying on the accuracy of the aggregation information that was originally captured by the manufacturer at the time that the drug packages were packed into the cases.

What happens if aggregation information is inaccurate?

What if a distributor's customer receives a case of product that contains one or more packages whose serial codes are incorrectly associated with some other case sent to some other distributor?

In that instance, once the distributor eventually opens the case and reads the serial numbers on the packages, they will find that they do not have any record of those serial numbers, and they will not have a valid transaction for those packages. Without a valid transaction, the drugs cannot be sold, returned, or dispensed after federal regulations go into effect.

And the same problem will occur at whatever company received the other case that was involved in the error. Both companies will need to work backward through their supplier until someone reaches the manufacturer where the error may be solvable. If the manufacturer agrees that a mistake has been made, they may be able to transmit the corrected transactions to the distributor. The distributor may then be able to update those updated transactions to reflect their corrected shipment and pass it on to their customer.



WHAT'S FDA'S STANCE ON AGGREGATION ACCURACY?

Some FDA watchers believe that questions of aggregation accuracy could raise questions with the agency about whether a manufacturer has its process under control, depending on which part of the FDA is involved. If a manufacturer is inspected by the part of FDA focused on process control, that inspector could in theory deem inaccurate aggregation on the same level as putting the wrong label on a drug. At that point, things could begin to unravel pretty quickly, potentially triggering the shutdown of lines and plants.

That customer would then have to update the corrected transaction, thus finally clearing the way to sell, return, or dispense the drugs.

That's a lot of very inefficient interaction. In the meantime, the drugs sit on the shelf unusable. So for inference to work, the manufacturer's aggregation information must be 100% accurate. Failure to maintain accurate aggregation may have an effect on the availability



Inference: The importance of aggregation accuracy | continued

of your brand in the market and confidence in the product, and result in shortages while inference issues are resolved. As stated earlier in this document, the same process that ensures the correct pill is placed in the correct bottle with the correct label may be employed to improve the accuracy of aggregation. +



Strategies for accurate aggregation

The actual electronic association of the serial numbers of individual unit packages to a case is done after an inspection system on the packaging line visually inspects individual packages (or they are manually scanned) upon going into the shipping case.

In theory, there are (at least) three possible ways of handling aggregation.

The first method is by using non-line-of-sight RFID tags as the data carrier at the item level. Each drug package would have a unique RFID tag attached to it. The existing case-packing operation would require very few if any changes.

After the cases are sealed and an RFID tag containing the case-level serial number is attached, the case would be run through an RFID reader where all of the unit-level serial numbers and the case-level serial number would be read at once. The serialization solution would electronically bind those numbers to one another to form the aggregation information for that case.

Since the cases are already sealed, there is no chance of discrepancies such as a mix-up of contents between two cases. If the RFID reader



KEY
CONCEPT

AGGREGATION

Aggregation refers to assigning child-level serial numbers (such as on individual packages) to a unique serial number at the parent level (e.g., a case), thus forging an electronic association between the children and the parent so that the numbers in the sealed container can be “inferred.” Each time goods are grouped, that’s an occasion for aggregation: individual unit packages to bundles; bundles to cases; cases to pallets. Aggregation is essentially an electronic data representation of grouped goods, sometimes interchangeably used with “hierarchy.” Regardless of what you call it, the electronic representation must always match the physical, or else bad things will happen.

doesn’t pick up all of the expected serial numbers, the case would be rejected for quality inspection and rework.

The reason this works is that RFID doesn’t require a “line-of-sight” to read. That is, the RFID reader can read directly through the



Strategies for accurate aggregation | continued

corrugated case material and pick up all of the tags in a very short time.

The benefit is that this operation would produce 100% reliable aggregation, so inference could be relied upon as a downstream strategy.

In the past, biologics manufacturers expressed concerns that the energy from RFID might damage the proteins in their products. Because RFID offers advantages with cold chain products, which are often biologics, and because they can be used to track when goods move in and out of temperature-controlled areas, some biologic manufacturers have performed studies to test the impact of RFID on their goods. Reports were published in mid-2012 on tests that indicated RFID does not harm biologics.

However, few if any companies are likely to put their unit package-level serial numbers into RFID tags unless a given country or region specifically requires it (which is always a possibility). The reality is that the vast majority of drugs will be serialized using DataMatrix symbols. These symbols, while much cheaper than RFID tags, require “line-of-sight” to work.

Which brings us to method number two, which is pre-aggregation inspection. Essentially, a vision system would be placed at the entry to the case packer (or bundler or cartoner).

The serialization system would keep track of individual package serial numbers as they file into the case packer. So for example, for a 12-count case or bundle, it will count the next 12 bottles that stream by the vision system and associate those numbers with the case-level serial number for the case that’s being loaded.

The benefit of this type of inspection is that it requires minimal modifications to the packaging line, which lowers costs and reduces the validation burden.

The drawback, however, is that it’s prone to unreliability. If a bottle is removed or falls off the line after that vision inspection occurs, the sequence of bottles will get out of sync by one. That means incorrect aggregation information is attributed to not only that case, but also every case after it.

This risk can be reduced by maintaining the count of items and detecting when an item was removed after entering the case packer and another item is needed to complete the case. Camera inspection systems may

Strategies for accurate aggregation | continued

be used to confirm a complete count, and control systems can eject cases with questionable aggregation.

Inaccurate aggregation in a case packer would be a disaster from a data integrity standpoint.

Which leads to the third, and likely most realistic, option for most pharmaceutical manufacturers: post-aggregation inspection.

The way to always generate 100% accurate aggregation information is to read the unit-level serial numbers only after the packages are bound together in a grouping—either a multipack or full-case grouping.

In this scenario, a vision system would essentially take a picture of all the packages in a case right before the flaps are closed. But for this to be possible, the DataMatrix symbol would need to be visible on the part of the package that is exposed when loaded into a case. With respect to individual unit cartons, it

may mean relocating the DataMatrix symbol to a side panel from an end flap, or vice versa. And changing the package graphics can result in further delays.



Temporary bottom codes can be scanned in one image, after the grouping is formed.

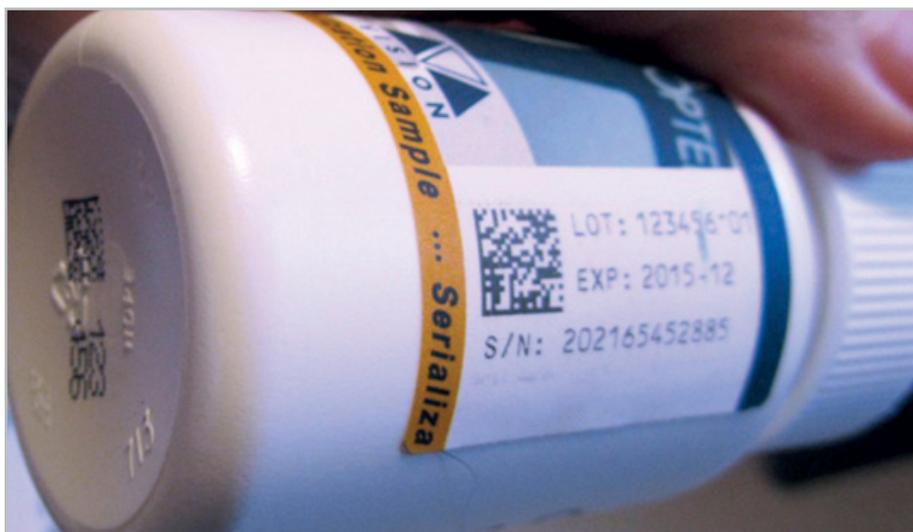
Source: Omega Design

For a case that has multiple tiers of primary packages, this inspection would need to be performed each time a tier is loaded. For example, as bundles or convenience packs are assembled, and

Strategies for accurate aggregation | continued

as they are placed in a shipper case.

For plastic bottles, the DataMatrix symbol on the label isn't likely to be visible once the bottle is in the case. So what to do?



DataMatrix code containing serialized NDC is on the side of the bottle, separate from the “temporary” 2D code on the bottom.

Source: Optel Vision

Temporary DataMatrix symbol

Some vendors have come up with a workaround. It entails the use of a “temporary” DataMatrix that is ink-jet printed onto the bottom of all empty bottles. This barcode contains a unique bottle identification number, or bottle ID, that is unique for all of the bottles within the current batch of the drug being bottled. The purpose of this barcode is to keep track of each bottle as it progresses through the packaging line and into secondary packaging operations—shrink bundlers, cartoners, case packers, etc.

As bottles emerge from the labeler, a vision system would verify that the DataMatrix symbol (along with lot and expiration date) is readable. A second vision system would read the temporary DataMatrix bottle ID code.

The packaging line management system would then create a one-to-one relationship of the “real” serialized NDC number encoded in the DataMatrix with the “temporary” DataMatrix symbol printed on the bottom. (This is not aggregation—it’s a one-to-one relationship that’s used only during the packaging process.)

Strategies for accurate aggregation | continued

Once the bottles are shrink-bundled or grouped for loading into a case, a vision system would take a picture from the bottom—thus capturing all of the temporary DataMatrix symbols in one image.

Once the line system “knows” which bottles are in that aggregation (as determined by the temporary DataMatrix symbols), it can easily cross-reference each of those DataMatrix symbols with the “real” serialized NDC number, thus successfully building a bundle or case-level aggregation without actually having to scan the labels on the bottles. The result is 100% reliable aggregation.

Considering each of the techniques discussed above, a key aspect is to collect the item serial number as close to placing it in the case as possible.

One often-overlooked aspect is to ensure the grade of the barcode is maintained during packaging. A vision system may read a DataMatrix symbol just fine, but a barcode scanning system may not, depending on the grade of the code. This discrepancy could potentially render goods unusable in the supply chain. Many companies are adding barcode grading and in-line continuous grading to their QA inspection during packaging.

Manual case packing

Manual case-packing operations are somewhat more cut-and-dried in terms of the complexity (or lack thereof), since individual packages can be manually scanned as they are placed into the case. The downside is increased case-packing time. Extra labor may need to be added in order to prevent line output from being affected.

Many manual case-packing operations use a system, sometimes referred to as a label rewinder, to print and spool serialized labels, or preprint cartons, with serial number, lot, expiration, and DataMatrix symbol.

Manual case packing does not preclude the use of a fixed “supermarket”-style scanner to capture an entire tier of product, though that is subject to the same constraints as described previously. When it comes to aggregating during a manual case-packing operation, the more you can structure your workflow and line operation to be less dependent on the operator for a successful aggregation, the better off you’ll be in the end.

Regardless of the method you choose to aggregate, remember that the most reliable way of assuring that aggregation data is accurate

Strategies for accurate aggregation | continued

is by capturing the aggregation at each level only after the packages are already grouped together.

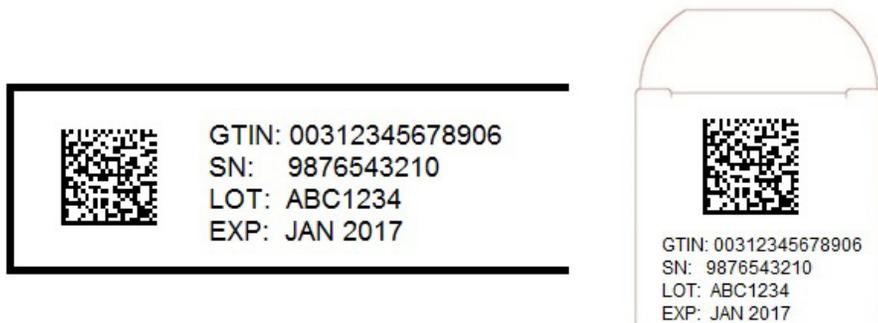
Finally, an investment in improved material handling can go a long way in limiting rework required from aggregation and serialization errors +



Nine coding and marking considerations for serialization

While the long arm of serialization reaches deep across multiple silos in the organization, one could say it starts with the physical code applied to the package. There are several things to consider:

1. Define where on the package you want to print. As in real estate, the three most important factors here are location, location, location. Whether it's on a top flap, one end flap, or both end flaps, the physical location of the code will make a huge difference in



The example above illustrates typical blister carton and bottle carton package encoding on saleable units. Information encoded in the DataMatrix symbol is also displayed in human interpretable format where the label for each value can be understood without understanding GS1 application identifiers (AI). An alternative is to replace the labels with the GS1 AI in round brackets, such as "GTIN" being replaced with (01) and "LOT" replaced with (10).

Courtesy of Pharma Logic Solutions, LLC

cost, whether you need to make a label change, and even whether you need to change the size of your shipping case. It can also have huge implications for aggregation. (As an example, one pharma manufacturer was printing a DataMatrix symbol for a temperature-sensitive product on the side of a folding carton, which was causing a lot of aggregation issues, so they moved it to the end flap. But that required a slightly bigger carton, which in turn required a slightly bigger shipping case, which in turn required the revalidation of the entire cold chain.)

Some aggregation schemes call for printing a separate DataMatrix symbol on the top or bottom of each bottle in order for a camera to capture an entire tier of bottles as they are being put into a case (or through a clear-film shrink bundle) for a higher degree of aggregation integrity.

It is also a bad practice to place the DataMatrix symbol close to the linear barcode containing the GTIN or NDC (required under separate FDA rules). Scanners may have a difficult time locking onto the desired symbol and result in reading errors when the linear code does not present the serial number. Keep in mind that the U.S. federal DSCSA requires a DataMatrix symbol.

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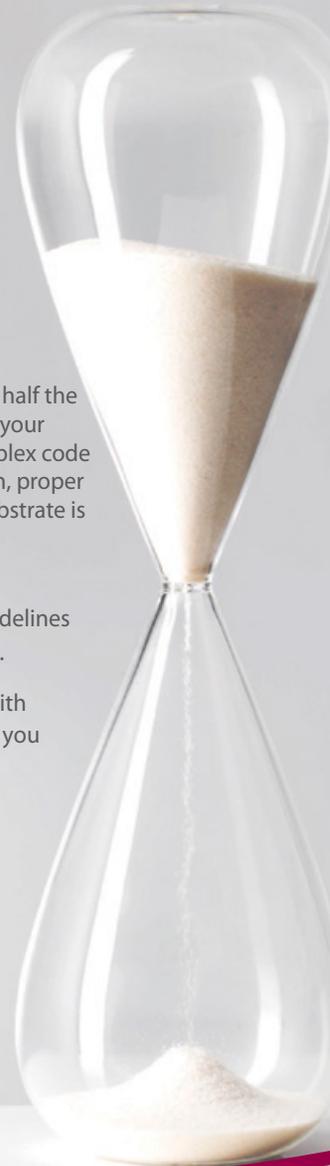


Serialization ready printers are only half the solution. You also need to consider your labels and cartons. Due to the complex code requirements driven by serialization, proper interaction between printer and substrate is more vital than ever.

With recent passing of the DQSA legislation, federal serialization guidelines are in place and the clock is ticking.

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Nine coding and marking considerations for serialization | continued

2. Specify exactly what's going to be on the label. Prepare a label schema document for your coding/marketing vendor that specifies exactly what elements are to be printed. You should also endeavor to have a drawing or rendering of what the finished, printed label should look like, including size of the DataMatrix symbol, font size for human-readable text, and so forth.

3. Printing on round bottles is problematic. Printing on a flat, true surface is always better than printing on a curved surface. A flat surface, such as found on square containers, provides a consistent throw distance for ink-jet coding systems. Since round bottles are more common than square, most companies avoid this altogether by printing the serialization code directly onto the label while it is still on the label web, rather than onto the bottle itself. This typically allows for excellent web control and consistency, leading to a more reliable and consistent code—regardless of whether the coding technology is ink-jet or laser ablation. Other options are printing on the top or bottom of bottles, though real estate can be trickier here.

4. Assess whether your existing coding equipment is serialization-ready. The trick here is not in the printing of a DataMatrix symbol, as even printers upwards of eight years old can do that. To be truly serialization ready, a printer must have two-way communications

1.800.444.4512
www.codingforcompliance.com

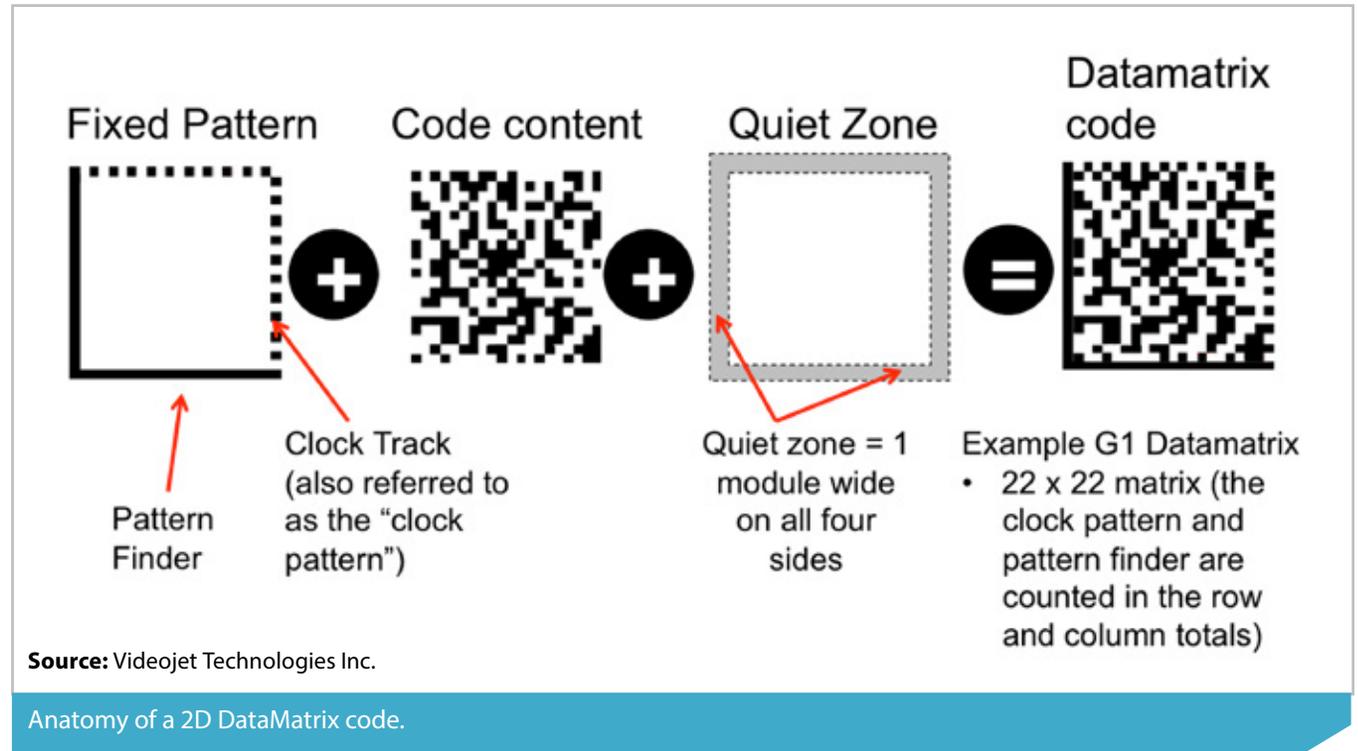
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Nine coding and marking considerations for serialization | continued

built in—to be able to receive as well as transmit information, all without impacting existing line speeds. As a general rule of thumb, printers five years old or newer are more likely to be serialization-ready. Some newer laser systems are serialization-ready as well. One gotcha: Continuous ink-jet technology (CIJ) is typically not serialization-capable due to print quality limitations.

5. Pick your coding technology. Your choices are typically going to be thermal ink-jet (TIJ), laser ablation coding, or some form of print-and-apply. If you are switching away from CIJ, this means you may need to alter some internal processes and factor in some additional training of operational teams. Considerations will include substrate, line speed, material handling, and printer mounting. For TIJ, dry time differences across similar carton stocks can be meaningful. Line speed constraints for laser are a function of substrate, lens size, code size and complexity, product pitch, code orientation, and



power requirement. Line speed constraints for TIJ are largely dependent on the chosen resolution. For example, 600x600 codes may limit line speeds to 100 fpm; 300x600 codes may allow a line speed of 200 fpm. Finally, always factor maintenance of the coding

Nine coding and marking considerations for serialization | continued

system into your decision, as it could have an impact on downtime.

6. Vibration on the line can impact printing (and scanning).

When choosing conveyor components for the transport of bottles across areas of the production line where coding takes place, be on the lookout for potential vibration.

7. Consider cost and maintenance when selecting a coding system. Ask about systems that prevent clogging of nozzles, cleaning of the head, etc.

8. Pick your data carriers. While pilots with RFID were popular four to five years ago, the price of the tags never came down sufficiently at the item level to make this data carrier take off. Many companies are standardizing on DataMatrix symbols at the item and case level, and GS1-128 codes at the pallet level.

9. Grade yourself. Failure to grade the barcodes may mean that your goods cannot be read later in the supply chain using traditional scanners. High-resolution cameras in packaging can often read symbols that will be rejected by hand scanners. This may not be uncovered until later in the supply chain, resulting in returned goods and the potential for product shortages.

Coding/marking for serialization – Four questions to ask:

- Do proper drivers or protocols exist to communicate between the coder and the serialization platform?
- Can the coder process serialized data quickly enough for the application?
- Does the coding system provide the ability for the host system to monitor the coder's status/health?
- Does remote troubleshooting exist?

Source: Domino

Include barcode grading as part of quality inspections using a barcode grading station on the QA table. Because each DataMatrix is unique when serialized, the grade may drop during normal packaging to a level that cannot be read. Grades of B or C may be your trigger to resolve an issue. Develop SOP to deal with barcode grading and mitigating poor grades. +



Vision system considerations

One of the key considerations for vision systems pertains to the industry's predominant use of round bottles. Being round, of course, they tend to spin on a conveyor. That means at least two and likely three cameras need to be mounted to a conveyor in order to capture the DataMatrix symbol from any possible angle. Experts estimate this need for additional camera coverage can increase your total serialization budget by 5% or 10%, depending on how many lines are running round bottles.

A second issue pertains to how codes are printed onto folding cartons. Some have found that the printing area is not always uniformly presented to the print head when the printing panel is located on a closure flap of the carton. There can be varying degrees of curvature following closure. This curvature has an impact on the online inspection process, which is sensitive to changes in the light that is required to fully grade the DataMatrix symbol. The result can be false rejects of otherwise acceptable cartons. Adjustments may be necessary to improve package handling to address the problem at the coding or lighting stage.

Specifying vision systems

When specifying a vision system, it is important to consider factors such as software accuracy, reliability, and local factory support.

Generally, today's vision systems are divided into two groups: PC-based and smart camera. Key differentiators between the two include architecture, cost, capability, and development environment. The primary architectural difference between PC-based vision and smart cameras is one of centralized versus distributed image processing.



FACTORS INFLUENCING VISION ACCURACY

- Type of substrate and shape of package
- Technical competence of operators
- Sunlight variations though the day
- Poor lighting, heat, dirt, or dust
- Poorly printed characters/codes
- High line speeds
- Quick changeover
- Highly reflective packaging materials
- Difficulty in presenting product to camera to achieve image consistency

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This ultra-compact and fully autonomous carton serialization unit is designed to handle a wide range of carton sizes to **ensure accurate serialization and aggregation.**



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Vision system considerations | continued

PC-based systems generally multiplex industrial cameras on a production line to a single processor to process images. These systems are often sold in proprietary industrial computers and offer limited redundancy for hard drives, lack support for virus/malware protection (a problem when networked), and use embedded operating systems that are not easily updated. Some include swappable drives, which present a risk for validated systems if each drive has not been validated to confirm its configuration.

Smart cameras (sometimes referred to as distributed, embedded, or IP cameras) are self-contained and include a CPU, image sensor, and communications and network connectivity, and do not require a PC. They combine distributed processing with high-speed networking to provide highly scalable systems.

Both approaches have advantages. PC-based machine vision systems provide great flexibility in the number of options users can select (e.g., line scan or area scan camera). They are easily used with third-party software, and tend to offer more power and speed due to sophisticated processors. PC performance increases with each boost in processor speed, which makes new PC-based vision systems well suited for the most complex or mathematically intensive applications.



Vision system considerations | continued

However, because PC technology changes so rapidly, it is not as easily replicated as off-the-shelf smart cameras. Smart camera systems cost less to purchase and implement than their PC-based counterparts. They are simpler to operate, maintain, and integrate into the manufacturing environment. As they are less complex than computers, they are also more reliable, with fewer components presenting operational risk.

PC technology offers a central human machine interface (HMI) to centralize setup and configuration. Discrete smart cameras on the other hand may require longer to configure each system. Also, older PC technology, especially systems in proprietary industrial machine housing, may impose technology limitations and older risky embedded operating systems, and may not take advantage of advances in technology. (Would you buy a phone from 2006 today?).

Smart cameras can offer these advantages:

- Smart camera vision systems can be less expensive to install, less complex to validate, and less costly to maintain.

- With advancements in miniaturization and the power of digital signal processors, traceability applications such as code reading, text verification, mark quality assessment, and label inspection can be accomplished economically. Because they are solid state, smart cameras can provide a more stable platform than PC-based alternatives.
- Configurable, rather than programmable, smart camera vision systems can make it easier to accommodate changes in regulations and standards.
- Most advanced vision systems now offer advanced networking and communication capabilities and powerful factory integration tools.
- Cameras are now available with gigabit Ethernet 2.0 transfers at speeds of up to 125 MB/s. These cameras deliver high bandwidth with very long cable lengths at low cost without the use of repeaters. Connectivity is limited only by the number of available ports on your Ethernet switch. +

How to avoid a big barcode gotcha

With mass-produced packaging, barcodes are preprinted as part of the package artwork. As such, no one has had to really worry about whether those codes will scan throughout the supply chain.

However, because serialized DataMatrix symbols are coded onto the package, versus preprinted, it opens the door to degradation. Depending on your coding technology, the tolerances of the equipment, and the substrate of the package, tiny variances can creep into the code quality such that at the end of a packaging run, the quality may be worse than it was at the beginning. This degradation can be caused by vibration, smearing, particulate buildup, etc.

What's particularly insidious about this is that today's vision systems on the actual packaging line are of such high quality, they will read degraded codes that a typical barcode scanner will not. So your code may pass your vision system as readable but the item may be returned once serialization is required by those with less sophisticated scanners in the supply chain.

The risk is that goods with unreadable barcodes may be returned, resulting not only in unnecessary costs, but also in product shortages.

How to avoid this? That's where what is known as barcode "grading" comes in. The readability of any barcode can be graded on a scale of 0.0 to 4.0 (F to A). Grades are based on many different parameters, including sharpness of edges, quiet zone, overlap of bars or symbols, relationship of one square to another within a DataMatrix symbol, etc.

So it is entirely possible for the first package of the run to have a grade B, and the last package to end up with a grade D or below. To pick up these sorts of problems, it is essential to deploy continuous in-line grading, which can be something that the vision system can be programmed to handle, although experts will tell you that offline grading systems provide a more comprehensive review. Barcode grading can be incorporated into the QA sampling process.

You can also purchase special grading cards from GS1 that have samples of barcodes that can be used to calibrate your barcode grading system.

Barcode verifiers should comply with the ISO/IEC 15426-1 (linear) or ISO/IEC 15426-2 (DataMatrix) standard. This standard defines the



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How to avoid a big barcode gotcha | continued

measuring accuracy of a barcode verifier.

The current international barcode quality specification is ISO/IEC 15416 (linear) and ISO/IEC 15415 (DataMatrix). The European Standard EN 1635 has been withdrawn and replaced by ISO/IEC 15416. The original U.S. barcode quality specification was ANSI X3.182. (UPCs used in the U.S.—ANSI/UCC5).

Depending on the parameter, each ANSI test is graded from 0.0 to 4.0 (F to A), or given a pass or fail mark. Each grade is determined by analyzing the scan reflectance profile (SRP)—an analog graph of a single scan line across the entire symbol. The lowest of the eight grades is the scan grade, and the overall ISO symbol grade is the average of the individual scan grades. For most applications, a 2.5 (C) is the minimum acceptable symbol grade.

Compared with a reader, a verifier measures a barcode's optical characteristics to international and industry standards. The measurement must be repeatable and consistent. Doing so requires constant conditions, such as distance, illumination angle, sensor angle, and verifier aperture. Based on the verification results, the production process can be adjusted to print higher-quality barcodes that will scan down the supply chain.



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How to avoid a big barcode gotcha | continued

This standard defines the quality requirements for barcodes and Matrix Codes (also called Optical Codes). As of 2011, the ISO work group JTC1 SC31 was developing a Direct Part Marking (DPM) quality standard, ISO/IEC TR 29158. International standards are available from the International Organization for Standardization (ISO). These standards are also available from local/national standardization organizations, such as ANSI, BSI, DIN, NEN, and others.

Grading barcodes is a step that's often overlooked because it's never been an issue before. Be sure not to get caught in this trap. +



Label and panel redesign considerations

Many package design professionals have discovered the hard way that serialization has a deep impact on labels and panel design. These are often left out of the equation in early pilot tests.

For smaller items, there is an actual physical real estate issue. You have to add a GTIN and serial number, and it has to be readable to a human and to a scanner.

Many smaller packages have just enough space for lot number and expiration date, but the remaining blank area is not sufficient for adding a unique serial number or a DataMatrix.

That could necessitate the addition of a new outer carton.

For primary packages consisting of folding cartons, the location of the DataMatrix symbol may need to be relocated to a side panel or end flap to maintain line-of-sight visibility while in the case. This is in order for them to be read in a post-aggregation

situation, such as inside a case before the flaps are sealed.

The longevity and readability of the codes becomes an issue as the product moves through multiple steps in the supply chain. The code-printing surface must be resistant to environmental conditions, and codes may have to be relocated to a place on the package that is free from abrasion that can occur on conveyors, carton packing systems, and palletizers.

These artwork and structural changes can take up to six months to implement.

And of course, any change in labeling (either on the primary package or on the case) means refiling an NDA with the FDA. Typically FDA handles these quickly, but if hundreds of thousands of labels are being filed in a race to comply with looming deadlines, one could expect a slowdown in approvals. +



Impact on production line speeds and OEE

Of utmost concern to production/operations teams is the impact serialization will have on production line speeds. If you're installing a brand new line, this is less of a concern. But it is likely the overwhelming majority of lines will be retrofit.

One of the elephants in the room is line downtime itself. A packaging line may be out of service for at least a month, and possibly up to six months, to allow for line retrofits, new

equipment implementation, controls integration, testing, and validation. Plus a big chunk of packaging lines simply don't have the room for additional inspection and reject stations on the line. It's not uncommon for facilities to be altered to accommodate these new stations.

With the addition of codes that take longer to print, along with multiple inspection and rejection stations, there's no question that performance will take a hit. Estimates vary for how much of a speed loss to expect once the line is back in operation. Many experts believe an initial loss of 8% to 10% in Overall Equipment Effectiveness (OEE) should be expected when a line is restarted. With ongoing efforts at line optimization (which needs to be built into the schedule, by the way), some have seen the drop in OEE stabilize at around 4%. If the engineering team is being evaluated on the basis of OEE, this may have to be examined and adjusted in light of serialization's impact on line performance.

(There is another view. Some experts say using the serialization project as a catalyst to change out older machines may in fact lead to greater productivity.)

One technique is to create parallel conveyers to manage serialization

OVERALL EQUIPMENT EFFECTIVENESS:

Overall equipment effectiveness (OEE) is a hierarchy of metrics developed in the 1960s to evaluate how effectively a manufacturing operation is utilized. The results are often for comparison between packaging or manufacturing units as a key performance indicator (KPI) in conjunction with lean manufacturing efforts to provide an indicator of success.

KEY
CONCEPT



Impact on production line speeds and OEE | continued

on two tracks. This helps maintain line speed and provides redundancy should something fail on one track. Electronic batch records and integration with enterprise systems help to reduce the impact of having to configure systems for two tracks, but the payback in speed and redundancy may be worth it.

One item that often gets overlooked as a source of productivity problems is the automating of the serialization system with the MES and ERP system for master material data. Facilities that choose not to automate the integration with these systems are looking at additional line start-up time, changeovers, and reconciliation of loose product at the end of a lot. Efforts to streamline or automate such reconciliation procedures can help reduce downtime between changeovers.

Of course, aggregation itself can slow down a line, particularly one with manual case packing. One pilot test revealed that the act of picking up each bottle, manually scanning the barcode, and then placing the bottle into the case took double the time of the previous process of simply placing the bottle into the case. This is another area where using two tracks may balance the effects of serialization on OEE.

Scheduling will be affected too. It's important to get a handle on the estimated reduction in throughput in order to rethink all of your scheduling. If you're running single or double shifts, you may need to periodically schedule an extra shift on a night or Saturday to make up for the lost output.

As a rule of thumb, validation adds 25% to the cost of any changes required by serialization. One way to get a leg up on validation is to rely on vendors that can provide the engineering resources to create the required validation documentation. Such documentation should include the serialization qualifications, operational qualifications, and acceptance test protocols. The vendor should have the ability to execute those protocols.

Another technique is to follow Good Automated Manufacturing Practice (GAMP) and develop a User Requirement Specification (URS) that may form the basis for future validation materials.

The vendors, not the user companies, are the ones most knowledgeable about how their systems work. If the vendor does not provide validation documentation, then the pharmaceutical company must hire a third-party validation company that is not familiar with the technology. While those firms understand commodity technologies,

Impact on production line speeds and OEE | continued

they are unlikely to be familiar with specific serialization technologies, resulting in a cost exposure for the manufacturer.

Another potential problem exists for the many pharmaceutical companies that handle validation differently at the corporate level versus at the plant level. A plant-level validation change might require three signatures: the person initiating the change, one level up, and the plant manager.

A validation change at the corporate level—say for a change in a business process— may require 15 or 20 signatures. That's two weeks versus two days. That two-week process simply won't fly with all the changes that serialization requires. As a direct result of dealing with serialization, some companies are issuing revised internal procedures for how they handle validation changes at the corporate level, to streamline such validation changes. +

Impact on production/operations workflows

Pharmaceutical companies are finding that the cost to upgrade a typical packaging line for serialization runs at around \$1 million, give or take. With that level of investment, it's only natural to focus on the equipment and engineering changes involved in reconfiguring the line itself.

However, equally as important to consider are the many changes to standard operating procedures and workflows involved in that line's operation. Here are a few key considerations:

1. Technician and operator training and SOPs. Because serialization involves additional equipment, typically coding, and inspection and reject stations, mechanics and technicians will need new skills to monitor, maintain, and fix the new equipment that they didn't have before. The operators will need new training as well. What will success and failure look like, and how will they manage it? What happens when a printer breaks? What happens with rejected product—is it discarded, or opened up and poured back into the hopper? Developing draft SOPs for your pilot may help test the new procedures and facilitate the pilot process.

2. Quality assurance SOPs. Ensure that any un-aggregated

numbers (due to QA inspections) are de-commissioned at the end of a packaging run.

3. Correcting line issues and machinery jams.

Ideally the serialization system should allow an operator to easily correct an issue on the line without having to do a lot of manual processing. This may require companies to revisit the flow of product on a line in order to minimize the possibility of compromising any aggregation points.

While manual overrides aren't desirable, they must be in place so packaging

Item	Description	Priority	GxP
1000	System shall be capable of applying Serialization information at xx units per minute		
1001	System shall be capable of applying and verifying Serialization information for units oriented in a (horizontal/vertical) configuration.		
1002	System shall be designed to apply serialization information for all product container size		
1003	System must be capable of operating 24 hrs/day, 7 days per week		
1004	System components and wiring must be labeled		
1005	Components installed on the line must be cleanable and not interfere with line clearance		

Note: Physical Components (Printer, Scanner models) specification should be limited to not constrain Supplier unnecessarily.

Sample User Requirement Specification for serialization

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Source: ProPharma Group, Inc.

Impact on production/operations workflows | continued

can continue if equipment goes down. Any time an operator has to manually pack and label a case, the system solution should have checks and balances so operations— including aggregation— can be completed when there is a problem or discrepancy.

On the line itself, machines need to be able to signal the line serialization software when a jam occurs, in such a way that the serialization system knows which particular packages are affected by that jam. Similarly, when the jam is cleared, there needs to be a way for the serialization software to recognize those packages that are being reintroduced back into the infeed of the cleared machine.

4. Reject handling and rework. Obviously any kind of reject handling is closely tied to the inspection portion of any line serialization system. The software should automatically decommission the serial numbers on rejected product at the end of packaging by decommissioning all serial numbers that were not aggregated into cases. The software also needs to detect if someone picks product out of the reject bin and reintroduces it onto the line if aggregation is tracked before case packing. Some companies are looking at lockable bins.

If you don't have room to expand your packaging line to accommodate a reject station, you'll need to figure out what kind of alarm or alert to use to signal plant personnel. At the software level, new reason codes may need to be introduced to represent illegible or incorrect serial number codes and barcode symbols in addition to lot and expiration printing.

There must be processes in place to address physical changes in the packaged product. Removing additional samples, replacing damaged packaging, replacing damaged labels, or changing shipping configuration all require an update of the data to match the physical world. Rework stations may need to be placed closer to the line as well. For security reasons, you may want to consider decommissioning these unused numbers.

5. Reconciliation procedures. When a run is completed, end-of-lot reconciliation should verify that the product in the physical world matches the stored data. Systems should provide reconciliation reports prior to ending the packaging lot, giving operators visibility to the commissioned, decommissioned, packed, and orphaned products. This allows operators to verify the physical

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Impact on production/operations workflows | continued

product against the recorded data, ensuring that what was produced was not inadvertently modified through manual intervention. Maintaining the data integrity for offline use cases is important.

6. Additional procedural controls and SOPs. You will find there is a need to devise additional procedural controls such as a process to follow after an in-process aggregation error occurs, such as when an incorrect package is added to a case. +



Section Four: The Supply Chain: Beyond the Four Walls



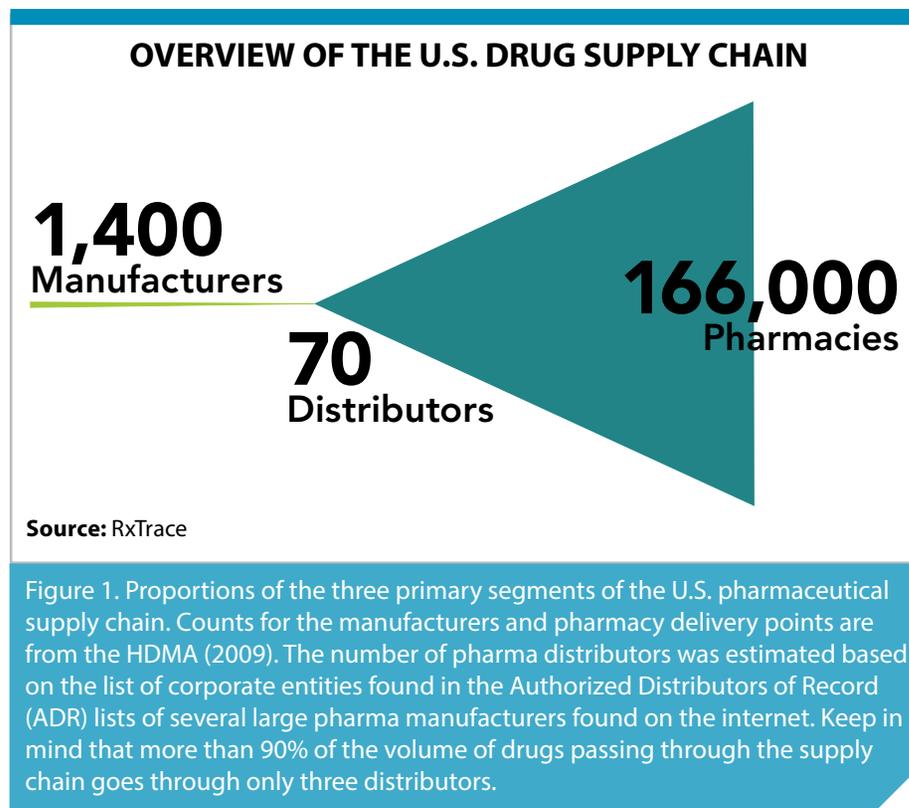
Transaction models and the U.S. drug supply chain

The debate over transaction regulatory models in the U.S. pharmaceutical supply chain often centers on how much data for each package of drugs needs to be moved between trading partners as those drugs physically move through the supply chain. The ideal model would minimize the amount of data moved yet always allow each member of the supply chain to check the prior history—the transaction—of the drugs they are about to buy.

At a superficial level, this appears to be all you need to do, but when you take a closer look at the details of how the supply chain actually works in the U.S., you will see that there are other characteristics besides data volume per package that need to be considered.

Four views of the U.S. supply chain

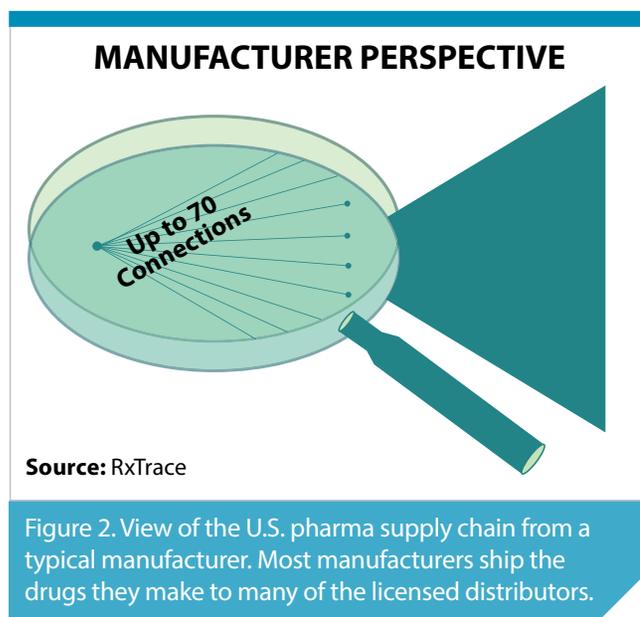
In the debates and discussions over traceability regulatory models, we are used to seeing a view of the supply chain that shows one manufacturer, one distributor, and one pharmacy. That view masks so much important complexity that if we were to select a regulatory model or solution based on that view, it would be far from ideal.



Transaction models and the U.S. drug supply chain | continued

Figure 1 shows a view of the supply chain where the vertical scale shows something closer to the true proportions between the three segments.

The most striking thing about this view is that it shows how few distributors there are compared with the number of manufacturers and especially compared with the number of pharmacy delivery points.



Now let's take a detailed look at the immediate view of the supply chain from the perspective of an average drug manufacturer (Figure 2).

Manufacturers typically want to maximize the availability of their products to all licensed

pharmacies in the U.S., so they work to set up and maintain connections with as many licensed distributors as they can handle. The largest manufacturers deal with most or all of the roughly 70 distributors in the U.S. Of course, there is bound to be some selectivity by smaller manufacturers, but probably not as much as you might find with many non-commodity consumer products.

Now let's take a detailed look at the immediate view of the supply chain from the perspective of an average pharmacy (Figure 3).

The majority of drugs dispensed in U.S. pharmacies are initially sold by the manufacturer to a distributor, which then sells them to the dispensing pharmacy. Pharmacies typically only buy their drug supplies from a small number of the distributors. In fact, most have a single primary distributor and a small number of secondary sources, which they usually order from only when their primary supplier is out-of-stock of a given drug that they need.

This is true even of chain pharmacies, although chains maintain their own internal distribution networks. (The largest chains are big enough to buy the highest-volume drugs directly from the manufacturers.) This is an important exception when considering transaction models, although even chain pharmacies buy a large number

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Transaction models and the U.S. drug supply chain | continued

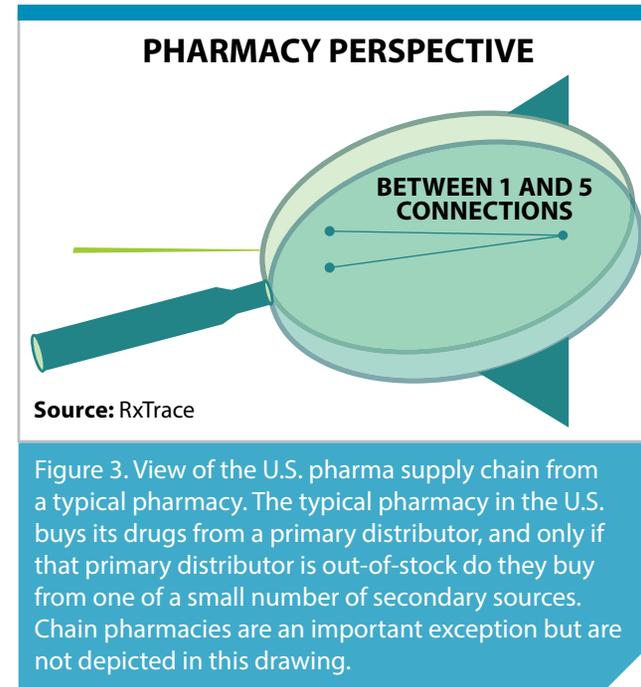


Figure 3. View of the U.S. pharma supply chain from a typical pharmacy. The typical pharmacy in the U.S. buys its drugs from a primary distributor, and only if that primary distributor is out-of-stock do they buy from one of a small number of secondary sources. Chain pharmacies are an important exception but are not depicted in this drawing.

of lower-volume drugs from distributors.

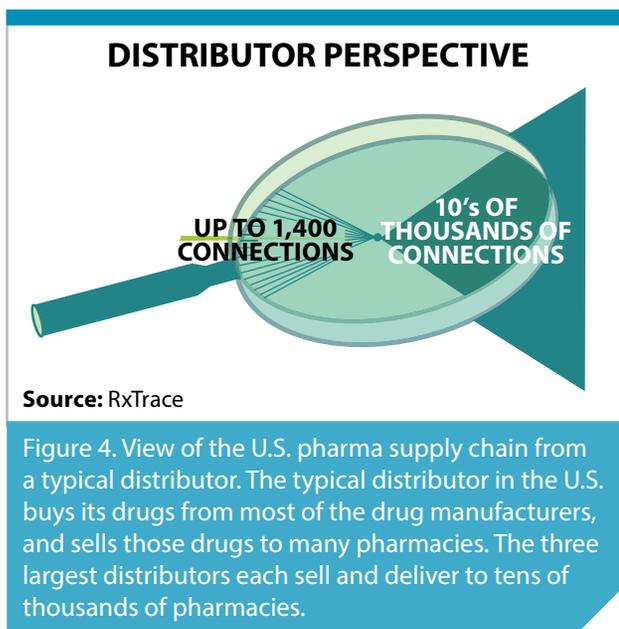
Now let's take a detailed look at the immediate view of the supply chain from the perspective of an average distributor (Figure 4).

Distributors are at the center of the typical drug supply chain for most

drugs in the U.S. To offer a complete catalog, the typical pharma distributor buys its stock from many of the 1,400 manufacturers. The larger the distributor, the more likely they are to buy from most if not all of these manufacturers.



Transaction models and the U.S. drug supply chain | continued



The typical distributor sells to a large number of pharmacies, whether as a primary source or as a secondary source. The number of pharmacies that a given distributor sells and delivers to is one of the primary components in the determination of how “large” they are. The three largest distributors

each sell and deliver to tens of thousands of pharmacies. +



Transaction implications of the four views

These four views of the supply chain expose an implication about the various transaction models that wouldn't be obvious if you only looked at the simple three-trading-partner view of the supply chain. Because some data would need to move somewhere in all transaction models, these views can help us evaluate those movements.

In the illustrations, we refer to “connections” between trading partners. These refer to direct business relationships, but they can also refer to data connections in any model that requires data to be passed directly from seller to buyer. For example, the basic model defined by the GS1 Drug Transaction Messaging Standard (DPMS) would need to pass data along these connections.

Distributed transaction models, like those that make use of the GS1 Electronic Product Code Information Services (EPCIS) standard, would also need to pass data along these connections. But in these models, each downstream trading partner would also need to communicate directly with every prior owner of the drugs they buy.

For example, each pharmacy would need to have a data connection to each of the manufacturers that made the drugs that they received, even those they bought from one of the distributors. You can see that the number of connections that a given pharmacy

would need to deal with would become much greater than just the small handful they would need to deal with in a DPMS model.

On the other hand, Centralized and Semi-Centralized models would not need to pass data along these connections because in these models, each trading partner communicates directly with a relatively small set of transaction data repositories.

One common thread between all current transaction model solutions under consideration in the U.S. right now is their use of Applicability Statement 2, or just AS2, for the secure nonreputable transmission of data between entities. AS2 is already in use within the U.S. pharma supply chain for the exchange of EDI (Electronic Data Interchange) documents, but not all companies make use of EDI, and not all companies have AS2 capability. Few pharmacies do.

As used today in the supply chain, each AS2 connection has a setup cost, which entails, among other things, exchanging encryption keys between the parties. For every pharmacy to do this with every pharma manufacturer, as would apparently be needed in a distributed transaction approach, is almost inconceivable. Once set up, keeping up with the changes stemming from mergers and acquisitions activity alone would be a reoccurring nightmare for any company, including



Transaction implications of the four views | continued

the largest distributors and chain pharmacies.

But when you look at it from the perspective of a pharma manufacturer that, in a distributed transaction environment, would have to deal with an AS2 connection to every single pharmacy that buys their drugs—up to 166,000 of them—and you can see how unreasonable and impractical this is. +



Minimizing the complexity of connections

A single AS2 connection is not overly complex as long as you understand the technology and make an investment in the right software to handle it for you. Once you have the software, a few dozen connections are reasonable to deal with if you have an IT person who can handle their setup and maintenance. Setting up and maintaining a thousand AS2 connections would be a major complexity. Clearly, any viable U.S. transaction model must keep the number of AS2 connections that any given company must deal with to a minimum.

While the traditional approach with AS2 is to exchange digital certificates, other techniques do exist to simplify establishing encryption and security for exchanging trading information and certifying the exchange. These include techniques used for consumer online banking, health information, and business virtual private networks (VPN). AS2 actually provides for encrypted communications while avoiding the necessity of obtaining certificates for each connection, in the same

way your bank does not have to establish individual certificates with you or other customers when you connect securely to their website using your web browser. These alternate techniques may need to be explored so that the industry can realistically scale to the level that a truly interoperable transaction framework will require.

According to RxTrace in the essay “Serialized Transaction Models,” DPMS does a better job of minimizing the number of AS2 connections than a distributed transaction model based on EPCIS. The Centralized model would limit the number to just one per company, regardless of supply chain segment, and the Semi-Centralized model could also limit the number to just one per company, if a connection service provider is used.

For a possible alternative approach and reader comments, see the full essay on RxTrace: <http://bit.ly/serialize-pedigree-models>. 



Impact on wholesaler/distributors, pharmacies, clinics, and hospitals

Wholesaler/distributors face an incredible challenge. They will receive data from hundreds of suppliers—and must disseminate it to thousands or tens of thousands of customers—and have to figure out how to manage it all.

A large wholesaler receives product from as many as 8,000 OTC and pharma companies. They break down most cases for outbound shipping, and every single unit of sale is hand-scanned—this is done in as many as 26 different distribution centers.

Distributors are faced with mitigating the impact of serialization on product flow through the distribution facility. They cannot depend on a system where a human is making decisions about how to manage each product as it moves through the facility; they must automate as much as possible.

One of the issues facing wholesaler/distributors is their ability to depend on the accuracy of aggregation data. The transaction data they receive from manufacturers must match what's inside those cases—100% of the time. To do this, they must be able to rely on the concept of [inference](#).

Because aggregation is not required by the U.S. law, U.S. wholesalers may not use the information. Manufacturers may still aggregate serialized contents to the serialized container to maintain records and track which serial numbers were shipped to a specific wholesaler at a specific price and to comply with requirements in other countries.

Pharmacies, clinics, and hospitals

Under most state or proposed federal transaction rollout plans, pharmacies do not have to be ready until much later than wholesalers/distributors. Last in the U.S. transaction rollout plan, pharmacies do not have to be ready until July of 2017. This has caused much complacency.

Smaller pharmacies will struggle to find resources to invest in scanning and storing transaction information. Many of these pharmacies will have to lean on their major distributors for help gearing up to meet requirements.

Pharmacies will eventually be required to have systems deployed that

Impact on wholesaler/distributors, pharmacies, clinics, and hospitals | continued

will be capable of receiving the transaction already mistakenly invested in transaction technology and approaches that are not interoperable with those that the wholesalers select will be forced to invest further to be able to participate.

Contract manufacturing and contract packaging strategic considerations

It's become a fact of life that the North American pharmaceutical industry, while still firmly rooted in manufacturing of its own products, also makes heavy use of outsourcing to contract manufacturing/contract packaging organizations. When it comes to serialization, however, pharma companies cannot simply drop the ball in CMO/CPO's laps and simply say, "Do it." There are a few reasons for this.

First, under most regulations, the brand owner (CMO's client) is ultimately responsible for serialized packages coming off the CMO/CPO's packaging lines. As such, the client company will want a firm hand in how that serialization happens, even if it's on someone else's packaging lines.

The second factor has to do with how CMO/CPOs are staffed. Over the years, CMO/CPOs are able to remain cost competitive

by keeping extremely lean staffs. That becomes an obstacle when it comes to implementing serialization. While some CMO/CPOs may have the engineering resources to adapt their lines, many lack the resources to handle the IT side of things.

Indeed, it's not unusual for some CMO/CPOs to outsource their entire IT function. The pharma client company may need to be involved at some level in order to support this transition.

Third, the business process connections between CMO/CPOs and client companies today are largely manual—e-mail, spreadsheets, and fax. Going from largely zero real-time visibility today to the complicated data interconnections required to exchange serialization information is a quantum leap that will require a lot of back-and-forth discussions, meetings, and time. The process of onboarding new CMO/CPOs, again a largely manual process today, will need to be completely rethought from the ground up for pharma client companies.

CMO/CPOs slow to act

If the pharmaceutical industry has been reluctant to move into serialization, then the CMO/CPO industry has been even slower to act. There are two factors that are responsible for what might be

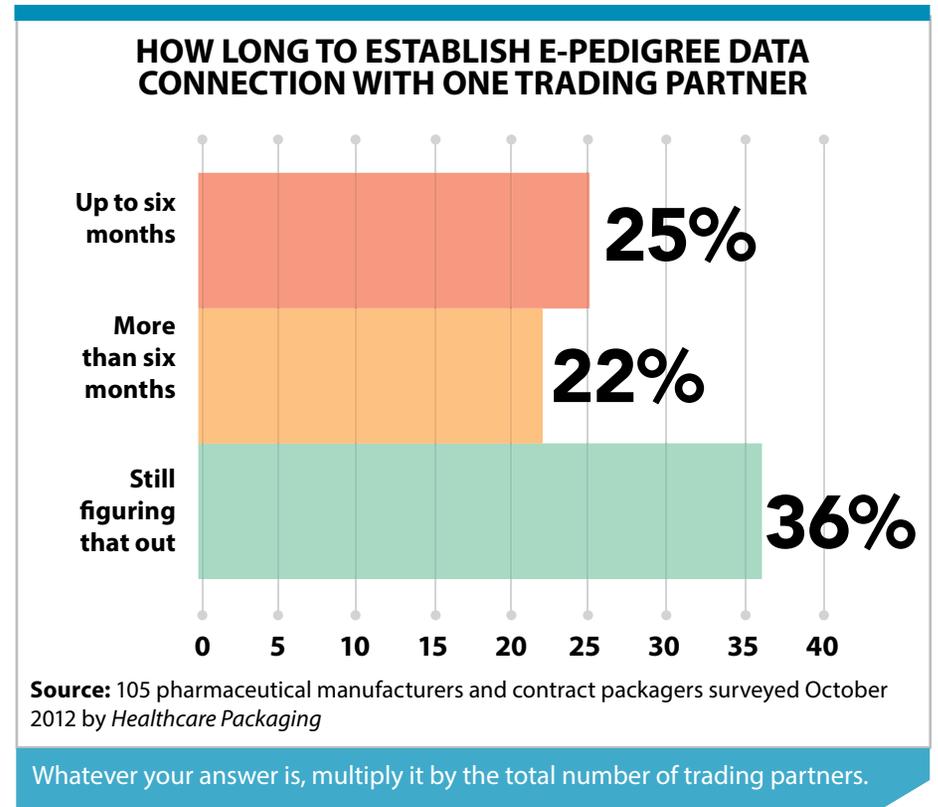
Impact on wholesaler/distributors, pharmacies, clinics, and hospitals | continued

described as paralysis in the CMO/CPO sector when it comes to serialization.

One is the fact that pharma client companies tend to focus on serializing their internal packaging lines first, a pre-occupation that seems to come at the expense of pushing their CMO/CPOs into serialization. This can be reflected in the finding by Healthcare Packaging's survey, conducted in October 2012, that reveals that only about a third of respondents have even surveyed their trading partners for serialization readiness, with another third not even knowing whether their companies had even surveyed trading partners!

Anecdotal conversations with industry experts reveal while many pharma companies are engaging in pilot tests, only a small fraction of them involve CMO/CPOs.

The second, and likely larger, reason for the delay is the sheer complexity of the connectivity involved. In addition to the work required to serialize their packaging lines, CMO/CPOs must work out IT connections to each of their clients, for products destined for various markets around the globe, all with different regulatory environments.



The engineering and IT gymnastics involved to pull off such a feat—let alone the time—is enough to overwhelm even the most seasoned professional. It's not surprising that we see answers all

Impact on wholesaler/distributors, pharmacies, clinics, and hospitals | continued

across the board when we asked what it would take to establish, test, and validate an electronic data connection with a single external trading partner.

One thing's for certain—that time frame will almost certainly be measured in months, not weeks.

In addition to the connectivity, CMO/CPOs have to figure out how to layer serialization on top of the client company's business processes (plan/procure/receive/stock/ship), as well as the CMO/CPO's own internal business processes (plan/ make/stock/ship). At the heart of this is determining the sort of site-level repository of serialization numbers and event data that will connect multiple lines to multiple customers. It also involves the technique to be used to share the serialization information. Not a cakewalk.

Finally there is the question of cost: Who pays? Neither party wants to, yet it must get done. No wonder things are moving along at a glacial pace.

However, there is a bigger threat to CMO/CPOs than noncompliance. It is the threat of letting 100 different pharma company clients dictate 100 different ways of handling serialization interfacing. While

it's true that the industry is coalescing toward GS1 standards for the standardized exchange of EPCIS event data, there are still many potential speed bumps inherent in any given implementation, due to the flexibility built into the EPCIS standard. In addition, a number of exceptions simply aren't addressed yet by EPCIS.

Many CMO/CPOs are already sharing shipment information using Electronic Data Interchange (EDI) with trading partners and have expressed a desire to leverage Advanced Shipping Notices (ASN) with Hierarchical Level (HL) to communicate serial numbers and aggregation. In short, there are many ways to skin the serialization cat. Pharma companies may be tempted to insist that their CMO/ CPO partners adopt the same serialization vendor they use. While that may seem logical on its surface, it's a sure recipe for confusion for CMO/CPOs, which will have multiple clients that use multiple serialization solution providers. Better to simply write serialization governance on how numbers get allocated, coded onto packages, transmitted, etc.

The main reason for CMO/CPOs to act now—versus remain on the sidelines—is to be the one to standardize on one way (or a small handful of ways) that pharma company clients can connect. In other words, instead of waiting for clients to issue their blueprint for connectivity, the CMO/CPOs should preempt by issuing their own.



Impact on wholesaler/distributors, pharmacies, clinics, and hospitals | continued

Unless the CMO/CPO tries to impose some level of standardization to the approach it takes with integrating with each customer, it can make integration a never-ending nightmare.

The CMO/CPO's standardized approach may inevitably be subject to massage by each client. But by shaping that conversation up front, at least it gives CMO/CPOs a fighting chance to stay on top of the integration burden that lies ahead. The window on exerting influence on pharma client company requirements has not yet closed.

That's not to say that CMO/CPOs should dictate to their client companies any more than the client companies should dictate to the CMO/CPOs. The main takeaway is that CMO/CPOs should not be making serialization decisions in a vacuum. CMO/CPOs should initiate three-way discussions among themselves, their serialization vendors, and their pharma client companies.

As expensive as serialization is, "Wait and see" is an approach that will only end up costing CMO/CPOs more down the road. +



Five implementation tips for CMO/CPOs

One of the biggest challenges that CMO/CPOs will face when it comes to serializing their lines is how to sort through the complexity of integrating their internal serialization solution at the line and plant level with their customers' business systems (see previous article). Here are a few things to look out for when designing and implementing a serialization solution:

1. Make sure your serialization solution can interface to multiple client company ERP systems or leverages standards to ensure interoperability. Most serialization solutions are designed to interface to enterprise systems within a single company, but not all of them are designed to connect to ERP systems across multiple companies. In other words, the plant-level serialization solution at a given CPO must not only talk to that CPO's enterprise-level serial number management solution (such as SAP's Aii module), it must talk to the Aii module (or equivalent) at each of its pharma client companies and keep that data separate. This is a challenge specific to CMO/CPOs that they need to keep in mind when shopping for a serialization solution.

To simplify the exchange of serialization information, many companies are turning to time-tested and widely used solutions found in other industries. A popular choice is the use of Electronic Data

Interchange (EDI) Advanced Shipping Notices (ASN) with Hierarchical Level (HL) serialization. These solutions are offered from many software companies and cloud-based solutions from Value Added Networks (VAN). For example, the latest release of SAP Auto-identification infrastructure (Aii) includes support for serialized ASN.

2. Be flexible in receiving or originating serial numbers. Most pharma client companies will choose to allocate serial numbers and send them to the CMO/CPO, but there may be some occasions where the CMO/CPO needs to originate the numbers. The serialization solution must be flexible enough to handle either requirement (or serial numbers generated by government agencies). CMO/CPOs will need to figure out how to easily toggle from their own serial number management to a client's (or a government's) with each job.

3. Support serialized and non-serialized product from the same customer. We will be living in a mixed serialized and non-serialized world for the foreseeable future. Your systems should be able to handle both simultaneously.

Five implementation tips for CMO/CPOs | continued

4. Understand what solution providers your customers are working with. And more importantly, what can be leveraged from their experience?

5. Determine how to support varying label requirements. Your system will need to account for the following customer requirements:

- **Summary of actual requirement**—for example, full serialization versus an enhanced encoding.
- **Permitted data carriers and sizes for units, cases, and pallets**—for example, DataMatrix at unit level, GS1-128 at case level, use of square and rectangular codes, and print quality standards.

- **Encoding formulas**—such as GTIN versus modified CIP and format of serial/batch numbers.

- **Plain text printing requirements**—such as format of expiration date, plain text, and the data carrier.

Some sort of internal review process will be necessary to compare the customer and product requirements against the specific country and region requirements. +



Questions to ask your CMO/CPO about serialization

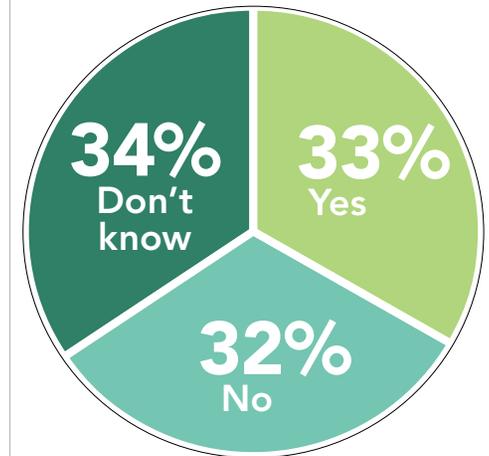
While the focus of many pharmaceutical manufacturers is on their own internal infrastructure, it's prudent for manufacturers to begin surveying their contract manufacturing and contract packaging organizations for serialization readiness. Below are a few questions to ask.

- Have you developed a strategy for serializing product? If so, what is your go-live date?
- What is your plan for managing serialized data (provisioning, exchanging, receiving, sending, storing)?
- How are exceptions handled?
- Do you have the ability to handle both serialized and non-serialized product?
- What contingencies do you have in place to ensure that there will be no disruption in production of customer's products due to complying with serialization mandates in a timely manner?
- What printing technology or technologies are utilized?

(i.e., impact printers, thermal printers, laser printers, ink-jet printers, etc.)

- Do you have the ability to print GS1 Standard barcode symbols (GS1-128, GS1 DataBar, GS1 DataMatrix, etc.) that meet minimum print quality requirements?
- Do you have the capability to verify/scan GS1 format barcode symbols?
- Can you grade the barcodes to ensure readability in the supply chain?

WE HAVE SURVEYED OUR TRADING PARTNERS FOR SERIALIZATION READINESS



Source: 105 pharmaceutical manufacturers and contract packagers surveyed October 2012 by *Healthcare Packaging*.

Lack of awareness of trading partner readiness signals a lack of attention being paid to this critical part of the serialization puzzle. Traceability isn't done in a vacuum—by definition it means connecting to someone outside your four walls.

Questions to ask your CMO/CPO about serialization | continued

Do you have the capability to receive a range of serial numbers from customer's system? (Separate from your other clients?)

- If yes, describe the communication methods supported (direct integration/web services vs. manual e-mail/text file/spreadsheet).
- Do you have the capability to communicate serialization event data to external systems? If so, in what format (e.g., flat file, XML, EPCIS)?
- Do you use Electronic Data Interchange (EDI) Advanced Shipping Notices (ASN) today, and have you considered it for sharing serialization information? (flat file, XML, EPCIS)? +

Section Five: Software and architecture



Line- and plant-level software implications

While GS1's Electronic Product Code Information Services (EPCIS) protocol standardizes the way serialization data is transmitted between trading partners, there is no such standard for communicating between a company's internal serialization solution and its Manufacturing Execution System (MES), Enterprise Resource Planning (ERP) systems such as SAP, and ERP modules that handle serial number management (such as Aii in the case of SAP). And therein lies the rub.

It's not uncommon for companies that have performed pilot testing in the last two to three years to have focused mainly on testing serial number management—getting the numbers from SAP Auto-identification infrastructure (Aii), for example, applying them to the packages, and sending back commissioning information.

But now that serialization is becoming a “real” concern in life sciences, the realization is dawning that it needs to be integrated into all the major business platforms in an automated, not a manual, fashion. Many IT staffs are trying to figure out how their manufacturing and enterprise systems will connect with the serialization solution beyond the serial number itself. A lot of infrastructure decisions—file structures, platforms, how to move data—need to be thought out ahead of time, rather than on the fly.

Integrations at the enterprise

As mentioned above, companies have typically focused on integration with SAP Auto-identification infrastructure (Aii) or Oracle Pedigree and Serialization Manager (OPSM), or equivalent serial number management components of the ERP system. That's just one piece of the integration puzzle, and the only piece that people typically focus on during pilot testing.

Connecting to the EPCIS layer

The lack of standard connections to manufacturing and ERP systems is also a problem when connecting to the EPCIS system. Again, communicating with external trading partners with EPCIS is straightforward, as long as everyone's using GS1-compliant XML interfaces that comply with the EPCIS standard. But communicating internally between the line systems and the system that handles EPCIS communications is not through a standard interface. For example, Optel Vision may connect and pass data differently than Acsis, Laetus, or Seidenader (Körber Medipak). It's not unusual for custom interfaces to be written, which often require care and feeding, especially in the first few months after launch. Nevertheless, as EPCIS grows in popularity, packaging control system vendors are beginning to comment that they will support the standards.

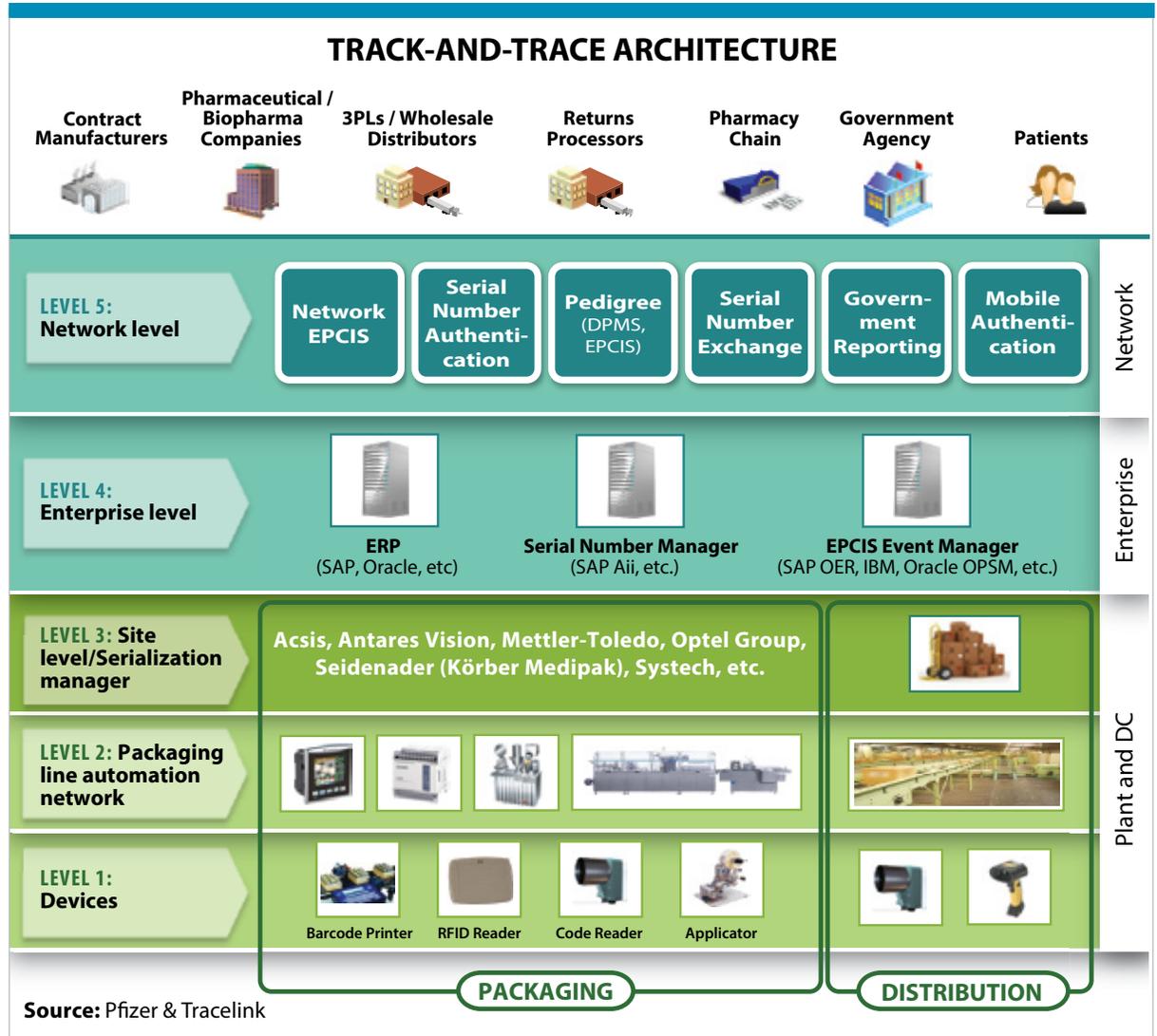


Line- and plant-level software implications | continued

But there's more to serialization integration than serial number management. To create recipes within the serialization solution, a lot of material master data that has nothing to do with the serial number itself—for example, GTIN information, package item information, multipack counts, case counts, pallet counts, and variable formats for label files—needs to flow into the serialization solution as part of a recipe. That data resides in enterprise systems. Figuring out how it gets into the serialization solution is the trick.

During pilot testing, it's common for this type of information to be entered manually into the serialization system. But when you're running 15—or 50—packaging lines, a manual process is not scalable. Many companies are considering electronic batch records (EBR) as part of their serialization project to help address this issue.

A proper serialization program extends way beyond the packaging line, up through the enterprise and out to the entire extended supply chain.



Line- and plant-level software implications | continued

For the manufacturing site layer, the primary question is how to get the production order into the serialization system. How are you starting and ending batches? How does that trigger access by the serialization system to the ERP system to obtain that material master data?

Because these integrations are different for each company depending on its mix of manufacturing and ERP platforms, the serialization solution needs to be configurable to provide a way of connecting these systems that can be validated. +



Avoid these EPCIS interoperability pitfalls

One of the greatest challenges facing the pharmaceutical supply chain is hooking up multiple ERP systems and business applications across the supply chain, spanning the manufacturer, contract packager, wholesaler/distributor, and pharmacies. Ensuring interoperability of the data across the supply chain is a challenge, even if all parties adopt GS1's EPCIS standard.

Pfizer shared the results of an EPCIS pilot test it conducted with McKesson, during [a webinar it conducted with Tracelink](#) in April 2012. All participants in the pilot were well-versed in EPCIS, yet they still ran into interoperability issues because different companies were using and interpreting the standards in different ways.

Because the EPCIS standard was designed to be highly flexible to support a variety of use cases across many industries, there is room for different interpretations of how those standards might be applied.

Here are the interoperability pitfalls Pfizer uncovered:

1. All trading partners must adopt the EPCIS guidelines in the same way. This includes:

- Rules for common use of GLN, DEA, or HIN for identifying Sold From, Ship From, Sold To, and Ship To parties
- Common interpretation of what value to assign to data elements: Sold To is different from Bill To address
- How to represent the Sold From and Sold To party if they lack a GLN
- Agreement on which method should be used for the business transactional identifier, since several are allowed in the GS1 core business vocabulary—for example, PO Number, ASN Number, RMA Number, etc.

2. All trading partners must follow a common interpretation of EPCIS events and extensions for each use case.

This includes:

- Shipping product, confirming product receipt, returning product, confirming return receipt, shipping a repackaged product, exception use cases, etc.

Avoid these EPCIS interoperability pitfalls | continued

- Which combination of EPCIS events is used for each use case
- Which event business steps and dispositions are used
- Which GS1 US Healthcare extension data elements are used
- Which data elements are truly required versus optional for each use case
- When a data element is optional in the XML schema, when is it conditionally required for a specific use case
- The GS1 US Rx Guideline (www.gs1us.org/RxGuideline) spells out the exact format of each and every EPCIS event and attribute.

3. Watch out for dependencies, repurposed data elements, and precedence relationships:

- **Avoid creating dependencies on the presence of optional data elements.** Otherwise your software application may break when that data element is not present in a given transaction.



KEY
CONCEPT

EXCEPTIONS

In the world of serialization, an “exception” is an event that happens in the supply chain that interferes with, or is not part of, the expected flow of goods from manufacturer to wholesaler/distributor to pharmacy/clinic/hospital. Examples include damaged product, returns, incorrect transaction information, etc. A working group within GS1 is currently maintaining a list of such exceptions with an eye toward augmenting the EPCIS business vocabulary to account for them.

- **Avoid repurposing data elements for different meanings.** Not everyone may provide a given data element in the way you expect. Always try to follow the intended meanings of the guidelines. This can be hard sometimes, because the standards can be a bit ambiguous.
- **Avoid building in restrictive precedence relationships for events created by business processes managed by upstream supply chain partners.** A classic example is the relationship



Avoid these EPCIS interoperability pitfalls | continued

between the commissioning event and the aggregation event. If your software assumes that the event time for when the aggregation occurs must always be after the commission time, it creates a potential point of failure. That's because it is possible for the item- and case-level aggregations to have identical event times, depending on how aggregation capture is implemented on the packaging line. Overly restrictive rules that make assumptions about one event preceding the other could cause product to be rejected by a downstream trading partner.

If in doubt, check with your supply chain partners to confirm you are both following and interpreting guidelines in the same way before you begin exchanging event data.

Exception 1: Overage

Exception 2: Shortage

Exception 3: Transaction Serial# Discrepancy

Exception 4: Transaction Lot# Discrepancy

Exception 5: Transaction Serial# And Lot# Incorrect

Exception 6: Product Inference Problem

Exception 7: Quantity Inference Problem

Making exceptions for the exceptions

Not all supply chain events can yet be depicted in EPCIS events. These are known as exceptions, and they tend to fall into the area of reverse logistics, such as returns or recalls. The Rx Secure Supply Chain Working Group within GS1 US maintains a list of exceptions. The list can be found in the current Rx Guideline (www.gs1us.org/RxGuideline). The next version of the guideline is expected to provide the choreography of EPCIS events that trading partners can use to address problems if they occur.

Exception 8: Physical Inventory Overage

Exception 9: Physical Inventory Overage (Concealed Overage)

Exception 10: Physical Inventory Shortage (Concealed Shortage)

Exception 11: Transaction Contains Incorrect Customer/ Location Information

Exception 12: Transaction Contains Incorrect Product Information



Avoid these EPCIS interoperability pitfalls | continued

Exception 13: Transaction Contains Incorrect Reference# Information

Exception 14: Transaction (Or EPCIS Ship Event) Not Received By Customer

Exception 15: Undelivered Shipment

Exception 16: Lost Shipment

Exception 17: Received Physical Product From An Unidentified Sender

Exception 18: Missing

Exception 19: Could Not Read Transaction Data Due To Security Mismatch

Exception 20: Transaction Data Not In Correct Format

Exception 21: Good Product - Damaged Barcode Or RFID

Exception 22: Damaged Product - Good Barcode Or RFID

Exception 23: Damaged Product - Damaged Barcode Or RFID

Exception 24: Damaged Shipment

Exceptions 25 And 26: Resolved – Have Been Accounted For In Other Exceptions

Exception 27: No Parent-Child Aggregation

Exception 28: Transaction Data Incomplete

Exception 29: Transaction Data Has Broken Chain

Exception 30: Shipped Product To Wrong Customer & Transaction Data To Correct Customer

Exception 31: Customer Refuses Order

Exception 32: Unauthorized Return

Exception 33: Shipment For Wholesaler “Y” Arrives At Wholesaler “X” +



Issues with master data

Trading partners with whom you exchange EPCIS event data will request what is known as “supply chain master data” about your products, company, and locations that will be referenced in EPCIS events. This data takes two basic forms:

Product master data: NDC, GTIN, drug name, manufacturer, dosage form, and other product details.

Location master data: Business name and address details associated with a company GLN or other identifier.

There are a couple of issues with master data when it becomes supply chain master data—data that is shared with trading partners. One is the lack of automation involved in its exchange. When trading partners begin pilot tests with one another, the exchange and configuration of such data is typically done manually (such as through spreadsheets). There are several problems with this:

1. It doesn't scale. Manual setup is fine for a pilot or two, but such a setup process doesn't scale across dozens or hundreds of trading partners.

2. Standardization doesn't yet exist for some of the specific data elements that need to be exchanged.

3. Different companies may request different formats with different data element names depending on their EPCIS implementation.

4. Supply chain master data changes over time. Package configurations, dosage changes, and other product details may change over time. A manual data exchange process is an inefficient (and tough to validate) way of transmitting those updates.

As you scale your deployment, it becomes important to automate the file format and the method for exchange. Some thoughts to keep in mind as you ponder supply chain master data:

1. What do you need from others? You need to understand what supply chain master data you need from your trading partners.

2. What do your supply chain partners need from you?

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Issues with master data | continued

3. How will you manage updates? Until you can automate a scalable synchronization process for exchanging supply chain master data, you will need to put into place some sort of process for all trading partners to manually keep one another's master data up-to-date. +

How to avoid the leading zero issue

There are a number of layers of software systems involved in serialization: line- and plant-level serialization systems, ERP-level serial number management systems, and network-facing EPCIS systems. It's important to understand how each of these systems represents, processes, and transforms serial numbers internally.

It turns out that some systems express serial numbers as character-based entities (letters), others express them as numeric entities (numbers).



Tip: You can avoid the leading zero issue altogether by simply starting at a high number (e.g., 100000001) and fixing your serial number length.

What may seem like a quotidian trifle, of interest only to math geeks, can actually turn into a major business issue. Why? Character-based formats preserve any leading zero that may be present in a serial number. As you were taught in

grade school, numeric formats don't. For example, "00012345" in a character-based system would become "12345" when stored in a numeric-based system.

When two software systems must communicate—either within your company or between you and your trading partners—this difference can result in a mismatch between the two systems, and a mismatch is likely to cause rejections of product, causing real headaches.

Leading zero are also not acceptable when using RFID, so if your electronic systems expect the leading zero, they will be lost when the serial number is encoded into an RFID tag. Even if you are not using RFID today, it may become desirable in the future, and this issue will rear its head.

Make sure to audit all systems that exchange your serial numbers—both inside and outside your company—to ensure they follow GS1 standards closely and express them the same way, or that functionality is put into place to prevent this from becoming an issue. +



Preventing counterfeit transaction data

Although many people may think of serialization and transaction as the industry's final checkmate in the counterfeit arms race, nothing could be further from the truth.

Counterfeiters—which are organized crime enterprises, not petty criminals—will attempt to counterfeit not only your packaging, but also your electronic transaction data itself, along with authentication portals and websites.

GS1 is working globally and in the U.S. on the issue of product security, not only with regard to the physical product itself, but also the transaction data as it flows through the supply chain.

Due to the complexity of the supply chain, GS1 uses simulation software to help expose security vulnerabilities that may exist in the supply chain, to allow new ideas to be tested to close them up, and to try to avoid creating new vulnerabilities or vectors of attack that criminals can leverage.

From a manufacturer's standpoint, once a product ships from their loading dock, they essentially lose sight of it. From a data point of

view, once they send an ASN or shipping event via EPCIS, it's off their radar screen.

These transition points in the supply chain are essentially the vectors of attack. It is possible for someone to pose as the manufacturer and falsely pass EPCIS data to a wholesaler/ distributor. (A secure communication mechanism such as AS2 is designed to prevent such hijacking of identity.)

The fundamental question is one of authentication: How do the trading partners across the supply chain know they have an electronic connection that's secure and that the trading partner sending data to them is who they say they are?

One solution that's being explored is the idea of having a manufacturer start what has become known as a Chain of Custody List (or CoC-List) for each item. This simplified list can act as a "proxy" for the full transaction data. At the time of receipt, the next trading partner will know which other trading partners had held custody of the item and be provided a mechanism by which their transaction system could verify the information directly with the trading partner

TAILOR MADE SOLUTIONS DEVELOPED BY THE TRACK AND TRACE EXPERTS OF OCS

BOTTLE SERIALIZATION

TQS-SP-Bottle prints auxiliary codes and verifies bottles and vials. Printing is completed by the CIJ printer either on the underside or the top of the container (utilizing ultra-violet activated ink or standard black ink depending on requirements). Subsequently, the machine verifies the previously serialized bottle or vial labels for downstream aggregation utilizing the auxiliary code.



TQS-SP-Bottle



TQS-CP-Bottle

SHIPPER/CASE AGGREGATION

TQS-CP-Bottle is designed for the perfect integration in bottle or vial production lines. The system can be set up directly at the outlet of any conventional labeling machine to verify the previously serialized labels on individual cylindrical containers via an omnidirectional, 360° inspection. Registered bottles/vials are then released in a controlled manner for the manual case packing (aggregation) process.

Preventing counterfeit transaction data | continued

who is represented as having asserted the original portion of the CoC-List. This mechanism simplifies the amount of data passed between trading partners, allows companies to leverage their Master Data Management efforts further, and provides a means for trading partners and inspectors to analyze, verify, and react to simple mistakes and nefarious activity appropriately. +

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Section Six: Pilot Testing



Determining goals and metrics for pilot testing

There are two schools of thought when it comes to pilot testing. One is that you go in knowing it's a 100% disposable test, for pure R&D purposes, and that you have no expectations about reusing the equipment or software in that test as you scale up for real production. The second school of thought says, quite simply, there isn't time for that!

Do your homework, make your plan, write your strategy, pick your technology, and pick one real line running one real product as your pilot test. Most importantly, link up with one real trading partner to see if they can read your codes and understand your transaction data. Your "pilot" should be a real implementation from which you can scale, not an academic exercise.

Before you jump into a specific pilot, however, you should know what the goals of the pilot test are. Here are some goals to consider:

1. Understand the potential organizational impacts. This could mean gaining a better understanding of the implementation process, the impact on company resources to roll out serialization, the need for external support, and the costs, or assessing the feasibility of the

requirements and timelines. Developing experiential knowledge on the installation process, testing, and verification of actual installation time should be some of the main desired outcomes for the pilot.

2. Assess the impacts on line efficiency and uptime. This breaks down into several sub-areas:

- Identify impacts to line efficiency stemming from process or equipment changes
- Measure and record impacts to line efficiency
- Define mitigation plans to reduce line efficiency impacts
- Define inventory build-up plans to mitigate risk of inventory stock-outs during serialization implementation
- Define actual timeline for the implementation of serialization on the packaging line (hardware installation, IQ, OQ, and PQ)
- Define assignments of backup lines for serialized SKUs

Determining goals and metrics for pilot testing | continued

3. Identify and develop new packaging-related documentation and processes necessary to support and implement a serialization project, such as:

- Use cases and functional specifications
- Standard operating procedures
- Bills of specifications
- Artwork documentation
- Validation documentation
- Process mappings
- Project plans

4. Assess serial number coding and aggregation capabilities. This involves gaining insight into your ability to accurately print serial number information onto the package. But more importantly,

this is where you can learn how to build aggregated hierarchies of item-to-case and case-to-pallet. Doing so consistently with a high degree of accuracy is the challenge. Don't forget to involve an actual downstream trading partner such as a wholesaler/distributor. This is necessary to help test the readability of your serial number encoding at the item, case, and pallet levels on their equipment, as well as test the accuracy of aggregation transaction data you are sending to them.

5. Assess how trading partners prefer to receive serialization and aggregation data. Some may prefer ASN, though the industry is moving toward EPCIS.

6. Test your ability to successfully send and receive transaction event information electronically. This one breaks down into several sub-goals:

- Identify the communication channels your trading partners prefer (web services, subscribe-push, query-pull, etc.).
- Test your ability to exchange EPCIS event data using GS1 US Rx Guideline (www.gs1us.org/RxGuideline).

Determining goals and metrics for pilot testing | continued

- Understand how to use extension data as documented in the GS1 US guideline.
- Decide what to communicate regarding your supply chain master data (see “issues” for a discussion on this).

7. Test your trading partners’ ability to send and receive transaction event information electronically. This includes direct trading partners such as wholesaler/distributors, and ideally indirect trading partners such as pharmacies. The further down the chain you go, the tougher it will be to find trading partners that are able to actually receive



METRICS FOR PILOT TESTING

When working through your goals for pilot testing, you will want to choose your metrics carefully. Some sample metrics are listed below, though don’t try to use all of them. Limit yourself to the most important ones to avoid drowning in metrics data.

- Unit RFID read rates during packaging
- Unit RFID read rates during distribution
- Unit DataMatrix read rate
- Case label reject rate
- Pallet label reject rate
- Unit-to-case aggregation exceptions
- Case-to-pallet aggregation exceptions
- Unit/case/pallet aggregation accuracy
- Duplicate serial number exceptions
- Time to serialize one lot
- Average time to process a pallet shipment
- Time for unit-to-case aggregation
- Time for case-to-pallet aggregation
- Time for case-to-pallet disaggregation
- Serialized ASN exceptions
- Transaction creation/processing/signing exceptions
- Integration exceptions between serialization infrastructure and EDI
- Integration exceptions between EDI and serial number management system



Determining goals and metrics for pilot testing | continued

your data, since the transaction deadlines are a year later for wholesaler/distributors and two years later for pharmacies.

8. Identify exceptions and best practices for handling exceptions. Currently not all supply chain events can be depicted in EPCIS. These exceptions tend to consist of reverse logistics such as returns (possibly due to shipping errors) or recalls. This is an area that's in flux, so over time, these exceptions should be fewer and fewer. Consider contributing your findings to GS1 to inform its exception handling usage guidelines.

9. Assess network-centric transaction models as they are defined. There are several models defined by GS1 that consist of variations on centralized, semi-centralized, or distributed. You may want to try different models to assess the pros and cons of each approach.

10. Test failure scenerios. Develop a pilot script to test various “what if” failure scenarios and to help with the development of Risk Evaluation and Mitigation Strategy (REMS) and SOP. +



Getting started with pilot tests

Once you've identified your goals, you should start giving thought to selecting one or more sites, lines, SKUs, vendor technologies, and trading partners for your pilot test(s).

The temptation may be to start with one line or SKU, but much can be gained from testing two different lines, at two different sites, or two different package types, two different vendor technologies, or two different trading partners. Testing two of any of the above will accelerate your learning and reduce risks associated with meeting compliance deadlines— but it will take considerably more effort!

Pre-pilot prototyping off your packaging line, using test enterprise systems, can smoke out important issues before moving to actual lines. Many jump right to a packaging line and run into issues that delay the start of the pilot and threaten to compromise the overall test.

Site, line, and SKU selection criteria

There are several things to consider when selecting just where to locate your pilot test:

1. Site selection: The main thing here is picking a site that serves

different global markets so that you can test your ability to meet multiple regulations.

2. Line selection: You will want to consider lines that can accommodate different package types (bottle vs. carton vs. blister), as well as lines that have availability during the pilot phase for running serialization tests. You may want to try to test aggregation with automated as well as manual case packing (and if applicable, aggregating with automated vs. manual palletizing). You may also want to test a high-speed line.

3. SKU selection: A high-volume SKU is a good thing to look for, along with variations in package types, or a SKU that is available in multiple trade packaging configurations.

Equipment install timeline

Although getting the IT architecture in place for a serialization pilot can take as long as a year, the actual modification to a packaging line may be anywhere from one to six months. The detailed installation schedule will depend on plant activities, product launches, and line shutdown plans. Activities and milestones to include in your timeline are:

Getting started with pilot tests | continued

- Software updates to equipment already on the line to enable serialization
- Management of all subcontractors and schedules
- Changes in packaging equipment hardware and software
- Addition of new equipment to enable serialization (printing, inspection)
- System integration of all packaging line equipment to enable serialization
- System troubleshooting
- IQ, OQ/PQ

- Training of operational personnel and other site functional groups

Selecting partners

While it may be tempting to focus solely on internal testing for your pilot, it's not a true test unless a trading partner can scan your code and reconcile that with the transaction data you're sending. Identifying pilot partners is not so much a matter of willingness, since many may express interest, but rather a question of whether they have capabilities in place to receive serialized product and serialized data. They also need a commitment not only from their organization but also from their solution providers to work with you to test the process. Finally, they need to have the dedicated resources in place to be able to follow through with all of the work associated with a pilot test. +



“Preflight testing” your supply chain pilot

Once you start shipping live product as part of a pilot test, it is not easy to revert back into test mode. You’ll need to wait for another order to be placed in order to see the results of a change. Before you begin, here are a few things you can do in the way of a “preflight check” to avoid problems once you’re underway:

- 1. Exchange and pre-test samples of serialization encoding and carriers**, such as sample DataMatrix, before starting the pilot to flush out barcode reader and format compatibility issues.
- 2. Agree on how EPCIS events and vocabulary will be exchanged.** Test the communication link (e.g., AS2 or web services)

and message exchange up front to make sure the security, the connectivity, and the processing work correctly.

- 3. Exchange and process EPCIS events in test systems before starting the supply chain pilot to flush out issues quickly.** This can save a lot of time in the supply chain pilot process, especially for EPCIS interoperability issues such as supply chain master data-exchange requirements, consistent use of EPCIS event and extension data for supply chain use cases, consistent use of company and location identifiers in EPCIS events, and precedence relationships of EPCIS events. +



Lessons learned: Project and vendor management

Here are some key lessons learned from those who have conducted live supply chain pilot tests. This article focuses on lessons learned about project and vendor management.

Project management

1. Start simply with goals and metrics. When conducting pilots, there is a strong temptation to test as many goals and collect as many metrics as possible. In actual practice, some serialization teams have found that defining too many goals and metrics up front simply overwhelmed the team with data before they had a good grasp on what goals were really viable. Beware of defining too many goals and metrics at the beginning because it's likely you won't know enough at that point to understand what goals are achievable, or what metrics are valuable.

2. Getting adequate testing time on production lines can be a major challenge. Especially for high-revenue products and highly utilized production lines, it can be very difficult to get time on the line to make improvements. Scheduling requirements, revenue targets, and production needs will always work at cross purposes with pilot testing. Buy-in from top management regarding the importance of pilot testing is key to keeping the project moving

forward. Pre-pilot prototyping can help smoke out issues before the pilot and maximize the time on the actual packaging line.

3. Frequent meetings are necessary. The plant-level project team should plan to meet about every other day two weeks prior to and during the implementation and go-live phases. Such feedback helps to solidify plans and identify many minor issues for corrective action.

4. Consider producing more serialized product than you need for your current pilot. That allows you to respond to trading partners that request serialized product for their pilots without having to touch your production line.

5. Don't rely on a sandbox as your only pilot. Sandbox environments can never duplicate the real flow of products and data, and hence will not give you good visibility into the actual problems you're likely to encounter once your volumes scale.

6. Don't pilot-test with just one trading partner. The more trading partners you test with, the more you will stress-test your own system by careful scaling, and the more use cases you will encounter, to assure you're building a robust serialization capability.



Lessons learned: Project and vendor management | continued

7. Give your wholesaler/distributor a heads-up when the first serialized pilot shipment is released. This ensures that the wholesaler/ distributor's staff is ready to watch for and oversee the first few shipments, where processing exceptions could be likely.

Dealing with vendors

1. Vendor evaluation is important. How does their technology contribute to accurate aggregation? Does the price go up depending on how accurate a level you require? If they do not bring aggregation up themselves, it may signal a lack of experience. Confirm the vendor's knowledge of the industry. Identify weaknesses such as ability to scale, staffing, global support, familiarity with standards, etc.

2. Beware of multi-vendor software collaborations. Having two vendors collaborate on software requirements, design, and implementation on your behalf may not work out for the best. It can be preferable for one vendor to own the total solution. Consider leveraging vendor-independent subject-matter experts to ensure that the requirements are tailored to your business and not the limitations of the vendor solution.

3. Consider speed and quality when selecting individual system components.

4. Dedicate a project management resource to each external vendor. This helps properly manage delivery. +



Lessons learned: On the packaging line

Here are actual lessons learned about what actually happens in the plant and on the line, from those who have conducted live supply chain pilot tests:

Printing and reading codes

1. Move DataMatrix away from other barcodes on the label.

Multiple barcodes, such as a UPC/EAN and a DataMatrix, on a label should be separated so that scanning is more efficient and accurate. This is especially important for hand scanning—in some situations operators had to cover a traditional linear barcode with their finger so that it would not be read.

2. Use a fixed barcode scanner on the conveyor that can read across the conveyor.

3. Watch for vibration. It can affect both printing and scanning.

4. Make sure label roll changes on label printers don't cause serial numbers to get out of sync.

In one pilot, when the printer ran out of labels, the system buffered the current label and paused to wait for labels to be reloaded. However, upon reload, the system printed the label again, causing all aggregations to be

off by one. Make sure your QA process is modified to check not only whether the label printed properly, but also whether it was the correct number in the serial sequence.

5. Manual scanning slows down the process.

Picking up each bottle, scanning the barcode, and putting the bottle in the case takes more time and precision than just packing the bottles in the case and taping it up.

6. Test printing on multiple carton substrates.

During typical production runs, you may use multiple lots of cartons from different suppliers, each of which might have subtle but meaningful variations in printing due to substrates from different batches or board suppliers. Ensure that all conceivable variations are tested.

7. Use rails and clear covers to control access to serialized items on the packaging line.

This helps to control sampling and product movement.

8. Employ barcode grading to detect the degradation of symbols that can result in unreadable barcodes in the supply chain when traditional hand scanners are used.

Unreadable codes may result in returned goods and product shortages.



Lessons learned: On the packaging line | continued

9. Control pallet aggregation to avoid cases being moved between pallets before they are wrapped.

Equipment and workflow

1. Conveyor solutions need stress testing. Ensure that the interface between the serialization application and conveyor PLC is robust.

2. Physical keyboards are easier to use than virtual ones. On-screen keyboards are difficult to use and slow down the process.

3. Adding serialized barcodes on cases in addition to normal barcodes may cause confusion. Workers may not know which barcode to scan; additional training and clear instructions will be necessary.

4. Disaggregating units from a case (or cases from a pallet) before aggregating to a shipment is inefficient. Manual rework and aggregation is extremely labor-intensive and error-prone. A process is needed that supports scanning once to perform both functions.

Software

1. Create an easy software update process. As you receive software updates from vendors, ensure the vendor is providing clear release notes for what is being updated. Work with the vendor to ensure the process to apply the upgrade is very easy and that the upgrade can be quickly validated.

2. Data volumes can clog your pipes. Some companies have found that, depending on the speed of the packaging line, the processing speeds of legacy controllers, hardware, and infrastructure on the line cannot keep up with the input/output rates associated with transmitting serialized data.

3. Beware of embedded operating systems in the packaging control system that are difficult to upgrade. As more and more serialization control systems are networked to receive batch information, an outdated embedded OS can create an issue with your network governance policies and make it difficult to use malware and antivirus software. +



How GS1 can help with pilot testing

GS1 US offers a Readiness Pilot program that offers a simple approach for initiating and managing pilots. The program was developed for serialization required under California law but still applies to serialization under the U.S. federal law. It provides a ready-made structure, support tools, simulation methods, and GS1 Standards expertise. Participants also benefit from a collaborative environment for sharing experiences, lessons learned, outcomes, and best practices across all pilot activities.

The GS1 2015 Readiness Pilot program is based on the concepts developed by the GS1 Healthcare US Traceability Adoption Workgroup, the Secure Supply Chain Task Force, and 2015 Readiness Program members to support industry-wide implementation. A key component of this work is the U.S. Pharmaceutical Industry Reference Model (IRM-Rx), which includes the simulation of business processes and data collection across the entire supply chain using GS1 Standards for serialization and visibility, as well as an analysis engine that can be used to assess your results.

Advantages of readiness pilots

- Get started quickly using a ready-made pilot structure
- Join established pilots
- Design your own pilot based on individual readiness and needs
- Easily manage your pilot with the tools and resources provided
- Find pilot partners through GS1's industry network
- Connect with industry members that can share experiences specific to your pilot
- Learn from other pilots



How GS1 can help with pilot testing | continued

Support for your pilot:

- Access GS1 experts for standards-related implementation questions
- Test your readiness against the Industry Reference Model and explore the results with the analysis engine
- Leverage a virtual pilot partner for hard-to-test processes such as recalls, serial number discrepancies, concealed shortages, and more
- Gain insights and share learnings across all Readiness Pilot participants to support industry-wide implementation
- Test your case and pallet aggregation
- Transaction data exchange for recalls, returns, and forward logistics
- Single-tier and multi-tier scenarios

Share your results

When you contribute what you learn back to GS1 US, the entire industry learns more quickly, solidifying standards and reducing costs at every step of the supply chain. Much of what you read in the “Lessons learned” section of this Playbook came right from those pilot results, and would not have been possible without those companies having shared what they have learned. Please consider doing the same.

To learn more, please contact Bob Celeste, Director, Healthcare, GS1 Healthcare US, at rceleste@GS1US.org. +

Readiness Pilot examples include:

- Serializing your products

Business process considerations for mixing serialized with non-serialized shipments

You might need to implement special business processes for handling serialized versus non-serialized shipment processing with your supply chain partners during piloting. Here are a few items to contemplate:

- 1. Use special purchase orders** or special indicators on purchase orders to indicate a specific order that contains serialized product. That will indicate to the manufacturer that an order specifically requires serialization. It signals back to the wholesaler/distributor that the shipment should go through a serialization-specific receiving process.
- 2. Coordinate with your customer service personnel** when initial pilot orders are placed to permit such orders, even though they are for (smaller) nonstandard ordering quantities.
- 3. Coordinate and train warehouse personnel** for pick/ship and receipt handling of the serialized product.
- 4. Create a process for bleeding out non-serialized inventory** while you are introducing serialized inventory and managing what gets shipped to whom.

5. Store serialized product in specialized locations to help manage different processes for serialized versus non-serialized product.

6. Create differentiated processes for managing non-serialized and serialized product at the unit, case, and pallet level.

Two business processes to think about

There are two business processes that your serialization system must take into account:

Exception use cases. For example, what happens if transaction information is already transmitted from the manufacturer to the wholesaler/distributor, and something physically happens to the pallet that results in a case of product being destroyed? The aggregation of cases to pallets needs to be rebuilt.

Returns processing. Similar to the above, if a product is shipped, and the transaction information is transmitted, what happens if some of the shipment is returned? Depending on the reason for the return, you may either destroy or reshelve the product. If it's restocked, it will be reshipped to another wholesaler/distributor—but transaction data associated with that inventory says it was already shipped once. Logic must be built into the serialization solution to handle this.



Business process considerations for mixing serialized with non-serialized shipments | continued

7. Create new GTINs for serialized goods. GS1 guidance recommends the GTIN change when labeling changes. The addition of a serial number and logistics data carrier such as a DataMatrix may dictate a change. The use of specific GTIN for serialized goods takes the guesswork out of identifying them. +



Section Seven: Vendor Selection Resources



Questions to ask serialization solution vendors

Shopping for a serialization solution can be daunting. Use this list of topics and questions to compare responses from different vendors.

Develop User Requirement Specifications (URS) tailored to your business to establish use cases and specific requirements. Convert the requirements into a set of questions and require the vendors to respond with how their solution addresses the need. This provides a method for comparing and scoring vendors and reduces subjectivity. Consider an independent subject-matter expert to leverage their experience and lessons learned when developing the URS and questions.

Serialization system questions

1. Data flexibility. Can the system be configured to capture additional user-defined data fields that may be required for future mandates or for specific business benefits, or are the existing fields hard-wired into the system? In other words, to obtain business benefits from track-and-trace beyond mere compliance, you may need to capture additional data, but if the system isn't flexible enough to do that, it constrains your ability to enjoy that business benefit.

2. Internal connectivity flexibility. Is the solution capable of

delivering the results of the serialization to multiple systems such as the serialization repository, ERP system, quality system, etc. Is the format for this communication configurable?

3. External connectivity flexibility. How easily does the solution allow communication with outside parties, either regulatory entities or trading partners? Is it highly configurable without the need for significant programming?

4. Speed. Can all of the components of the serialization solution keep up with existing line speeds?

5. Rework/aggregation management. Does the solution include the ability to manage manual aggregation during rework scenarios?

6. Distribution. Does the solution have the ability to manage serialization beyond packaging?

7. Internationalization. Does the solution support all of the current international requirements for serialization?

8. Maturity of technology. How long has the vendor been



Questions to ask serialization solution vendors | continued

developing the hardware and software that constitute the serialization solution?

Support and experience questions

Here are a few questions to ask about the company behind the serialization solution:

1. Availability and timelines. What is the vendor's promised timeline to implement?

2. Thinking beyond compliance. Does the serialization provider understand the big picture, and are they architecting a solution that will provide long-term business benefit, or is the focus solely on compliance?

3. Pilot experience. What pilot experience does the vendor have?

4. Support. Does the serialization provider have the required post go-live support to manage supporting a fully deployed solution? Is the provider's customer support program capable of supporting 24/7 service needs on a global basis, with personnel to support different time zones? If not, what is their support strategy?

5. Project and vendor management. Do you need to manage multiple vendors, or will the solution provider handle full program management (hardware, software, validation, etc.)?

6. Global footprint. Does the serialization vendor have the required project delivery personnel to support the installation, validation, and training of their solution on a global basis?

7. Partner resources. If the serialization vendor is partnering with third-party integration suppliers to assist as part of their global rollout strategy, what is the vendor's ability to transfer the required product and packaging knowledge to the integrator to support their global commitments? What is the realistic timeframe for this transfer of knowledge so the integration supplier can be considered a viable partner?

8. Machine vision support. How will the serialization provider support their machine vision system offering on a global basis (both services and stock)?

9. Training capabilities and training content. What kind of training does the company provide? How long? In what format? +

Vendor Selection Resource Guide

Most experts agree, rather than trying to fit a supplier's solution to your problem, it's better to develop a requirements document that spells out what you need to accomplish on every line, with every product, in every state or country.

Suppliers should be required to answer "yes" or "no" to the criteria and certify their solution does or does not meet this specific requirement. A review of suppliers based on their ability to meet your requirements, not on their sales pitch, will reveal the best supplier for you and reduce subjective decisions.

The vendor's answers to the questions may then be used to develop contracts and ensure the vendor delivers what they promise.

This requirements document is valuable because it will also help you

understand what you will need to monitor, measure, and validate.

You need a partner to help you understand the specific requirements in Turkey, Brazil, Italy, India, China, South Korea, and the U.S. Look for a solution provider that has the experience and knows how to apply their solution in a variety of countries.

The good news is there are vendors that have successfully worked to serialize lines. Capitalize on their hard-earned experience and save yourself a few headaches.

On the pages that follow are suppliers of devices, hardware, equipment, machinery software, and consulting services to help you get started. Many of them contributed their expertise to this Playbook. And it is their sponsorship that has made this Playbook possible. +





HEALTHCARE PACKAGING SERIALIZATION
EXPERT NETWORK

Have a serialization question? Ask our roster of supplier experts in the Serialization Playbook expert network!



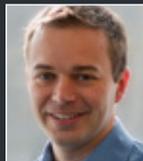
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Adents Significantly Increasing Its Footprint In Pharmaceutical & Life sciences Industries



Serialization software from Adents has several key differentiating attributes, including:

- 1. Speedy Deployment:** Implementation up to five times faster than competing serialization solutions
- 2. Easy Configuration:** Plug-and-play modularity for existing hardware
- 3. Lower Cost:** Implementation included
- 4. Maximum Flexibility:** Easy, centralized changeovers

Adents Pharma Suite

Adents' core solution for the phar-

maceutical sector, Pharma Suite, is unparalleled in its combination of fast implementation, user simplicity and cost-effectiveness. Efficient and reliable, Adents Pharma Suite is fully interoperable, easily scalable and exceptionally flexible to the ever-shifting needs of pharmaceuticals manufacturers and contract packagers.

Adents Pharma Suite has three key components:

At the enterprise level, Adents Pharma Exchange serves as a gateway to transit ERP/MES data and serialization data, ensuring product authenticity. The software is centrally deployed on each production site and is capable of exchanging data with third-party entities such as regulatory authorities, strategic partners, and customers.

At the site level, Adents Pharma Supervisor manages and distributes serialized codes. Deployed on a central server at each production site and capable of steering several production lines simultaneously, the module is the key central component of Adents' serialization and aggregation suite at the plant level. All line configuration is handled at the site level, leading to quicker implementation and scalability while greatly reducing the effort to revalidate the line when changes are made.



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At the line level, Adents Pilot drives the printing of unit codes and controls their conformity. The solution directs printing and vision systems, and manages communication with line equipment to deliver a customer's choice of item-level serialization; item-to-bundle aggregation; bundle-to-case aggregation; or case-to-pallet aggregation.

Our Mission

Headquartered in Massy (Paris), France, Adents is a leading developer and provider of unit-level serialization software solutions. After an initial focus in the European market, Adents is significantly increasing its footprint in the pharmaceutical and life sciences industries in the Americas, where it has opened offices in Montreal, Canada and Princeton, New Jersey in the past year.

Adents utilizes ergonomic, standardized turnkey software compatible with both information systems (ERP, MES) and existing production and packaging equipment. Easily upgrade-able, the software is designed to address both current and emerging regulations to help pharma companies remain in compliance long-term.

Developed in compliance with GMP and 21 CFR Part 11 regulations and following GAMP5 guidelines, Adents serialization software solutions perform a variety of crucial track-and-trace capabilities, including:

- Generation of unique barcodes and importation of serial numbers
- Affiliations management, and distribution of various types of serialized code
- Facilitate and drive the printing and verification of unit barcodes
- Centralized configuration, management and reports processing. +



Antares Vision

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www.antaresvision.com



Your solution from the World leader in Serialization

Antares Vision is the world's leading provider of serialization solutions, trusted by over 200 clients worldwide, including 8 of the 20 top Pharma industries and the largest CMO in North America. Our solutions are installed on more than 1,200 production lines worldwide, with over ten billion SKUs serialized, aggregated, shipped, and notified. Whether you are a large multinational or a small CMO, we have the right solution for you.

One stop solution

Antares Vision's platform includes the widest range of modules for serialization and aggregation (Level 1) line and site manager (Levels 2 and 3) and comprises a fully integrated warehouse/distribution center solution. This assures customers of all-inclusive costs, no hidden fees, and a single point of contact and accountability – a streamlined process that, by not involving third-party vendors, eliminates unforeseen problems and unnecessary delays.

We can have you compliant in less than 10 weeks

With the November 2017 DSCSA deadline fast approaching, our **Quick Compliance Program** is designed to provide a fully integrated, validated, and complete serialization program in so short a timeframe.

The program is based on a **large inventory of pre-configured modules** and a standardized package of software, documentation and services, minimizing Project Management Office (PMO) efforts.

Here, a key differentiator is that, through Antares, there is no reliance on third-party serialization modules, whose availability can delay implementation.



Antares Vision

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Featured **hardware** in the Quick Compliance Program includes:

- **P&C EVO Ready:** A version of the popular P&C EVO preconfigured for the November DSCSA compliance guidelines.
- **Reel 2 Reel module:** An off-line labeling printing station producing reels of serialized labels suitable for bottle labeling
- **Manual station:** Manages printing of serialized labels on cases (bottles and cartons) according to DSCSA requirement

The **software** comes preconfigured and ready to manage the line serialization, to import or generate serial numbers, and stores all data while interfacing with Level 4 repositories. As needs evolve, this scalable software can be expanded to manage additional lines and other communication layers such as interfacing to ERPs, and WMSs.

Widest range of equipment

Antares has the broadest range of serialization and aggregation equipment, including labelling, tamper evident, and check-weighing functions.

The latest addition to our range is the Print & Check Flex, the most flexible high-capacity unit on the market. With line speeds up to 300 cartons per minute, the machine can print with TIJ and laser technology and handles cartons ranging in size from “match box” to “shoe box”.

Full aggregation solutions include automatic and manual bundling, wrapping, case packing and palletizing stations, as well as all use cases of post lot reworking and shipping in serialized mode. +



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Providing Pharmaceutical Coding Solutions for over 30 years



There's no time to waste. Are people in your organization asking: "When's the best time to make sure our coding systems are on-track for serialization compliance?" The Answer is now!

Building DCSA serialization plans that include your code printing solution on the front end will save you time and headaches. Working with

Domino brings a wealth of benefits, including:

- A thorough understanding of serialization
- A breadth of technologies to meet varying needs
- A global presence and proven scalability

Domino brings more to the discussion

Domino has committed significant resources throughout the years to develop and implement global solutions that comply with all relevant industry standards and regulations, such as 21 CFR Part 11, GAMP 5, CFIA, and the U.S. FDA. Close collaboration with OEMs, vision system manufacturers, and integrators on these projects has led to excellent overall performance of the system, not just the code quality, to the satisfaction of customers, and has thus led to the successful implementation of the statutory requirements.

These efforts have uniquely positioned Domino to quickly grasp, understand, and develop solutions that comply with the far-reaching, complex, and demanding global serialization requirements being implemented now and throughout the next several years. Domino solutions are



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installed at many of the largest companies in the industry, and around the world.

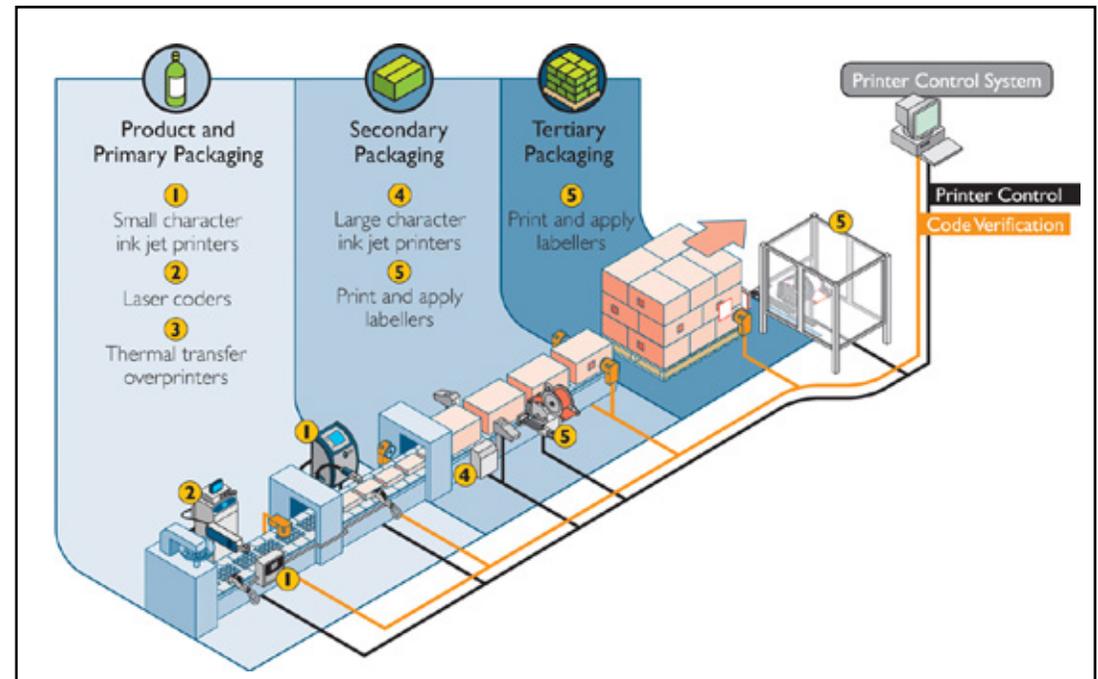
Interaction with global regulatory bodies, such as GS1, ensures that Domino remains at the leading edge of requirements to ensure solutions are reliable, scalable, and future-proof.

Start the dialogue

Contact Domino and leverage our resources and experience to help you with your serialized coding solution.

Visit us at www.codingforcompliance.com or contact us at 1.800.444.4512 +

Domino. Do more. Feel Better



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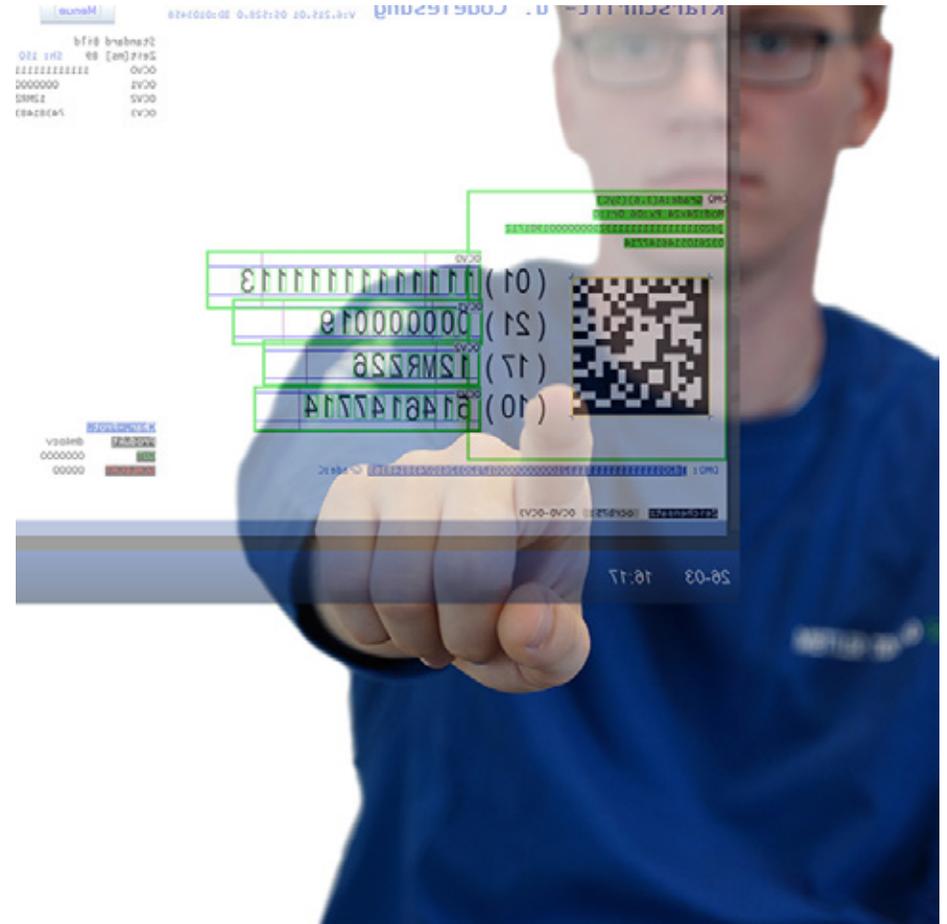
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Leading Supplier of Inline Vision Inspection Solutions for the Pharmaceutical Industry

As a pharmaceutical industry specialist, METTLER TOLEDO PCE provides comprehensive solutions for Track & Trace, including serialization and aggregation tasks and vision inspection equipment for packaging lines. Systems are available to mark packs with individual serial numbers for full traceability of the production or packaging process and collect critical corresponding process data. All packaging formats from single cartons and bundles through to shipping cases and ready to ship pallets can be marked and verified. A PCE system installed in your process provides the assurance that you meet today's legal requirements and that your reputation, brand, and customers are all well protected.

Production Site Management

Today's businesses require fast and reliable information about production processes. Regulatory authorities and other parties require accurate and up-to-date information about production performance, product and packaging quality and coding. The PCE site management software (PSM) is directly connected to the production database and can be linked to upper-level ERP/MAS systems or cloud services, for access to production status information covering any production line or order, worldwide.



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METTLER TOLEDO

Seamless Track & Trace Data Flow Integration

It is important that each link in the tracking chain speaks the same language, regardless of whether it is hardware, such as labelling devices and camera inspection systems, or software, like those used for production line management (PLM). Implementing seamless product inspection for Track and Trace purposes frequently calls for much more attention from pharmaceutical companies than originally thought. Serialization and aggregation requires the entire value-added chain to be integrated. As such, marking is no longer just an issue for a single department. The packaging, packing and marketing (packaging design) sectors as well as the IT, certification and validation departments in particular are affected on a much greater scale. Issuing serial numbers dynamically from a higher level IT system with subsequent feedback to the central database, as is necessary for serialization, requires a particularly close connection to the company's entire IT infrastructure. +



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Datamatrix Station XMV

– the all-in-one solution for marking and verification of folded boxes, cartons and rectangular bottles.



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WEIGHING AND INSPECTION SOLUTIONS

Pioneering and future proof: Serialization and Aggregation via the TQS System from OCS

About Us

OCS is a wholly owned US subsidiary of Wipotec GmbH in Kaiserlautern, Germany and USA Headquarters are located in Lawrenceville, Georgia. The main business being: Dynamic in-motion checkweighing (pharma, food industry), Dynamic weighing equipment for weight and volume determination (mail & logistics industry), X-Ray systems for product inspection (pharma, food industry) and Track & Trace systems for serialization and aggregation (pharma industry). As a global company, Wipotec and OCS have over 600 employees with offices of dedicated team members in the USA, Great Britain, Germany, Italy and France OCS is your worldwide partner.

Consult With The Experienced Leaders In Track & Trace

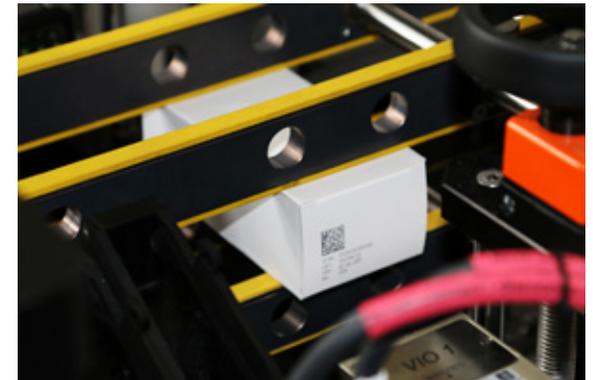
The Traceable Quality System (TQS) is a comprehensive Track & Trace system. TQS covers the serialization of the individual packing units and their continuous aggregation. The requirement is to achieve a traceable product flow from drug manufacturer through the distribution chain to the patient. The result of this joint effort is optimal consumer protection and another weapon in the long term fight against life threatening product piracy. TQS is an intuitively operated system, which combines the greatest possible flexibility with easy handling.

A fully integrated ConfigureFast manages the operation of all three functional units (product handling, coding, and camera inspection). This thorough integration continues across all levels of aggregation. The TQS system reliably prevents operating errors and interface problems, while delivering the maximum safety and the greatest ease of use. The approach of our Traceable Quality System – TQS is unique in the world and developed out of the huge experience of more than 500 systems built and rolled out.

TQS By OCS – Integration And Flexibility From Serialization To Final Aggregation

TQS-SP - FOR SINGLE PACKS – User friendly serialization for small packages / folding cartons & bottles.

TQS-HC-A - FOR SERIALIZATION, LABELING, AND COMPLETENESS CHECKS, AN ALL-IN-ONE SPACE SAVING UNIT – This unit expands



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in functionality with the addition of weight determination and with the ability to close the folded boxes with tamper evident labels and apply vignettes as required.

TQS-BP - FOR SETS, FORMAT-INDEPENDENT AGGREGATION TAILORED FOR YOUR NEEDS – This unit is perfectly equipped to implement the first level of aggregation. Forming one serial number for the bundle by combining from the single packs.

TQS-CP – FOR THE END PACKAGING – COMPLETE AGGREGATION DESIGNED ALL THE WAY THROUGH TO THE END – This unit is a semi-automated aggregation system for manually packed cartons & bottles.



KEY SERIALIZATION CONTACT

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TQS-MP – FOR THE FINAL MANUAL PACKAGING – THE MOST FLEXIBLE AGGREGATION OF MIXED PACKS – This unit is a purely manual aggregation model that provides flexibility for operations of various scenarios.

TQS – Flexible Combinations To Meet Your Needs

No matter what your current IT structure, you are required to reliably TQS uses an open standard interface to eliminate the need for additional proprietary software packages. The line manager is installed in the line and is easily and conveniently connected via a standard interface to the site system (Level 3). The core of the line manager is a flexible SQL data base system that organizes the data management to the line level (Level 1). +

GUARANTEE FOR PROCESS AND PRODUCT SAFETY

EXTERNAL

L5

COMPANY LEVEL

L4

SITE LEVEL

L3

Standard Interface

LINE MANAGER

L2

- ✔ TQS - Traceable Quality System
- ✔ Highly flexible and open connectivity approach
- ✔ Supporting Open - SCS

DEVICE MANAGEMENT

L1



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Your One-Stop Serialization Partner

At OPTEL, we know that the enforcement of worldwide Track&Trace regulations is an incredible challenge for everyone involved, and our mission is to support you as you go through this major transition.

Providing all the necessary hardware, software and integration skills needed for successful serialization implementation, we're much more than just a supplier. We're a one-stop, long-term serialization partner who helps you meet your serialization deadlines and make sure your process is effective.

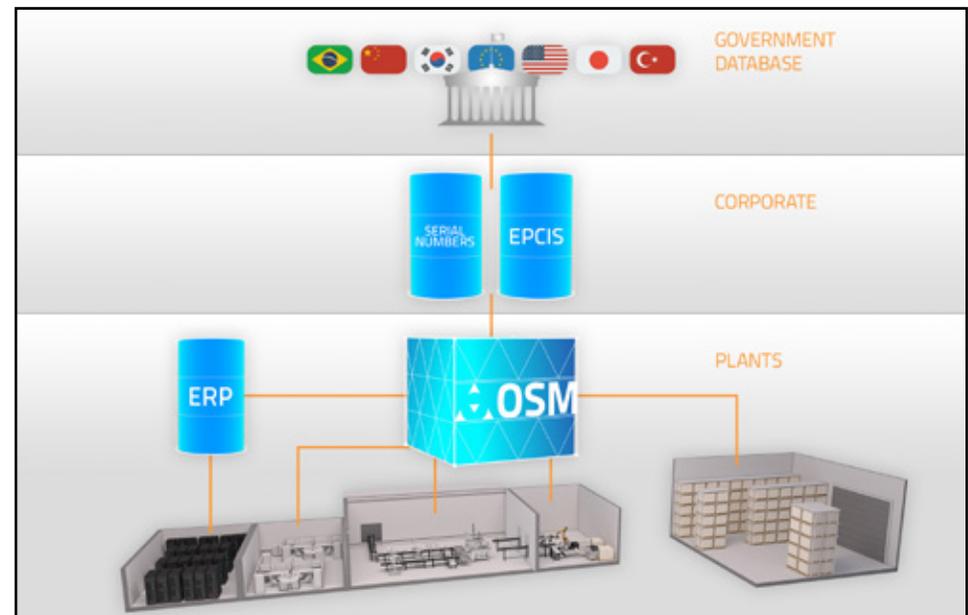
We offer proven inspection and serialization know-how, start-to-finish project assistance, and personalized technical services—regardless of where you're located.

Thanks to our quality mindset and unique client-centric approach, we have a long list of customers—including 8 of the top 10 generic drug manufacturers—that trust us to help ensure their products' safety.

With nearly 30 years of recognized expertise in pharma, a multitude of successful installations, 1,000+ employees worldwide, and 4 international locations, we're considered global leaders in serialization and aggregation.

What makes us different?

- Turnkey, custom solutions that are: effective, compliant, adaptable, agile, and scalable
- Easy integration with any system/machine—regardless of vendor
- Start-to-finish project assistance
- Personalized technical services
- Technology-oriented, with a human touch
- Global presence with worldwide support



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Turnkey, Yet Personalized Serialization Solutions

OPTEL knows that every packaging line is unique, so we provide turnkey, yet customized, serialization and inspection solutions that are specially adapted to each line. Our systems are designed to maintain your lines' efficiency, provide superior effectiveness and offer an unparalleled ability to integrate easily with any system/machine—no

matter which vendor.

Our solutions contain a unique open scripting component that not only allows for initial personalization, but also provides the agility and scalability to adapt to future needs, such as any changes in country regulations.



This feature also mitigates the inherent risks of proprietary systems, minimizing supplier dependency and vendor lock-in.

New vendors and modules can be integrated without the need to rebuild or reconfigure entire systems. Our cutting-edge solutions are totally independent, while fully secure; and they are completely configurable to operate autonomously or integrate into your current ERP landscape.

RECENT RELEASES:

FAST SERIES—OPTEL's Fast Series is a line of preconfigured Track&Trace products specially designed to help pharma and CMOs who have not yet started their serialization project or who may not have the means to invest in a full-fledged custom solution. These cost-effective, stand-alone and scalable units are the perfect solution to achieve serialization compliance quickly and easily, without breaking the bank or compromising line efficiency. +



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Pharma Logic Solutions, LLC

Introduction

Pharma Logic Solutions, LLC is a consultancy of experienced experts with a proven track record of assisting companies to improve their supply chain security and visibility, establish product traceability, serialization, product encoding (including GS1 and EDI standards) and compliance with legal and regulatory requirements relating to supply chain security. Within the life sciences industry, Pharma Logic Solutions has assisted companies in complying with electronic pedigree (e-pedigree) and transactional reporting in various countries around the world.

Since 2006, Pharma Logic Solutions has helped dozens of leading global life sciences manufacturers, repackagers, wholesalers/distributors, contract packagers (CPO), contract manufacturer (CMO) and Third Party Logistics (3PL). Clients have spanned multiple top 10 global drug manufacturers, mid-sized and small specialty companies, orphan biologic companies, low margin generics, large and small contract packaging and top 10 global logistics providers.

Compliance with traceability regulations has included the US Federal Drug Quality and Security Act of 2013 (DQSA) and its Title II: Drug Supply Chain Security Act (DSCSA), Turkey, Argentina, India, China, South Korea, Brazil, Saudi Arabia, Jordan, and European Union (EU) countries.

Our Projects

Our projects have provided strategy and charters, roadmaps and detailed project plans, user requirement specification (URS), vendor selection, Function Design Specification (FS or FDS), Standard Operating Procedure (SOP), Risk Evaluation and Mitigation Strategy (REMS), pilot planning and execution, GxP validation and packaging design and risk assessment (including improving OEE and managing exceptions). We often provide subject matter expertise (SME) and project guidance during implementation and pilots.



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Expertise

We are longstanding members of GS1 and Project Management Institute (PMI). Our staff includes GS1 Certified Professionals who have been accredited by GS1. This ensures the guidance your company receives is accurate, up-to-date and consistent with industry practices.

Our staff includes professionals who have been trained on SAP Auto-identification infrastructure (Aii) and Object Event Repository (OER) version 7.1 and can assist in implementation. Our projects have involved solutions from most solution providers of enterprise serial number management, warehouse management, Packaging Execution Systems (PES), edge-of-network (EDGE) solutions, Electronic Data Interchange (EDI) and more.

Leadership

Pharma Logic Solutions, LLC was founded by William Fletcher, who has spoken dozens of times on the topics above, including industry events around the world, the US Capital Building to congressional staff, and multiple times to the State of California Board of Pharmacy (BoP). Mr. Fletcher is an editor of this Playbook and provided new content on complying with the Drug Supply Chain Security Act (DSCSA) and various country requirements. +



KEY SERIALIZATION CONTACT

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Section Eight: Glossary, resources & Downloads



Serialization Glossary

Aggregation – The act of assigning child-level serial numbers (such as on individual packages) to a unique serial number at the parent level (e.g., a case), thus forging an electronic association between the children and the parent. Each time goods are grouped, that’s an occasion for aggregation: individual unit packages to bundles; bundles to cases; cases to pallets. Aggregation is essentially an electronic data representation of grouped physical goods. Sometimes interchangeably used with “hierarchy.” Regardless of what you call it, the electronic representation must always match the physical, or else bad things will happen (see discussion about inference).

Certification – One of the components of a “transaction,” as the US Board of Pharmacy defined it. (Certification of Transaction Authenticity. A certification under penalty of perjury from a responsible party of each source of a prescription drug that the information contained

in the transaction is true and accurate. (B&P § 4034(b).) The law requires that the transaction identify the individual (on behalf of each recipient) certifying delivery or receipt of a given dangerous drug, and further that the transaction include a certification under penalty of perjury from a responsible party for each source of the dangerous drug that the information contained in the transaction is true and accurate. The board anticipates that the required certifications, of delivery or receipt, and of the truth and accuracy of the transaction, will be achieved by use of or in combination with digital signatures.

EPCIS – Electronic Product Code Information Services. EPCIS is an EPCglobal standard of GS1 that specifies a uniform way to electronically transmit between trading partners a detailed representation of supply chain events. Transactions can be formed by combining this information with supply chain master data such as

product, company, location, and state of product as it moves between organizational boundaries (for example, from a pharma manufacturer to a wholesaler/distributor). The pharmaceutical supply chain appears to be coalescing around EPCIS as a way to electronically exchange transaction information.

Exceptions – In the world of serialization, an “exception” is an event that happens in the supply chain that interferes with or is not part of the expected flow of goods from manufacturer to wholesaler/distributor to pharmacy/clinic/hospital. Examples include damaged product, returns, incorrect transaction information, etc. A working group within GS1 is currently maintaining a list of such exceptions with an eye toward augmenting the EPCIS business vocabulary to account for them.

Transaction – An electronic transaction (“transaction”) refers to a record



Serialization Glossary | continued

containing information as defined currently by the US State Board of Pharmacy, subject to change. For example, U.S. law requires transactions to include information regarding each transaction resulting in a change of ownership, change of custody, or both, of a given prescription drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, repackagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the prescription drug. In some locations, a transaction can be created in a paper-based form, but in U.S., transactions must be electronic and must be maintained in an interoperable system, ensuring compatibility throughout all stages of distribution.

GLN – Global Location Number is part of the GS1 System of standards. It is a simple tool used to identify a location and can identify locations uniquely where required.

The GS1 Identification Key is used to identify physical locations or legal entities. The key comprises a GS1 Company Prefix, Location Reference, and Check Digit. A GLN is always 13 digits long.

GTIN – Global Trade Item Number. An identifier for products developed by GS1, uniquely identifying a specific product from a specific manufacturer. GTINs may be 8-, 12-, 13-, or 14-digits long.

Inference – Refers to the ability of a downstream trading partner to read the serial number of a case (or pallet), and “infer” that the individual-unit package-level serial numbers match the transaction information supplied electronically by the upstream trading partner, without having to physically open the case and rescan each item.

Interoperability – Generically, this refers to the ability of data or information created

by one computer system to be read by another. In terms of serialization, it can have multiple meanings. At the level of the physical flow of packages and cases, it can mean the ability of a trading partner’s scanning systems to be able to scan a barcode (or RFID tag) generated by the manufacturer or contract packager. At the transaction or data-sharing level, it typically refers to the ability of a trading partner to be able to read (or query) another trading partner’s data via a common protocol—typically EPCIS.

Master data – Persistent, non-transactional data that defines a business entity for which there is, or should be, an agreed upon view across the organization.

Supply chain master data – Persistent, non-transactional data that defines a business entity for which there is, or should be, an agreed upon view across the supply chain. +



Web resources

Here are some links to additional resources that you may find helpful as you start to work through your serialization plan.

Standards

[GTSH Standard](#) and [Implementation Guide](#) from GS1

[GS1 Traceability White Paper](#)

[EPCIS overview](#)

[EPCIS Frequently Asked Questions](#)

[GS1 Drug Pedigree Messaging Standard](#)

[Applicability Statement 2 \(AS2\)](#)

[2015 Readiness Workshops by GS1](#)

Pilot testing

[U.S. Implementation Guideline: Applying GS1 Standards to U.S.](#)

[Pharmaceutical Supply Chain Business Processes to Support](#)

[Serialization, Pedigree and Track & Trace](#) (Source: GS1)

[GS1 2015 Readiness Pilot website](#)

Talk with peers

[Food and Drug Serialization Professionals LinkedIn group](#)

(1,493 members)

[GS1 Healthcare LinkedIn Group](#) (1,794 members)

[Serialization in Pharmaceuticals LinkedIn Group](#) (738 members)

[Pharmaceutical Packaging and ePedigree Requirements LinkedIn](#)

[Group](#) (753 members)

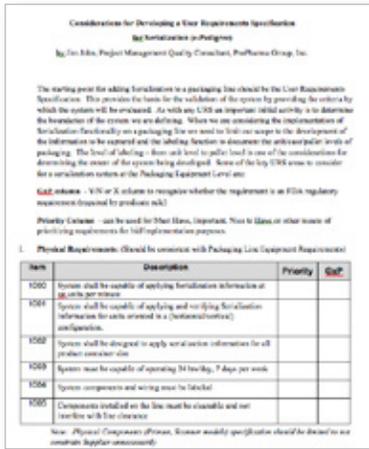
Other Resources

[GS1 Healthcare US Pharmaceutical Supply Chain Open Industry Call](#)

Have we missed any important links? [Let us know.](#) +

Downloads

Although you may recall seeing some of these downloadable resources sprinkled throughout the Playbook, we've gathered them all in one convenient spot for you, no extra charge:

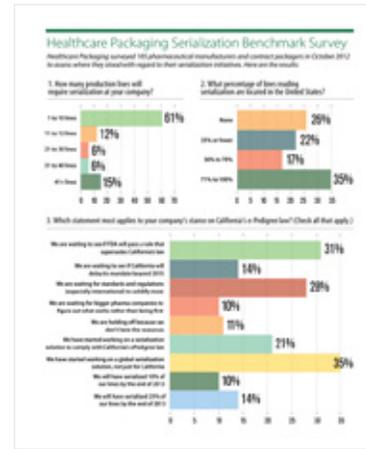


Sample User Requirements Specification for serialization

Download this user requirements starter spreadsheet complete with sample language that you can modify and adapt to your own needs.

[DOWNLOAD](#)

Source: ProPharma Group, Inc.



Serialization survey results

Download the complete results of the *Healthcare Packaging* survey measuring serialization readiness, and benchmark your company.

[DOWNLOAD](#)

Source: Healthcare Packaging



Thank you!

for downloading the Serialization Playbook.

Healthcare⁺
P A C K A G I N G

