Aggregation in pharma:
A must have for supply chain traceability

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SYSTECH®
connected solutions by **Markem-Imaje**®

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Intro: Serialization alone cannot keep the supply chain flowing

In today's pharmaceutical supply chain, optimizing the flow of physical products is no longer enough to ensure product safety, regulatory compliance and supply chain optimization. Now, meeting government regulations and changing expectations from supply chain partners demands secure and reliable data exchange at every stage between manufacturer and dispensers.

As companies develop comprehensive data collection and integration to get drugs through the supply chain—and eventually to the patients who need them—this has created an emerging dual reality: The flow of physical products from manufacturer to dispenser, and a parallel data flow tied to those products. Successfully managing this dual reality relies on data integrity, the ability to ensure that products in the physical world match their "digital twins," or data representation. Serialization has built the foundation for data integrity, and aggregation is a critical step.

When done right, effective aggregation enables true traceability and improves efficiency from line level throughout the supply chain. But not all aggregation solutions are the same. Unfortunately, some early adopters have found their vendor's systems do not work as promised: Product data doesn't always match the contents of actual physical shipments, and customized solutions that worked well initially are proving costly to maintain and scale.

Finding and implementing a reliable, sustainable aggregation solution may seem daunting, but it doesn't have to be. The right partner will help you design effective aggregation solutions with the flexibility and scalability to work seamlessly with your growing business—and create the right workflows to support it.
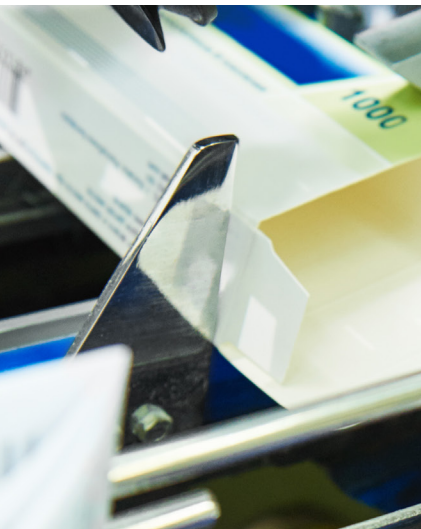
Systech pioneered pharmaceutical serialization, and we approach serialization and aggregation as integral parts of packaging operations. No matter what your product workflows look like—or where you are in your aggregation journey—Systech brings the experience, architecture and industry relationships to ensure data integrity and ease the process of implementing the right system. With our turnkey solutions and support, you can be confident that your product data stays aligned with the parallel stream of physical products it follows all the way through the supply chain.

Part 1: Aggregation is critical to data integrity

Why aggregation matters now

Aggregation plays an important role in industry compliance with Transaction Information/Transaction Statement (TI/TS) data exchange requirements. Most wholesale distributors have indicated that they will reject product without aggregation data—turning aggregation into a de facto requirement for operating in the US pharmaceutical market and in other markets where this level of tracking is required by law.

DSCSA does not explicitly require aggregation, but The FDA recognizes it as an essential process in pharmaceutical supply chains and data management, and all major players in the industry are aligned on the need for it. Wholesale distributors effectively become responsible for compliance of all product that moves through their warehouses and data systems. The sheer volume of medicines moving through these systems make it impossible to maintain compliance without aggregation.

What is aggregation?

Aggregation is the process of assigning "children" to a "parent" in packaging to more easily track and trace individual products throughout the supply chain. Packaging hierarchy rules specify what package types can be packed into other package types (boxes into case, cases into pallet, etc.), enabling one pallet barcode ID to represent all the unique products in all the cases on it.

| UNIT | BUNDLE | CASE | PALLET |

Benefits of aggregation

- Simplify reporting and minimize errors
- Streamline verification processes across the supply chain
- Improve recall management processes
- Promote efficiency and cost savings
- Comply with wholesaler requirements
- Optimize packaging operations

At peak times, more than one million units leave distribution locations each day, with the majority of them going through three companies: Cardinal Health, McKesson and Cencora. When a distributor receives a pallet of medications from a manufacturer, the distributor must "move" the associated data for all the cases and units (sometimes called "eaches") within an integrated Level 4 traceability system. Without aggregation to confirm TI from the manufacturer, trading partners would need to open every non-aggregated case and manually scan every unit. Distributors must be able to scan at the pallet level to provide compliant TI/TS electronic records at such volumes.

Effective aggregation optimizes operations up and down the supply chain and enables true traceability by making it easier and more efficient to document and share your product data with downstream partners. Suppliers can utilize EPCIS aggregation events and share them with receivers of the product, and this information exchange allows partners downstream to be more efficient and infer verification by scanning the highest-level containers in the hierarchy.

How aggregation works

Serialization can be a building block of traceability, and implementing it has been a tremendous achievement for the industry. But serialization is limited to a single item level. This means that if there's a data discrepancy at any point in the supply chain—for example if a distributor was expecting 10 cases on a pallet but received 12—companies using serialized-only data must reverse engineer the process to figure out the source of the discrepancy. Worst-case scenario: a recall where all product must be sent back to its origin.

Aggregation associates serialized "children" to a serialized "parent" so individual products are automatically linked to their secondary and even tertiary packaging.

Three main stages of aggregation

1
Provisioning

2
Commissioning

3
Aggregation

1

Provisioning

Aggregation starts with **provisioning**—or obtaining a unique unused serial number through serialization. Provisioning can be a manual or automated process and can be performed ahead of time or on-demand. Once a serialized number is available, the number must be formatted to comply with label formats, country regulations and data carriers. At this point, the serialized number has been issued and cannot be issued for another item. Now the serialized number can be sent for printing on the package.

2

Commissioning

Once the item passes all inspections, the serialized number assigned to an item can be **commissioned**. The commissioned item, or the **child**, now is available for packing into a higher-level package, or the **parent**. (Until the commissioned child has been packed into a parent, the child is considered an **orphan**.) In turn, to commission the parent, three things must happen:

1. The parent is issued a serialized number

2. All serialized children are associated to the parent

3. Required inspections must pass and the aggregation process completed (see "Aggregation" below)

Once these steps are performed, the commissioned parent may now become a child for higher level packages. For example, a case is the parent of a bottle but the child of a pallet.

Decommissioning is the result of a failed inspection or a manual operation. Once a serial number is decommissioned, its state cannot be changed. Decommissioned children cannot be packed (aggregated) into parents.

3

Aggregation

The aggregation operation checks the child's type and state, and it maintains a child count against the required count or **pack factor**. The aggregation rules are defined by a packaging hierarchy that specifies what package types can be packed into other package types (i.e. unit into case, case into pallet). The aggregation will fail if 1) the child type does not match, 2) a child is not associated with an existing case, or 3) the expected count is not reached.

At some point the product will reach the highest level of package, or **top-level parent**. The top-level parent is identified by the packaging hierarchy and can vary depending on the required serialization hierarchy. For a two-level hierarchy, the top-level parent would be the case; for three levels it would be the pallet.

Before ending the lot, all used serial numbers must be reconciled. All issued and orphaned serial numbers must be decommissioned, and all decommissioned items must be accounted for. The physical count for packed items also must match the packed count from the data record.

Part 2: Three keys to long-term aggregation success

Key #1: Choose an experienced vendor with a proven approach

Aggregation is not a bolt-on feature that can be added at the end of the line. Developing a reliable, scalable aggregation system requires thoughtful considerations at every step of the packaging process. Systech's turnkey approach is grounded in how packaging for the supply chain actually works in the factory and beyond.

Our teams understand that designing and implementing the right aggregation solution for your needs is just the beginning. Real people must adapt to new workflows from the packaging line to the loading dock. We help you establish holistic workflows that maintain data integrity by minimizing the possibilities for human error in supply chain processes.

As the pioneer in serialization for the pharmaceutical industry, Systech has worked with hundreds of customers and thousands of line implementations to meet ever-changing needs in the packing environment. We've systemized our learnings and treat serialization and aggregation as extensions of existing machine inspection and line management requirements. Our full-stack solution can be deployed rapidly on any line, site or enterprise in any region to meet regulations.

When you work with Systech, you are backed by our:

EXPERIENCE	RELATIONSHIPS	SUPPORT
Systech has delivered vision and packaging solutions for the pharmaceutical industry for more than three decades, so innate understanding of packaging operations and challenges is part of our DNA. Our aggregation solutions have grown directly from the innovations that make us the vendor of choice for the biggest names in pharmaceuticals.	Systech is backed by an extensive network of partners experienced in implementing our solutions. Our long-standing relationships with packaging machine vendors have enabled us to create documented implementation schematics for installing Systech in conjunction with most major packaging line devices.	Having a trusted vendor who understands the data integrations required between all supply chain participants is essential. We're here to guide you through the aggregation process with support before, during and after installation. Whatever your packaging and supply chain flow, Systech's repeatable, proven implementation methodology maintains flexibility and scalability while reducing deployment risks and total cost of ownership.

Key #2: Implement the right architecture to reduce risk and simplify integration

Aggregation requires commitment to getting the right workflows in place in order to reap the rewards. Unlike custom aggregation systems that can be cumbersome to maintain and expensive to scale, Systech's turnkey solution is straightforward and adaptable, making it easy to maintain data integrity as you develop the best practices that work for you and your customers.

We've been working with customers since 2005 to define extensive sets of packaging use cases and uncover risk areas related to packaging serialization. We've documented and tested our findings to build a standards library of proven work products based on actual deployments and turn them into a turnkey solution ready to be implemented throughout your facilities.

Systech's configurable solution is designed to meet changing market requirements, compliance regulations and a broad range of packaging environment challenges. The productized packaging technology ensures all your sites will have the same solution architecture, simplifying implementation and maintenance. Our expandable, modular architecture has two main parts:

- **Serialization Foundation** – Base set of functions used for serialization, independent of the packaging line

- **Packaging Integration Modules (PIMs)** – A library of reusable applications with unique workflows leveraging foundational elements as the building blocks to meet packaging line requirements

Serialization foundation

Our expandable aggregation solution is deployed across the packaging execution stack where it really matters. Each deployment contains a core set of functions including:

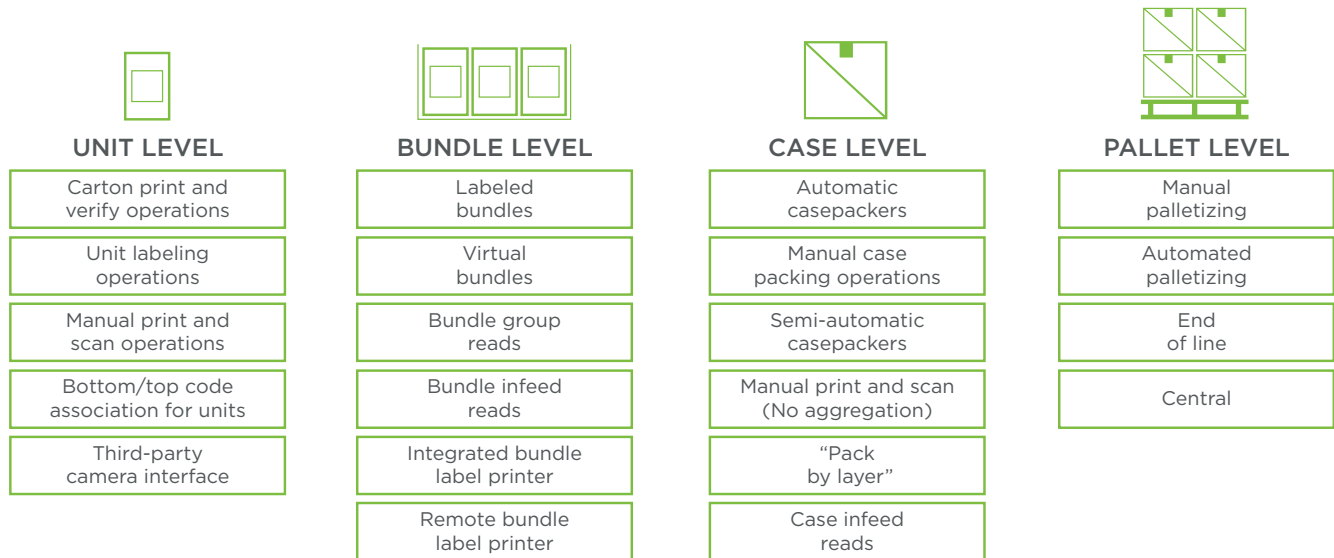| Rework operations	Reports	Master data download	Packaging work order download	Suspend/resume
Manual rework operations to build new parents, repack children, remove children, add children, etc.	View historical batch and serialization data. Reports can be viewed on the line, printed or saved/exported in multiple different formats such as PDF.	Leverage the master data contained in your enterprise resource planning (ERP) system to add new products into the Systech system.	Leverage packaging work orders contained in the ERP system to manage work released into the Systech system.	Suspend a running batch on the packaging line and resume it at a future time.

Systech Packaging Integration Modules

Systech's solution is built with hundreds of pre-configured integration modules that work with most of the packaging equipment in the industry. We defined and rigorously tested standard methodologies that are repeatable for every customer. For example, when we put bottles into a case, we figured out five different variations for our packaging modules. When we put cases into pallets, we tested a host of other variables that we ultimately categorized as standards.

As a result, Systech's configurable, standardized solution supports more than 250 serialization and aggregation workflow modules that can either stand alone or be connected with other modules that you can "mix and match" to meet the needs of your packaging operations.

Your data is only as good as its ability to be integrated and shared with internal systems, third-party providers and downstream supply chain partners. Systech's aggregation solution architecture is standardized and configurable to make integration into packaging environments as straightforward as possible.

Configurable, standardized solution

Supports over 250 serialization workflows on various types of packaging operations

UNIT LEVEL	BUNDLE LEVEL	CASE LEVEL	PALLET LEVEL
Carton print and verify operations	Labeled bundles	Automatic casepackers	Manual palletizing
Unit labeling operations	Virtual bundles	Manual case packing operations	Automated palletizing
Manual print and scan operations	Bundle group reads	Semi-automatic casepackers	End of line
Bottom/top code association for units	Bundle infeed reads	Manual print and scan (No aggregation)	Central
Third-party camera interface	Integrated bundle label printer	"Pack by layer"	
	Remote bundle label printer	Case infeed reads	

EXAMPLE: Automated pack by layer

Exponentially increase throughput of creating cases and fulfilling pallets by automatically scanning multiple items in a layer rather than manually scanning them one by one.

- Support aggregation for an automatic case packing operation on the line
- Ensure maximum data integrity with vision inspection at each layer
- Perform carton to case aggregation once commissioned cartons are placed into case

EXAMPLE: Packaging and supply chain rework

Systech's aggregation solution enables you to perform all standard rework operations without the complications:

- Check the status of any item or parent
- Perform in-lot rework at time of packaging
- Perform post-lot rework in your warehouse
- Rework both large volumes and small one-offs
- Repack, create new aggregations and print labels
- Decommission damaged items

Key #3: Create the right workflows

Aggregation requirements place a great deal of responsibility on operators and supervisors, as any aggregation process must rely on a large manual component to maintain the integrity between stored data and the physical product. Even on automated packaging lines, exception use cases deviate product from the expected workflow. The human factor changes day by day, and if not considered in the workflow, will result in an unstable, unreliable aggregation deployment.

Systech incorporates this critical human factor into our approach to solving aggregation use cases. When designing for a new use case, we look beyond the printer and inspection devices on the packaging line and evaluate how the entire packaging environment will be affected. Our requirement gathering goes beyond the standard workflows and addresses the exception cases. We then design functionality into the appropriate products to provide the complete solution that includes normal operation, exception handling and communications between the products.

The reality is that aggregation requires new workflows that force changes in standard operating procedures not only on the packing line but throughout the site, up until time of shipment. The key to success is to create workflows that reduce impact on business processes or operational processes not human processes while maintaining data integrity.

Benefits of Systech solutions

Lower total cost of ownership
Change control, support, training, flexibility, scalability and lower downtime all factor into total cost of ownership. Partnering with Systech provides recurring value that extends for years beyond the initial equipment implementation, non-recurring engineering and installation costs.

Reduced deployment risk
Systech combines productized software, proven standards and a repeatable methodology to reduce deployment times and risk. Our experienced teams take on the responsibility of the software development lifecycle for design, implementation, unit testing, formal testing and deployment packaging.

Flexible
Flexibility enables you to easily adapt to changing demands while introducing minimal impact. Systech provides three main areas of flexibility: site autonomy, workflow and configuration. Each packaging site and each line within a site has its unique set of requirements and challenges. Our architecture focuses on flexibility through configuration instead of custom code so you can maintain data integrity regardless of the packaging line configuration.

Scalable
Systech's aggregation solutions offer an entry level system that can be scaled to meet future demands. Our system lets you add functionality without replacing the base system so you can leverage previous equipment and engineering costs.

Conclusion

Aggregation improves the efficiency and security of the global pharmaceutical industry. Choosing and implementing the right aggregation system is key to ensuring data integrity throughout the supply chain and getting the most from your investment.

Unlike complicated custom solutions that can be difficult to adapt to changing workflows or business environments, Systech's proven turnkey solution is configurable, scalable and easily tailored to evolving needs.

Our experienced teams understand the realities of warehousing and shipping operations, and we know the most effective aggregation systems support and are supported by good workflows. Backed by our repeatable methodology, we work with you to develop and refine workflows that reduce deployment times, grow with your business, and increase efficiency in your operations.

The rewards of investing in the right aggregation solution go far beyond compliance. Call us, and let's start talking about how we can make aggregation work for you.

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