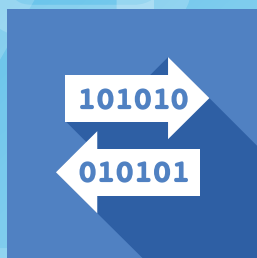


# Aggregation and the Life Sciences Supply Chain: Building Your Strategy



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# Introduction

Aggregation has the potential to add more complexity and cost to serialization, which will already pose significant challenges to the life sciences supply chain in coming years as companies prepare for global serialization deadlines.

How can your pharmaceutical company best approach aggregation? In this eBook, you will learn what you need to know in order to begin building your strategy, including:

- The basics of what aggregation is, which markets it impacts, and how it effects different supply chain segments
- How establishing and supporting aggregation would impact different levels of your operations
- How to evaluate if, how, and when you will enable aggregation

# Aggregation 101: What it is, who requires it, and what it means for the supply chain

Aggregation would impact serialization projects, not only at the packaging line, but throughout a manufacturer's operations and the overall supply chain. Let's take a look at what it is, which markets require it, who it will affect, and how it should be factored into the serialization planning process.

## What Is Aggregation?

Aggregation is the process of building a relationship between unique identifiers assigned to packaging containers. If you have a case with a serial number and within that case, salable units (bottles, cartons, syringes, etc.) with their own unique serial numbers, aggregation enables you to associate “child” items with their bundle or case “parent”, building a “parent-child” relationship. The aggregation relationship is made up of those three things: the outer container identifier, the identifiers of the inner units, and the quantity of those units. Often pack-out configurations consist of multiple levels of hierarchy and may involve shelf packs, bundles, inner packs, shipper cases, pallets and even shipping containers. These are also sometimes referred to as “logistical units.”

If you need to determine the contents of a case but don't want to open up the case and scan every unit, having aggregation in place lets you scan the case's bar code to get its serial number and then use the aggregation relationship to infer the identity of all the contents. Inference involves looking at one level of packaging to infer information about the next level in the aggregation hierarchy, assuming that the case has not been opened and the data set representing the aggregation has not been altered. Without aggregation in place, you would need to open that case and scan all of the individual products. This is one of the reasons that aggregation can facilitate the material handling aspects of serialized projects in a warehouse environment.

In order for aggregation to truly be valuable and reliable, the integrity of both the physical and the accompanying data relationships needs to be trusted throughout its lifetime. That means that when something changes – cases are removed from a pallet, or part of a case is damaged – the original relationship needs to be disaggregated and then rebuilt and these changes or “events” need to be closely tracked to maintain the integrity of the parent-child relationships.

Without the capability to perform exacting control of these hierarchies and account for each change, the risk is great that improperly serialized product will enter the supply chain.

## What Countries Require It?

Aggregation has not been universally adopted as part of track and trace regulations. The current requirements for major markets include:

- Brazil – For both phase one and phase two, required between transport container (case) and salable unit
- China – Required between all levels of sales packaging product up to but not including pallet
- European Union – Not applicable, since only unit level serialization is required
- India – A requirement is expected across all 3 levels of serialization, and the government's 4/1/2015 update implied it will need to be maintained across supply chain movements
- South Korea - Voluntary but encouraged and may emerge as a requirement when supply chain traceability is implemented
- United States – Not mandated; will be officially studied as part of unit-level traceability preparations and may become industry requirement
- Turkey – Required between unit level and transport units (cases)

## What Aggregation Means For Different Supply Chain Segments

While aggregation has the potential to create efficiencies across the entire supply chain, it also represents significant cost to the packaging process. For anyone downstream of the product manufacturer, the ability to infer contents based on the identity of a larger container is advantageous for receiving, put away, inventory management, and pick, pack, and ship procedures.

But while wholesale distributors, repackagers, and pharmacy chains with central distribution centers see most of the benefits, the cost burden for initiating aggregation falls almost entirely on manufacturers, making many understandably reluctant. Read on to learn what is involved for manufacturers and how they should determine their aggregation strategy.

# A day in the life: What aggregation would mean for you

If you manufacture drug products either within your own company or as a CMO for a pharmaceutical customer, you have begun to focus on global serialization demands and consider aggregation. What would it mean for your operations to establish aggregation and support it on a daily basis, not just in packaging but in materials handling scenarios all the way through shipment and beyond? Learn about the changes it would demand both at the packaging line level and during post-packaging processing.

## A Ripple Effect

Aggregation introduces complexity and alters materials handling processes throughout operations until product is received into your customer's dock. In order to aggregate, you need to invest in equipment to establish the relationships; define new processes throughout your warehouse facilities to protect the integrity of the aggregation associations; and dedicate staff time to support these operational changes. In the post-packaging warehouse environment, exception handling for sampling, decommissioning, dis-aggregation and other scenarios needs to be carefully thought through and integrated into every aspect of operations.

## In-Lot Line Changes

At the packaging line level, you must establish the aggregation relationships, confirm their validity, and then fix any discrepancies that are discovered, accounting for and establishing a status for each serialized product and its relationship within the packaging hierarchy.

## Automated Packing

At many large pharmaceutical companies, serialized salable units will come out of the item level serialization process and need to be aggregated into a bundle or case. This required the capability to inspect the serial numbers on the item through vision inspection stations and software that is configured to count and verify that the correct number of items have been aggregated to the higher packaging unit.

The automated aggregation process is especially challenging with round bottles prevalent in the US market, as direct line of site with each 2D bar code is required to accurately read the unit level serial numbers as they are sent to the bundle or case packing station. If an error is discovered, the case needs to go to a newly established rework station where designated staff must correct discrepancies. If aggregation is required up to the pallet level, similar capabilities are required on automated lines for case-to-pallet aggregation.

## Manual Packing

Your company may pack cases with physical staff rather than machines, making it a less controlled and less linear process with more room for error. You will need to institute written guidelines, a training program for current line staff, and ongoing sessions for new hires. Scanning stations and case label printing and control processes need to be established to control accuracy and quality in manual packaging operations. Employees will need to understand the relevant regulations, the implications of mistakes during the case packing process, and how to correct issues and manage exceptions.

## Post-Packaging Processing

Aggregation relationships need to be managed throughout post-packaging materials-handling operations to insure that the physical hierarchy and the corresponding data remains trustworthy. A relationship may be correct when it comes off the line, but there are many scenarios in which it could be compromised before it leaves your ownership. After it passes the inspection station, a case may go onto a pallet then into the finished goods area or to an internal distribution site. Somewhere along the way it could be damaged, or you may need to open it and ship just part of the contents. You might discover a miscount, or need to do some quality sampling. In a non-aggregated world, you can simply grab replacement units off the line and add them to your case. But if you have aggregation hierarchies in place, disruption between a portion of the original items and the larger case compromises the relationship.

These disruptions need to be carefully accounted for and reflected in status changes for each serialized item. Your aggregation associations are only valid when the parent item contains all of the original children; once some of unit items go their separate ways, adjustments must be made before you can ship the product.

## Disaggregation, Reaggregation, And Other Relationship Changes

Once your original aggregation hierarchy has been compromised, there are a half dozen or so steps that you may need to take to rectify your compliance records, including:

- Disaggregate – Dissolve the relationship between the parent packaging and all of its children
- Decommission/Destroy – Deactivate the serial number of any units that have been damaged or removed for quality sampling and or destroyed for any other reason (damaged, etc.)
- Disaggregate from container – Remove a bundle or portion from the container but keep the relationship between the larger packaging and the other items intact
- Replace item in a container – Provide replacements for any salable units that have been removed and correctly add the new serial numbers to the aggregation relationship
- Reaggregate – Create a new relationship with the larger packing unit and remaining salable units
- Reset container aggregation - Disaggregate all existing items in a container and then aggregates a new set of items to that container

You need to have the business processes and trained staff in place to recognize situations in which you need to manage exceptions and correctly account for any changes in product status that will impact packaging hierarchy, and a compliance solution in place to help execute them. In some markets such as Brazil and China, aggregation is a compliance event and when you alter a relationship, you may also have to trigger a reporting event.

## To Aggregate Or Not To Aggregate?

As a manufacturer you are already facing significant packaging line upgrade expenses just for serialization. Putting aggregation in place would offer some operational benefits, like inventory management, but it could drive costs even higher. Now that you know what aggregation would look like, how do you decide whether and how to implement it? In the next section, understand the top questions to ask to determine the need and potential strategy for your company.



# To aggregate or not: Five deciding factors

To come to an informed conclusion about enabling aggregation and start to shape your strategy, here are five things to evaluate:

## 1 – What Are Your Market Requirements?

How many of the countries in which you currently sell product require aggregation? Be sure to look beyond compliance demands for the most imminent deadline – some markets will phase aggregation in over time. You also need to evaluate what markets you're likely to move into and their aggregation mandates.

If at least some of your markets require it, then at least a portion of your lines will need to support it. In that case, you may want to weigh upgrading costs against operational simplicity: some manufacturers are deciding to enable aggregation across the board since having different line setups and processes for different facilities adds complexity. And some have designed aggregation capabilities into their packaging lines, but have initially only implemented item level serialization. This approach may help avoid re-design in the future.

## 2 - What Are Your Trade Partner Preferences And Requirements?

What are your wholesale distributor customers expecting in terms of aggregation? Most distributors are advocating for it. Aggregation would improve their inventory management capabilities and bring substantial efficiencies to their businesses.

With serialization, wholesalers will be able to identify inventory down to the specific unit and track it internally. With aggregation, they could do that for both opened and sealed cases, as well. It would greatly simplify cycle counting, which wholesalers periodically do to check their physical inventory against what their system thinks they have. Aggregation would allow them to scan just the pallet or case - depending on the hierarchy level - and instantly know the identities of all the individual units.

In a similar vein, aggregation would facilitate verification requests from a regulator or trade partner; if the distributor has a sealed case, they wouldn't have to open it up to determine if product in question is inside.

Understand how wholesalers would use aggregation hierarchies and how it impacts their business processes, and then ask your partners. Some downstream businesses may actually refuse to take non-aggregated product or require a surcharge to accept it.

### **3 – How Do Your Products And Competitive Landscape Factor In?**

For generic or highly competitive product, will trade partners have a preference for aggregated product if it makes their receiving and internal processes easier? Even if you manufacture an innovator drug, you still may face uncomfortable pressure from major distributors. Some manufacturers are enabling aggregation even when their markets don't require it in case it gives them a leg up on the competition.

### **4 – If You Enable Aggregation, At What Point Does It Make Sense To Do It?**

What happens to your products in your own distribution center? Some companies focus on building aggregation hierarchies at the line, but those hierarchies are promptly disrupted when they get to the distribution center and staff unpack cases to create small orders, repack for air travel, or accommodate other business demands. In these cases, aggregation for a customer order is actually done during the pick or post-pick process and not necessarily at the packaging line if those products are sold at the "each" level.

Make an informed decision based on your business needs. If there is product that you never sell in full cases, aggregating on the line may not be the optimal choice if you will only have to rebuild relationships before product goes out the door.

### **5 - Does Your Serialization Solution Enable Aggregation?**

Even if you're undecided about aggregation or are not enabling it now, you should still plan for it from a solutions perspective. Choose a serialization infrastructure with full aggregation capabilities in case your market needs – or the regulations for the markets in which you currently do business -- change. You will want a solution that can aggregate and manage all the related events such as disaggregate, decommission, destroy, reaggregate, replace items, reset container aggregation, and more.

Aggregation is likely to be a factor in many markets for years to come. Evaluate all these factors, and build for the future so your business is well positioned for whatever regulatory developments come along.

As you assess potential aggregation needs, you also need to evaluate how your serialization provider may be able to handle them. To learn more about TraceLink's serialization solution and how we can help manage aggregation, contact us.

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