DM logic

To Aggregate or Not to Aggregate. (It's not really a question)

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As the pharmaceutical world inches closer and closer to the Drug Supply Chain Safety Act (DSCSA) final regulations for total serialization and visibility across the supply chain, the question of aggregation is often debated. To many, aggregating their inventory is a daunting task and they are questioning whether or not to go down that road. Many are still trying to figure out how they can fully serialize their product without aggregation. However, unless the warehouse is simply a pallet in and a pallet out operation, to aggregate or not to aggregate isn't the question. The real question is when to take that leap to aggregation and where one should start.

WHAT IS AGGREGATION

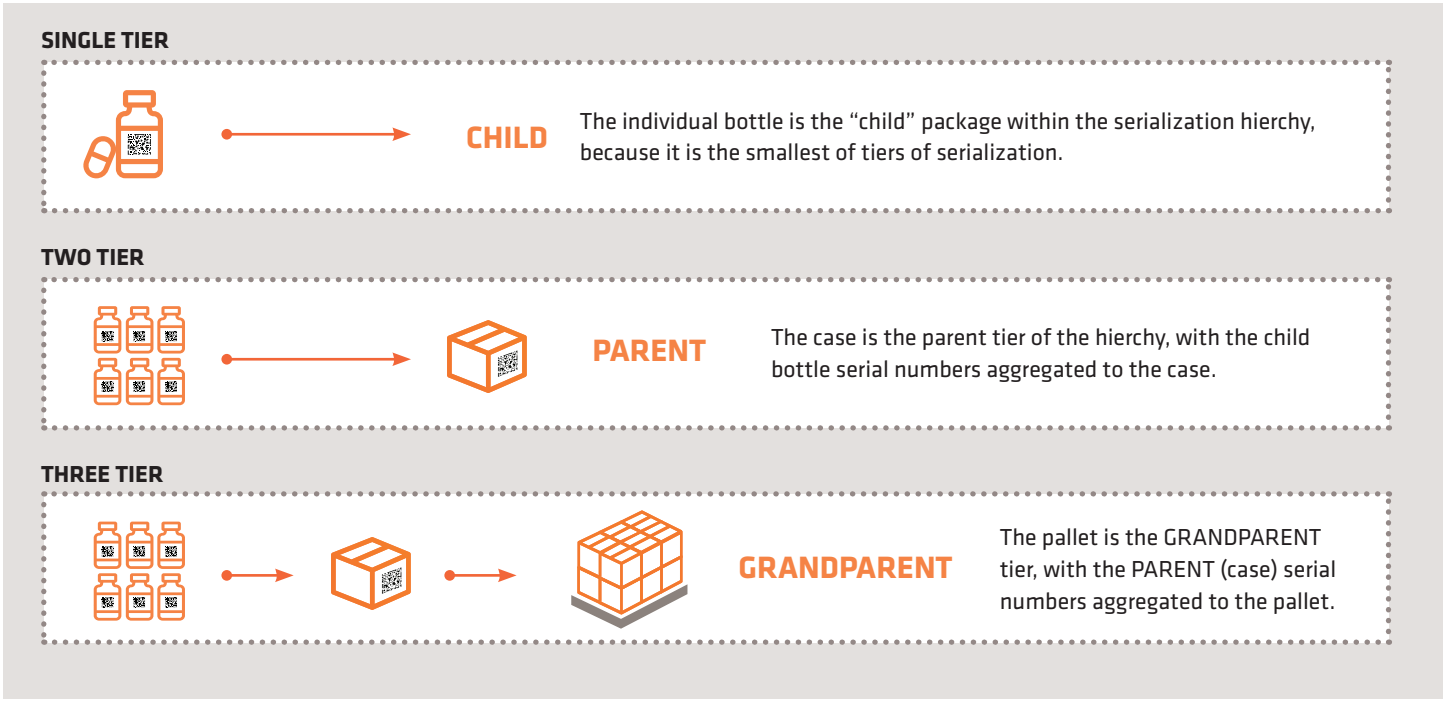
In the simplest of terms, aggregation in the pharmaceutical world is the ability to track serial numbers at multiple units of measure, even those you cannot see, by developing a systematic relationship among them. It is often described in terms of a parent/children/grandchildren relationship, where there is one associated parent while there could be many children and/or grandchildren. Let's explain.

Consider a pallet coming out of a pharmaceutical manufacturing plant. That pallet has 48 cases each containing 24 bottles of a drug intended to reach the customer at a pharmacy or hospital. In this example, the pallet is the parent. Each case is a child. Each bottle is a grandchild. While the manufacturing plant has made certain of the correct unique serial number on the bottle, on the case and on the pallet, full aggregation means that those bottles (grandchildren) are associated with one particular case (child) which is associated with that pallet (parent). The hierarchy is tracked to the bottle level and that level of tracking has to be systematically maintained as the product travels throughout the supply chain.

There certainly are warehouses where a full pallet comes in from the manufacturer and is never broken down in the warehouse and simply ships in the same way. That is a simple track and trace procedure that does not require aggregation. But it's not often that pallet will stay that way at the distributor. And the majority of pharmaceutical warehouses aren't shipping in a pallet-in and pallet-out model. Most warehouses are going to have some level of transactions that will require those full pallets be opened. Pickers may not be picking eaches or bottles but they are often picking cases and packers are building mixed pallets. That is where aggregation becomes extremely important in order to manage all the data associated with tracking the eaches/bottles back to where they came from off the pallet. Picking a case (child) off a pallet (parent) and putting it on a new pallet (new parent) means that case (child), along with the bottles inside (grandchildren) must be disaggregated or disassociated with the original parent and re-aggregated with a new parent. Tracking on every functional area such as receiving, adjustments, picking and making sure that each parent and child is associated correctly is key to a

WHY IS AGGREGATION SO IMPORTANT

An interesting challenge with aggregation involves the scenario where the warehouse is shipping in a six-pack of bottles that is wrapped in cellophane or an innerpack within the case. Now, the aggregation is not three but four levels (parent/child/grandchild/greatgrandchild.) With the inner pack, the barcoded serial numbers on the bottles might be hidden with no line of sight available. Without aggregation, opening the innerpack and scanning each bottle would be inefficient and would run a greater risk of error. With aggregation, however, the innerpack will already be serialized and therefore, even picking that one pack and creating a mixed shipping container would still allow for full visibility of where that pack originated.



Let's take a 24 per case model.

- Each bottle within the case has their own serial number. CHILD
- Each innerpack of six bottles has its own serial number. PARENT
- Combining the four six packs to make a full case would have another serial number. GRANDPARENT
- The pallet may have 48 cases with a top-most serial number.

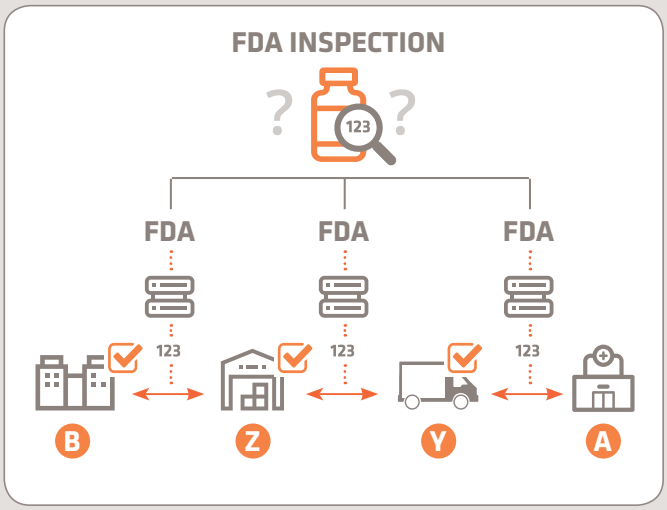
Another major challenge involves picking and shipping of mixed pallets. Perhaps 10 cases of an item are needed which comprise only a quarter of the pallet. If a picker is picking 10 cases to start building a mixed pallet, they will not only have to assign a new parent serial number to the pallet, they will then assign those 10 cases (children) to the new parent. And those 10 cases each have 24 bottles (grandchildren) that have to be reassociated to a new parent (the new mixed pallet being built). Imagine the impact to the operation without aggregation. If that original relationship wasn't known, then each unit would need to be scanned to associate them with the pallet. The idea of having to open each case and scan every each right before the product is shipped to the next link in the supply chain would cause major inefficiencies in the warehouse.

WHAT ROLE DOES THE FDA PLAY?

The basis behind the DSCSA is that every drug that enters the United States can be tracked along every step of the supply chain from manufacturing to the pharmacy level. The FDA wants to be able, at any time, to do a full audit of eaches as they travel through supply chain.

AN EXAMPLE MAY BE...

1. The FDA wants to inspect details from serial number 123 in Pharmacy A.
2. Pharmacy A reports that serial number 123 was received from Distributor Y, who confirms they in fact shipped serial number 123 to Pharmacy A.
3. Distributor Y also confirms that serial number 123 was delivered to them by Warehouse Z.
4. Warehouse Z can also report that they received serial number 123 from Manufacturer B and shipped it out to Distributor Y.
5. Once each step is verified that serial number 123 did arrive at Pharmacy A, then serial number 123 should never show up or be verified again and if it does the FDA will be able to catch the error and determine if the drugs are counterfeit, stolen, etc.



Got it? If aggregation wasn't used in that warehouse, at any point in the supply chain the questions the FDA may ask cannot be answered.

WHY WOULD YOU NOT AGGREGATE?

Obviously not everyone's system is running the same software. Some systems are archaic; some are brand new. But very few are prepared for this level of tracking and visibility across the supply chain. And the deadline of 2023 if fast approaching. Distribution issues such as these simply can't be solved using only ERP systems. Serialization needs must be dealt with in the warehouse.

Serialization is adding another layer of complexity through the entire receiving operation. Warehouses must pick up the hierarchy and the movement within the warehouse from location to location. Along the way, all of those warehouse transactions lead to making adjustments. Having pickers scanning every each will lead to delays in shipments. The process is not only too time consuming and inefficient but it will require the warehouse to bring in more labor and therefore raise costs, which will ultimately will be passed to the consumer.

Manufacturers simply aren't prepared for handling what's happening downstream in warehousing and distribution. The first part of the regulation is to put the serial number on the bottle but the second step is to track the pedigree as it goes through the supply chain to be able to confirm where it came from. Every touch point in the distribution process has to be effective.

Exceptions are the killer in any business, especially in distribution. If you open a case and find 24 bottles but one is serial number 25 and you are missing serial number 19, then you need to figure out where 25 was supposed to be and where 19 ended up. It is critical to get aggregation right in manufacturing but anytime you open a product case you potentially run the risk of tampering with the hierarchy. If you are shipping less than pallet size to customers then you have to manage aggregation and especially aggregation exceptions.

Studies have shown that with every 100 key strokes there is at least one mistake made. So while it may seem to be financially less cumbersome not to aggregate and do more manually, statistically there will be mistakes. When dealing with human lives, there is no room for error.

WHAT IS THE PROCESS TO IMPLEMENT AGGREGATION?

1. Evaluate what your product makeup is for customers.

What kind of handing units are you using to ship? If you are shipping full pallets it's a different conversation than if you are shipping eaches. If you are receiving in the same handling unit that you are shipping then you won't have as big of an issue to resolve and you may be able to deal with exceptions in a one-off system. But if you have to break down pallets or cases or make any changes in the warehouse then you have to evaluate the touchpoints to ensure the most efficient shipping process.

2. Identify what touchpoints in the warehouse you have when you are changing the unit of measure for the movement.

If you receive product as a full pallet and you don't break it down, again, there is no issue. But perhaps you are restacking a pallet or adding it to another pallet or making two partial pallets, if that is the case then you are changing the makeup from where it originally came in. The same goes for movement within the warehouse. If for example, you are replenishing to fixed pick locations and you use full pallet replenishment all the time the you may not need a touchpoint there but if you are picking on to a conveyor then the conveyor would scan that serial number creating yet another touchpoint. Or maybe you do full pallet movement all the way through the warehouse until packing so perhaps you just need a new solution at the packing station to avoid scanning eaches at that point.

3. Evaluate the exceptions that you have on a daily basis.

Talk to everyone from managers to supervisors to inventory control and find out why and when are the making adjustment that affect inventory. Assess those exceptions and see where the similarities are and how they affect your hierarchy.

4. Communicate with manufacturers.

You need a coordinated effort to know when product is going to be serialized. As companies move to serialization there will inevitably be non-serialized product and serialized product in the warehouse at the same time. And perhaps some serialized product that is aggregated and some that is not. While you evolve to having a full serialized product with full aggregation your system will have to be able to deal with serialized and non-serialized at the same time.

5. Ensure your system is ready.

You may be able to change your existing system to handle serialization. In many ways this may be the best solution if you already have a best-in-class solution. Your system must be prepared to handle as many serial numbers as the number of eaches in the warehouse, plus all hierarchies at any given time. If you decide to develop in-house, make sure your system is optimized for performance for queries not just on the inventory but on historic transactions for track and trace.

The discussion of aggregation is not about whether or not a company can choose to aggregate. The DSCSA is mandating this level of track and trace. However, the timeline for implementing aggregation can be complex. The expense and the effort that goes into this type system integration can be daunting and with the mandated timeline having been pushed out, many companies are putting off the investment. That begs the bigger question, when dealing with human lives, why would you not aggregate and sooner rather than later.

moving forward **with you**

DMLogic has already worked with Johnson & Johnson to full serialize and aggregate their entire warehouse. Read that case study here. Moreover, the DMLogic system, STEPLogic Trace, had been previously piloted at GlaxoSmithKline to prepare their warehouse for operation. DMLogic has been working with this problem since 2007. We are familiar with touch points and aggregation complexities and have seen and identified every possible exception in the process. Talk to us about what we are doing with our customers that are shipping right now.

inventory systems. We manage the warehousing of apparel, auto parts, electronics, food and beverages, and more. electronics, food and beverages, and more.

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