

# Aggregate Goals

As counterfeit drugs continue to pose a threat to supply chain security and patient health, more countries are putting track and trace serialisation initiatives in place. Aggregation and data integrity are of paramount importance when adhering to these emerging mandates

At its most basic level, track and trace is the ability to verify that a product is genuine at each location in the supply chain, and that it came from the expected source. Although, at first glance, achieving this initiative may appear simply to involve placing unique numbers on products, it is actually a far more complex process. Track and trace requires not only item-level serialisation, but also aggregation of serialisation data. What's more, to successfully execute both serialisation and aggregation, maintaining the integrity of data throughout the entire packaging process is crucial.

In light of emerging mandates, manufacturers are now evaluating various serialisation offerings. As they survey the market, they must consider a solution's ability to successfully execute both item-level serialisation and aggregation, as well as its ability to meet the three major objectives of serialisation implementation, which are maintenance of data integrity, packaging line throughput and system security. Manufacturers addressing these objectives will ensure they choose a solution that efficiently meets track and trace requirements.

## Aggregation Is Critical to Track and Trace

Because track and trace requires the verification of products at each step in the supply chain, it requires not just serialisation, but also aggregation of serialisation data. Aggregation is the process of assigning (packaging) children to a parent. The aggregation rules are defined by the packaging hierarchy, which specifies which package types can be packed into others (cartons into cases, cases into pallets and so on). Initially, a serialisation solution assigns

and verifies unique identification numbers at the item level. The solution then packs the now commissioned item (the child) into a higher level package (the parent), establishing a parent-child relationship between item, case and pallet. Manufacturers use aggregation to track which items within their facility have been shipped and where they have been sent.

So why does track and trace require aggregation? The only way to verify which individual products have been shipped and where they have been shipped to is to scan them. Without aggregation, all warehousing and shipping must break down pallets for inspection, open cases and scan all individual items – a tedious process that is both impractical and impossible given the timescale required.

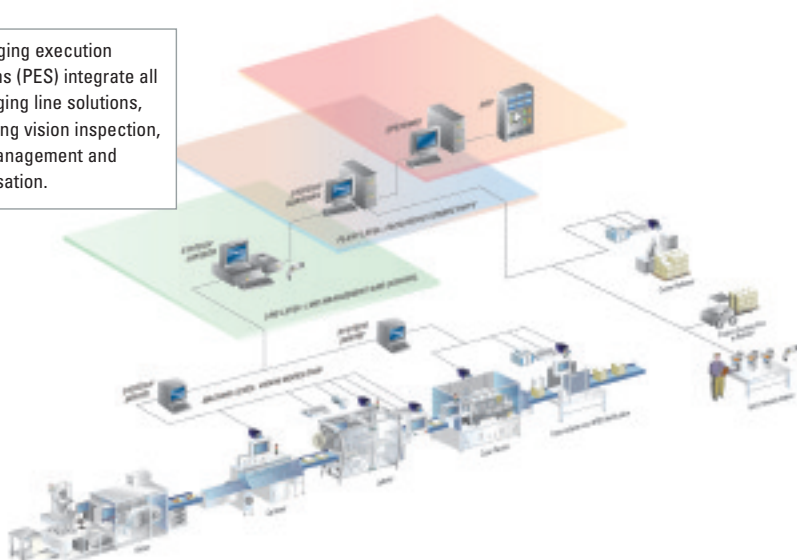
Aggregation provides the supply chain with the parent-child relationship information necessary to efficiently track and trace all products. This data lets the supply chain know that a particular pallet is at a particular location, the cases

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it contains, and that a specific set of serial numbers is inside these cases. Aggregation can therefore enable inference, meaning that warehouses can simply scan the case (parent) to identify the items (children) being shipped into the supply chain. From there, supply chain partners can send serialisation notifications of just the 'children'. Thus, in a controlled environment, aggregation allows the supply chain to effectively manage each 'child'.

More countries will soon be mandating aggregation as part of compulsory serialisation. For example, the Turkish Ministry of Health, which currently requires just item-level serialisation, will also require aggregation of serialisation data from the start of 2012. Both the item-level serialisation and aggregation data will have to be transmitted to a central repository.

Packaging execution systems (PES) integrate all packaging line solutions, including vision inspection, line management and serialisation.



## The Three Major Objectives of Serialisation Implementation

As manufacturers evaluate solutions capable of item-level serialisation and aggregation, they will also need to consider whether or not these solutions can address the three major objectives of serialisation implementation. The first of these objectives, data integrity, is fundamental to meeting track and trace requirements. In addition, the other objectives for manufacturers to consider are maintaining packaging efficiency and system security. The following paragraphs highlight why confronting these three objectives prepares manufacturers for the demands of today's global regulatory requirements.

### Data Integrity Is Critical

Data integrity guarantees that the physical world matches the list in the database and is essential for initiatives requiring serialisation and aggregation. In order to verify the legitimacy of products, manufacturers must know which numbers have been assigned to which products and batches, as well as be aware of which serialised products are in the supply chain or have been consumed. This requires that serialisation data in manufacturers' systems is 100 per cent accurate. To achieve this accuracy, serialisation solutions must control the numbers that are issued to a particular packaging line for a particular process, accurately account for numbers that may have been assigned to packages that were rejected during packaging both on and off of the line, and associate each serial number to the correct batch. This requires the solution to follow and maintain positive control of unique identity items throughout their entire journey on and off of the packaging line.

Item-level serialisation and aggregation require integrity of the individual numbers, as well as integrity of the relationships between the numbers. Any missing or overlapping information will make track and trace impossible. For instance, if data is inaccurate or missing, the manufacturer will have an orphan item that is not associated with any case. When this orphan enters the supply

chain, it will be considered 'bad' and 'out of place', resulting in the item being sent back to the manufacturer even though nothing is wrong with it.

### Maintaining Packaging Efficiency

The second objective for serialisation implementation is to maintain packaging line throughput without expensive and time-consuming disruptions. Serialisation and aggregation create the need for the enterprise resource planner (ERP) to communicate serialisation data down to the plant-level server, and for the plant-level server to then communicate this data down to the packaging line. The packaging line must then send precise serialisation data back to the plant-level sever, which goes on to send this information to the ERP. This bi-directional communication relies on the availability of both the enterprise and plant-level servers, so any issues related to these servers can impede the communication of the numbers down to the line, halting the packaging process.

To prevent line disruptions, it is critical to employ a plant-level server that can continue sending this serialisation data to the line, while in lot number, should any communication interruption occur with the enterprise servers. Likewise, the line management solution must be able to insulate the line while in lot from any potential communication interruptions with the plant-level server. Hence, regardless of the speed or availability of the servers, the packaging operation can continue running at maximum speed throughout.

### Security Is Essential

The third objective of serialisation is to maintain a secure information technology system. With serialisation and bi-directional communication now a part of the packaging operations, the manufacturer's packaging

line computer systems are now on their main business information systems network. These line systems must be protected from viruses that could ultimately infect the entire business system. The problem, however, is that virus protection can severely slow down line operations. To address this issue, manufacturers must invest in a solution that can protect the systems without degrading packaging line throughput.

### Conclusion

Track and trace mandates require complex changes to the packaging environment. In addition to placing a unique number on a product, manufacturers must also aggregate serialisation data. Furthermore, the key to successful serialisation and aggregation is maintaining data integrity throughout the entire packaging process. Accuracy of data is imperative for track and trace initiatives and thus a crucial factor for enabling supply chain visibility and protection. Manufacturers will need to keep these considerations and objectives in mind as they look for solutions to address global regulatory requirements.

## About the Author



Joseph Ringwood is the Chief Operating Officer for Systech International. With more than 25 years of sales, marketing, and general management experience, Joseph plays a key role in Systech's business operations.

He is responsible for directing Systech's strategies for growth, both domestically and internationally, as well as growing customer, business and technology partner relationships. His current responsibilities include the overseeing of domestic and international sales teams, development and execution of Systech's marketing and management of professional services team, new product development, strategic business development and management of central engineering. Joseph holds a BSc degree in Business Administration from Villanova University, and is an Adjunct Professor in the W Paul Stillman School of Business at Seton Hall University in the areas of sales force management, business-to-business marketing and new product development. Email: josephringwood@systech-tips.com