

BEST TECHNOLOGY PRACTICES FOR TRACEABILITY REPORTING

Whitepaper



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It has been a pretty good day on the floor today. Then, one of your quality engineers asks you if you have seen the urgent customer email sales just received, but before you can respond, your office phone begins to ring. It is your customer's director of purchasing calling you to explain that the federal regulatory agency responsible for safety standards in their market has contacted them to notify them of an official investigation into their consumer product. The director soberly reminds you of your contractual obligations to quickly and accurately support their own quality investigation of the component they purchase from your company.

As your mind begins to process the impact this hot request will have on your technical team and operations in the next couple of days, you remember that your company has planned well with a sound quality strategy and a modern enterprise information system. Your heart rate slows as you recall that you have a battery of software tools to conduct the analysis quickly, accurately and efficiently.

The good news - your manufacturing operations system has been recording (tracking) and ready to report (trace) the history of receiving, quality inspections, processes, work-in-process and final inventory and shipping records for lots or batches, and even serialized finished goods individual products.



TRACK AND TRACE REPORTING OPTIONS

Transactions and Summaries

These records can be reported as transactions and summaries in textual form. The information can be listed by process routing operations starting with receipt of raw material and purchased components with related supply chain information like material certifications and incoming inspections, through all operations to finish goods inventory, final packaging and labeling of top-level, sellable product. Finally, it is important to also tie these product records to shipment records (customer, logistics, date, time, ship-to, quantity and supporting documents) to complete the thread of information from source material and component ordering through production, shipping and delivery to your customer.

Traceability (sometimes called "Track and Trace") reporting serves two primary purposes:

1. Quality Investigations

Detailed traceability is a necessary component to support product quality investigations conducted internally, at the request of a customer or 3rd party regulatory body. Reviewing the transaction and process data in the investigation help to ascertain the magnitude of the problem or possible problem and then identify containment steps, root cause, corrective action and preferably preventative action. In these situations it is very important to limit the scope of the investigation and recovery plan to only the products really involved to speed the analysis and minimize plan costs.

2. Continuous Process Improvement

Used in large scale, "big data", analytics can be used to support continuous process improvement initiatives. For example, the data can be used to identify key process parameters to put under SPC, mistake-proofing (aka "poka-yoke") the setup of production runs, build predictive quality and maintenance algorithms for use with Real-Time™ process monitoring, all focused on improving efficiency and maximize throughput on the plant floor.

The trace history, usually stored in a historian database due to the sheer volume of detailed transaction records, is often displayed in a textual log format based on product item number, date range, source material or components, workcenter, employee and other criteria leading to reporting of item numbers, child item numbers, operation, employee user id, lot number, serial number, and timestamp.



Graphic Tree Relationship Reporting

A second reporting method is in a “family tree” graphic style with the same information rendered in graphical boxes representing lot / container / serial numbers which are linked visually by lines indicating parent child relationships. The finished good lot / container / serial number graphic icon can be depicted at the top or the bottom of the tree with the intermediate operations or sub-assemblies leading “back” to the source materials and purchased components.

The family tree view of the history is excellent for very fast discovery of relevant information for quality records related to a single finished goods product and production lot study. However, this method can be cumbersome when users have to work through a number lots or even finished product item numbers since the user must remember common source information when tracing “backwards”.

The tree view can be a powerful tool to quickly look forward to identify all of the downstream work-in-process or finished goods affected by a known issue with a single shipment, lot, coil or container of received raw materials or purchased components. In this case, a dramatic quality issue during early process operations on raw materials or purchased components may have made a problem highly visible or if a supplier self-identifies a quality problem (subtle, or otherwise) with a past shipment to your facility that they previously certified as good.

Analytic Reporting

If, however, a quality issue is identified by a downstream customer, or more significantly, by a third party regulatory body before being discovered by your team, then a more useful tool is an analytic report. This report should have input filters to identify shipped lots, containers or serialized individuals they believe may be flawed. The report should then work backwards through the associated live production (for recent shipments) transactions and/or focus on relevant historical data to identify links and correlations to identify common lots / shipments of raw materials and purchased components, work centers, tools, operators and inspectors in summary. As a best practice, any reporting tool should also have on-screen, detailed transactions drill down capabilities to help users gain more granular insights.



Integrating ERP & Manufacturing Systems

There is one more valuable use of track and trace capabilities in your manufacturing and ERP systems. If you sell serialized individuals, such as individual vehicle (options) sequenced product, assemblies with vehicle identification numbers, most product for aerospace, defense contract mandated, and finally FDA regulated medical devices, pharmaceuticals, foods and even now beverages. In these markets, it will be important to tie the source and manufacturing process trace records to the actual manufacturing bill of materials and process to account for any material, item or quantity substitutions in all of the involved operations. Any variance, approved or otherwise, from the engineering release can become a key part of trace reporting in warranty analysis, identifying repair parts for durable assembled products, and responding to safety-related recalls.

Assuring that track and trace capability is built-into your manufacturing operating system will give you the ability to practice continuous improvement with accurate product and process data and provide peace of mind if you ever need to urgently conduct a product quality investigation.

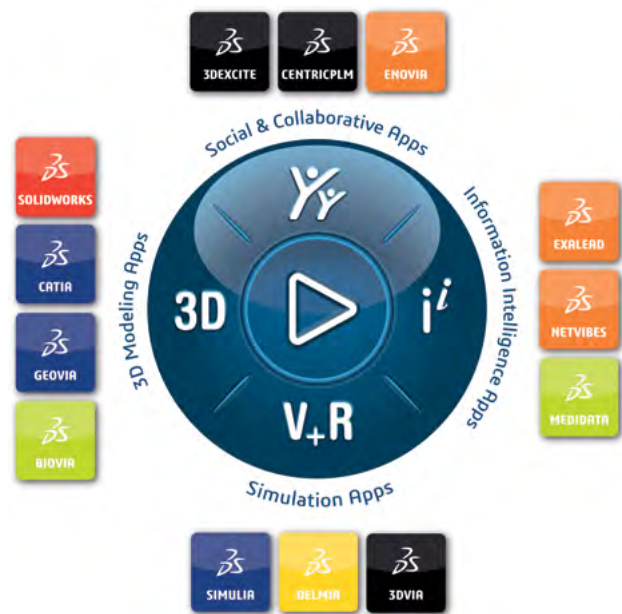
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