

Manufacturing Quality and Traceability for Discrete and Process Manufacturers

For manufacturers across industries, managing recalls can involve high costs or even life-threatening situations. Ensuring consistent quality and lot, batch and serial number traceability across the supply chain is crucial for controlling risks and safeguarding consumers. In regulated industries such as pharmaceuticals, deep traceability and detailed record-keeping are required for compliance. Capabilities in **e2open[®]'s Manufacturing Quality and Traceability application** enable manufacturers across all industries to trace the origin of products, lots, batches and even raw materials, and easily manage quality and recall risks to avoid costly disruptions.

Companies that contract some or all of their manufacturing enjoy the financial benefits of outsourcing, but that comes at the cost of reduced supply chain visibility. This is a problem because, to protect brand equity, manufacturers must be able to manage any quality concerns quickly and efficiently, especially in regulated industries. For instance, quality issues in the pharmaceutical industry require an immediate response to comply with regulatory demands from the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA). In the automotive industry, assembly lines can be halted by a single defective component whose origin and distribution are hard to trace, resulting in significant financial losses.

By leveraging capabilities in e2open's Manufacturing Quality and Traceability application, brand owners continuously monitor production quality and receive automated alerts for potential quality concerns. They reduce overall costs and manage recalls effectively by tracing products in the manufacturing cycle, the logistics network and customer channels. Customer service and manufacturing operations teams are empowered to trace and control inventory by lots and maintain material usage genealogy trees, gaining the ability to quickly understand the root cause of potential defects and pinpoint which goods are affected.

Key Features

- End-to-end manufacturing tracking and traceability for internal and external production
- Multi-level lot genealogy tree to enable lot, batch and serial number traceability
- Commonality analyses with algorithms to identify failure points and the associated lots
- Automated workflows to enable rapid issue resolutions across partners
- User-authored collaborative workflows for handling recalls

Key Benefits

- Significantly faster responses to supply quality or availability issues due to end-to-end visibility and specialized features that enable rapid action
- Automated identification of all materials across manufacturing and testing environments that share a common, identified quality issue
- Improved productivity for operations teams due to reduced manual tracking activities
- Reduced obsolescence costs through early visibility into quality issues
- Improved ability to act decisively during recalls based on full chain-of-custody records
- Improved assurance that contract manufacturers use only qualified materials for production

Start-to-Finish Tracking and Traceability

Companies can automatically capture all steps that occur during production, including assembly manufacturing, process manufacturing, testing and packaging. The system then uses an underlying data model to translate these steps into traceable, digital representations. When quality issues arise or recalls are required, brand owners can analyze the whole supply chain, including external manufacturers, to determine the root cause, track any affected products and efficiently conduct a recall.

Multi-Level Lot Genealogies

The application creates an automated, digital chain of custody for manufactured products, replacing the time-consuming and error-prone manual process many manufacturers use. Spanning internal and contract manufacturing and quality systems, the system converts transactions into a multi-level lot genealogy tree. This enables brand owners to keep track of each step in the production of complex finished components. For

example, in the semiconductor industry, many different suppliers might have a role in manufacturing a single chip. Companies with automated, detailed chains of custody can quickly address disruptions before they escalate into expensive recalls.

Cross-Functional Visibility and Decision Support

When a quality issue arises in the channel or at any point beyond finished goods manufacturing, the service organization can immediately identify the lot's chain of custody and begin to address the concern. For example, pharmaceutical tablets go through a complex set of manufacturing processes — including active ingredient production and dry mixing, granulation, tablet pressing, tablet coating and packaging — with a separate supplier at each stage. The ability to track and trace each lot in this type of multi-functional, multi-enterprise supply chain makes recalls faster and more efficient.



Commonality Analyses for Root-Cause Identification

After confirming a quality issue, the brand owner can minimize production downtime by running commonality algorithms. These analyses determine the source of the defect by identifying what each defective item has in common. If the defect appears in multiple lots, the application scans the genealogy tree, sifting through massive data sets to precisely identify the source and root cause of the quality failure. Brand owners can quarantine defective components and quickly release those that are not defective back into production.

Agile Responses Based on User-Authored Workflows

A convenient workflow engine enables business users to author their processes, ensuring that the appropriate personnel can monitor and resolve issues. Brand owners automatically capture manufacturing transactions and identify potential discrepancies, which then triggers user alerts. The system also initiates standard exception-handling workflows, automating processes and helping brand-owner teams respond more quickly to supply issues.

End-to-End Supply Chain Management Platform

Once an organization implements any e2open platform application, it is easy to add more capabilities in the future for better visibility, coordination, and control over the end-to-end supply chain. The e2open platform creates a digital representation of the internal — and optionally external — network, connects internal enterprise resource planning (ERP) and financial systems using SAP and Oracle certified adapters for timely data feeds, and normalizes and cleanses the data to make it decision-grade. Using machine learning-enabled algorithms and supply chain management applications, the platform processes the data and provides bi-directional, closed-loop communications back to ERP systems for execution. This facilitates the evolution of supply chain processes towards true convergence of end-to-end planning and execution.

Brand owners can safeguard brand equity, ensure compliance and limit liability exposure by quickly identifying the root cause of quality issues and enabling effective, well-targeted recalls.

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