

Risk and Quality Management

End-to-End Quality Control and Compliance with Brand Integrity Safeguards

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 Risk and Quality Management 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 integrity, 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. And in the apparel and footwear industry, brands must issue specific instructions to suppliers and manufacturers about which items to set aside for testing and coordinate with third-party testing specialists and laboratories to understand and store test results for future reference as violations could result in brand damage that can take years to reverse.

By leveraging capabilities in Risk and Quality Management, 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
- Centralizes all product testing — including components, bill-of materials (BOM) and finished goods — under one platform

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.

Achievement of Global Traceability

Through the system, brand owners collaborate with suppliers, manufacturers and other partners at any tier or

ecosystem, capturing component-level details for every finished unit and assembling all the data in a centralized way. For example in the apparel and footwear industry, if quality issues arise in the distribution channel, ease of access to manufacturing and testing data for each product helps achieve complete global traceability. This also strengthens compliance and quality while products are being developed and produced, reducing risk and enhancing efficiencies.

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, helping to ensure 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.



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

About e2open

E2open is the connected supply chain software platform that enables the world's largest companies to transform the way they make, move, and sell goods and services. With the broadest cloud-native global platform purpose-built for modern supply chains, e2open connects more than 400,000 manufacturing, logistics, channel, and distribution partners as one multi-enterprise network tracking over 12 billion transactions annually. Our SaaS platform anticipates disruptions and opportunities to help companies improve efficiency, reduce waste, and operate sustainably. Moving as one.™ Learn More: www.e2open.com.

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