Elemica

Assure | Traceability and Compliance

Digitize, connect and organize manufacturing data—harnessing it to strengthen and streamline overall QA/QC.

Challenge

Around the world, an enormous body of manufacturing data resides solely as "dark data" written down by hand and stored in binders, folders and files around thousands of facilities. These scribbled secrets capture important events, attributes and aspects relating to product quality, including the details of manufacturing materials, product serial numbers, ingredients/assemblies, lot information, documentation, how each input tracks to end products and more.

But in terms of a QA/QC professional's ability to practically access this data and use it to ensure quality and compliance throughout the manufacturing process—it might as well not exist at all. Analog data is often overlooked. It can't be searched or accessed quickly to help determine insightful trends or troubleshoot problems. And when it comes to auditing and compliance tracking, actual paper documentation makes even the smallest protocol or inquiry more stressful and time-consuming than necessary.

In addition, meeting enterprise quality and regulatory compliance documentation requirements is much more costly when dealing with dark data.

Solution

The Elemica Assure™ Traceability and Compliance module lets you capture this previously dark QA/QC data and share it digitally for a better return on information. Through a dedicated system portal, your team and trading partners can access real-time tracking and compliance insights that were previously unavailable digitally, such as:

- Comprehensive quality data relating to plant floor or total supply chain QA/QC operations
- Product genealogies informed by ingredient/component lot mixing at each step along the manufacturing process
- Total lot and serial number traceability, complete with batch records, shipment data and documented electronic certificates of analysis
- Audit status and milestones, as well as corrective action requests

The system can also capture and monitor specialized regulatory compliance data for the Food and Drug Administration (FDA), International Standards Organization (ISO) and the American Society of Mechanical Engineers (ASME).

This module takes the guesswork out of quality and compliance. Users better manage QA/QC risk, ensure transparency, reduce operating costs and more effectively leverage data. The result? Better accountability and more efficiency across the supply chain.

- **Ensure regulatory compliance**
- **Improve quality accountability**
- **Streamline QA/QC management**
- **Boost ROI of quality-related data**
- **Strengthen auditing performance**
- **Lower the cost of quality/compliance**

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At a Glance
Traceability and Compliance

Features

01 Integrates ship notices, COAs, source of supply, material specifications, internal batch test data, ingredient data, lot receipts, lab results and more

02 Correlate parts, components, materials and ingredients to final products

03 Archive quality and compliance-related documentation for easy access

04 Track audit results and certification status, and manage corrective-related tasks

05 Generate product genealogies that include parent/child relationships of material, components, processes, etc.

06 Trace lot and serial numbers both forward and backward, and join/split lots within the system

Benefits

Access integrated statistics using previously "dark" data to bring more transparency and better QA/QC performance

Reduce the cost and admin associated with managing the data needed for strong QA/QC execution and regulatory compliance

Improve your readiness position and responsiveness relative to regulatory tracking and auditing

Ensure material validations and streamline QA/QC protocols and corrections

Fight compliance oversights by going digital and getting hyper-organized

Work more collaboratively with internal and external stakeholders to fight quality risk

Elemica transforms supply chains by replacing manual and complex approaches with efficient and reliable ones. The world's leading business network for process-intensive industries, we drive bottom line results by promoting reduced cost of operations, faster process execution, automation of key business processes, removal of transactional barriers and seamless information flow between trading partners.

FOR MORE INFORMATION, PLEASE VISIT ELEMICA.COM

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