Achieving Cradle-to-Grave Bi-Directional Traceability with MOM

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Globally, medical device manufacturers continue to face stricter government regulations and escalating costs. This, coupled with the daily challenges associated with improving device quality, maximizing resources, reducing costs and maintaining competitive advantage, leads many medical device manufacturers to a Manufacturing Operations Management (MOM) system for streamlining and simplifying their operations.

Traceability throughout the Entire Production

By adopting MOM software, best practices are enforced and reinforced automatically throughout the entire production process to ensure a seamless operation. This seamless link from one process to the next ensures each step is controlled, validated, and fully traceable, simplifying a medical device company's ability to achieve FDA and ISO compliance.

Over the years the concept of traceability has changed, where in today's highly-regulated world the concept of cradle-to-grave bi-directional traceability[1] is no longer a nice to have, but a must have requirement. In the past, an issue was considered resolved if a serialized part could be traced back to all their component parts. Today, traceability requirements are much more detailed. In order to meet rigorous FDA requirements, manufacturers must arm themselves with the right software and processes to not only track every component on their production line, but as well as in the supply chain, or post sale warranty and repair work. Also, all the activity or information that took place regarding 21 CFR Part 11 needs to be instantly traceable and accessible.

Unfortunately, many manufacturers still struggle to adequately trace their products today. Most manufacturers still leverage a combination of disparate systems and processes to manage their data, for instance ERP systems, Excel spreadsheets, SQL databases, and paper-based DHR's. These disconnected silos of information increase the potential of duplicate data entry and errors. Depending on where the errors occur, it could cause unnecessary rework or worse yet, a missed delivery date to a customer.

Manufacturers can no longer afford to treat traceability as a separate function therefore they must look towards an efficient MOM system to adequately handle their traceability requirements and provide seamless integration to their ERP system.

Electronic Device History Records stores all History

A best-of-breed MOM system can automatically update an eDHR and stores all the history of every device, including all work instructions, data collections, buy-off signatures, discrepancies, rework, and complete device genealogy; which includes all the materials, components, and subassemblies used for each device, as well as the complete tree of nested components. MOM systems that support eDHR not only maintain all the original as-built production records, but all the service installation and removal records as well.

Product genealogy is maintained for products tracked by serial number, lot number, or work order number, and is preserved through work order splits and lot splits. Full audit trails of work process from design to execution and inspection are provided. Device history for the entire tree of subassemblies and components includes production data, product genealogy, discrepancies, changes to instructions, installation and removal of parts, rework and repairs. MOM also tracks all incoming supplier inspections, including discrepancies and automatically routes them to the appropriate personnel.

Quality and Compliance

To maintain quality and reputation, it has become increasingly important to be able to locate specific lots or serial numbers to easily speed up recalls when a defect or hazard of a particular part or ingredient has been identified. Recalls are generally vast in scope and normally are extremely costly, yet many manufacturers are still not investing in quality and compliance software until after they are faced with a recall or other significant loss. Increased productivity, improved customer service, reduced costs, and instant access to vital information is achieved through a fully integrated MOM system.

If for any reason a product is subject to recall or warranty issues, you can quickly query the product genealogy information to determine exactly which products contain or used a suspect component or material. Once a brand has been faced with a recall, it could take years to repair the damage, both in terms of reputation and cost.

Position ahead of the Compliance Curve with the right MOM System

Medical device manufacturers that successfully navigate the traceability maze can not only comply with FDA regulations, but ultimately reduce the risk and cost associated with FDA audits and mass recalls while improving operational excellence. Furthermore, these leaders will position themselves ahead of the compliance curve, and improve their competitive advantage. Cradle-to-grave bi-directional traceability doesn't have to be an IT nightmare when you have the right MOM system.