

MESWorks Case Study

Medical Device Manufacturer

"By partnering with Dataworks, we achieved substantial improvements in efficiency, quality, and compliance. The solution not only addressed the challenges posed by our old manual processes but also gave us a platform to become a more data driven organisation".

Operations Director.



CHALLENGE

A large multinational medical technology company had implemented a paper-based device history record (DHR). Tracking "critical to quality" information manually was time-consuming, open to human error and laborious to review. Recognizing the need for a more streamlined and efficient solution, the company sought to digitize and optimize their DHR process.

DATAWORKS ROLE

Dataworks, renowned for its expertise and pedigree in delivering innovative solutions, was engaged as the software development partner. Their task was to develop an electronic DHR system based on their proven MESWorks platform.

TECHNOLOGY

The solution uses Microsoft SQL Server as the database with a web based User Interface. Implementation was conducted in phases across the different manufacturing and packaging areas to ensure the smooth transition from paper to digital.

ADVANTAGES

The system helped build greater control into the manufacturing and quality review processes by digitizing and optimizing the data capture process. Routing, Bills of Materials (BOMs) and product testing were all digitized helping embed quality into the process and also guiding product builders along standardized paths.

All transactions were fully audit trailed and electronic signatures supported, ensuring compliance with regulations such as 21 CFR Pt. 11. Many logbooks and test sheets were also digitized and incorporated into the MES system.

The system enabled real-time tracking of performance metrics, serving as a vital data source for continuous improvement projects. By providing actionable insights promptly, the company could address issues proactively.

The system also helped with the reduction Corrective and Preventive Actions (CAPAs) and Non-Conformances at the site, yielding signification time savings and reduction in Work Order completion times.

The system facilitated the progression of the sites Digital Maturity Level by interfacing with the company's ERP system, Learning Management System and Document Management System.

The system has been a key enabler for many Continuous Improvement projects at the site.

CORE BUSINESS BENEFITS

OPERATIONAL & QUALITY IMPROVEMENTS

With a more robust DHR system in place, the company experienced an improvement in the flow of products and reductions in WIP. The digitized routings, material scanning, and capture of critical parameters and product test data led to improved quality across the production process.

COST SAVINGS

The transition from a paper-based system to an electronic one resulted in significant cost savings. Reductions in compliance costs, human errors, batch review times and paper usage throughout production contributed to improved operational efficiency and bottom-line savings.

REAL-TIME TRACKING

The Real-time recording and tracking capabilities of the system empowered the company to identify and address issues promptly. It also supported the recording and monitoring of KPIs across the Operations and Quality functions, eliminating time spend collecting, collating and presenting this data across all Tiers of the organisation. This helped the site with their Visual Management and Continuous Improvement strategy.

CONTACT US

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