MES IMPLEMENTATION FOR 21 CFR PART 11 COMPLIANCE AND ORACLE INTEGRATION

OVERVIEW

A medical device manufacturer failed 21 CFR Part 11 audits and was in danger of a partial shutdown. The solution required:

IMPLEMENTATION OF AN MES TO CREATE AUDITABLE PRODUCTION RECORDS

MIGRATION OF A PLANNING LIBRARY FROM A LEGACY PLANNING SYSTEM

INTEGRATION TO ENTERPRISE SYSTEMS FOR A SINGLE-SOURCE OF PRODUCTION RECORDS

PROBLEM

A medical device manufacturer struggled to meet 21 CFR Part 11 regulations with paper-driven production processes. Mistakes in data collection and disparate manufacturing databases led to discrepancies and errors in production records. The error-prone paper-driven processes hindered production and led to costly quality escapes and repeated failed audits. With an upcoming serious audit fast approaching and the possibility of a partial shutdown, the manufacturer turned to CIMx early in January for a solution.

RESULTS

The project successfully provided all required documentation and process support to pass the planned audit. The system automates routine tasks for regulatory compliance, eliminating the errors from previous audits. The manufacturer now routinely creates 21 CFR Part 11 compliant records for all production.

The legacy system has been retired. All required production information, including drawings from the PLM, is accessed from the shop floor in the new digital environment. The set-up, installation, production mapping and system rollout was completed in a few months. The integration to existing Oracle enterprise systems was accomplished in less than two weeks with no disruption to production. There have been no reported problems with the integration.

Standardized processes brought repeatability and simplification to the production environment. Users enjoy the increased productivity from the digital workflow over the error-prone and difficult paper-based processes. Since the company provides incentive pay for quality and quantity work output, the same production staff is now producing more than 20% more product with the increased efficiency of the MES solution.

Overall, the project has been a resounding success. The customer achieved 100% improvement in compliance records, more than 30% reduction in quality escapes, and more than 10% increase in production volume.

SOLUTION

After assessing the manufacturers' processes and workflow, CIMx suggested implementing an MES on the shop floor. This offered the quickest and easiest path to the comprehensive and auditable production records necessary for regulatory compliance.

The company's entire historical manufacturing planning library of 4000 part plans was migrated from a legacy production planning system to the CIMx MES. The project required multiple levels of data correction and close coordination with user groups, as data varied widely based on the initiating group and data usage. CIMx worked with users and the compliance team to standardize planning.

Next, CIMx integrated the MES to the existing Oracle JD Edwards ERP and Oracle Agile PLM enterprise systems. Through the integration, CIMx captured all the images and drawings from the existing enterprise systems as needed. This provides a single source of manufacturing data and auditable records. Automated tools in the CIMx Data Migration Engine efficiently managed the data matching process, eliminating errors while reducing cost.

The MES was installed on the shop floor early in March (two months after the initial meeting) and production processes mapped in the system. Required production data collections were applied to planning and a pilot was successfully demonstrated to the audit team. The MES was rolled out to the rest of the plant after an initial pilot program. All necessary travelers, production plans, and data collections are now managed in the CIMx MES.

CIMx SOFTWARE

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