

Selecting a Manufacturing Execution System (MES) Vendor for a CDMO

This client is a contract development manufacturing organization (CDMO) providing custom development and manufacturing services to many well-known pharmaceutical companies. The client produces biologicals that include plasmid DNA, proteins, and enzymes.

The client is currently using paper batch records and other paper-based systems in their manufacturing process. While the paper batch records are sufficient and compliant, it creates an extensive timeline for review along with generating numerous quality events that typically come from paper-based systems. Electronic Batch Record (EBR) capabilities of most modern Manufacturing Execution Systems (MES) offerings would reduce these quality events by providing material verification, step-by-step guidance, quality checks, and equipment/system integration capabilities that can be used to prevent common quality issues such as data entry errors while reducing the frequency of incorrect materials being used or material waste. Additionally, MES software can function as a central system that integrates LIMS, QMS, ERP, PAS, and data historians.

The client engaged Clarkston's MES experts to perform a review of their current manufacturing ecosystem and guide the client through a vendor selection.

Life Sciences Case Study

PROJECT OVERVIEW

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES :



Contract Development
Manufacturing / GMP
Contract Manufacturing

PRIMARY OBJECTIVES:

- Aid the client in the selection of an MES provider that aligns with their current processes and their future direction
- Identify business cases for MES from both an operational and business standpoint
- Identify the scope that's best suited to be used in a first-phase implementation of the selected software
- Estimate potential operational efficiencies and return on investment of MES implementation

RESOLUTION:

- Led end-user requirement gathering workshops to better understand the current business and manufacturing processes at the client
- Gathered pain points of the current business and manufacturing processes
- Advised the client on the initial list of vendors for demonstrations based on best-in-class MES providers
- Led debrief discussions on initial vendor sales demonstrations
- Created User Requirements document and authored Request for Proposal (RFP) documentation to distribute to vendors for RFP response submission and final in-depth system demonstrations guidance
- Documented business cases for full-scale MES integration, including cost savings estimations
- Crafted script for vendor demonstrations based on current processes in place at the client
- Developed cost models from vendor responses based on 10-year outlook
- Created scoring methodology and scorecards for final vendor demonstrations
- Provided training for client participation in the scoring evaluation to ensure consistency
- Created vendor scoring analysis and executive summary for client

KEY BENEFITS:

- Clarkston guided and led the client through the MES vendor selection process, providing industry best practices and relevant client experience for the client to make a final vendor selection
- Upon RFP completion, the client was able to narrow down the final decision to two vendors that met their functionality, infrastructure, and cost needs
- Clarkston provided a high-level timeline and cost comparison for the two vendors for the initial Phase 1 Implementation
- The client received cost savings estimates for a full-scale implementation with metrics for key benefits and operational efficiencies
- The client has a clear understanding of the business and operational benefits of implementing MES



KPIs

- **Estimated 80% reduction of batch review time by implementing MES**
- **Estimated \$7,000 quarterly savings on paper and ink from the replacement of paper batch records**
- **Estimated 99% reduction of quality events and incidents caused by illegible entries and incorrect in-process calculations**

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