

POMSnet MES in the Cloud

Customer deploys Validated POMSnet MES in the Cloud in 3 Months



Why MES

POMS Corporation has delivered a validated, cloud based Manufacturing Execution System (MES) to a Customer in 90 days. The Customer is pursuing biosimilar product offerings via manufacturing employing single use component methods to simplify manufacturing infrastructure and assure compliance with product integrity and isolation requirements. The company recognizes best practices for large volume production might look quite different from immediate small quantity needs, and desired a pathway to scale that can be implemented now and then in the future assure a seamless infrastructure to scale when business so requires. One key element in this strategy is the consideration of a Manufacturing Execution System (MES).

The MES implementation is reducing processing complexity, increasing operational and end product consistency, and decreasing risks. By electronically capturing processing data; exceptions to processing parameters are identified in real time and corrected or flagged for batch review purposes. Capture of genealogy, provides multi-level forward and backward reporting for full lot traceability.

The project approach was to implement the first phase of a future robust MES system that would provide material receiving, tracking and traceability to support submission of new products to the FDA, and then add additional MES functionality later as their scale up and needs warrants without the need for additional IQ or OQ validation.

The purpose of the MES at Customer Site is to:

- provide higher quality products
- improve traceability of materials
- improve consistency in product output

The initial implementation includes:

- Purchase Order Receipt for GMP items,
- BOM Management
- Transfer of Items from the Warehouse to Manufacturing for Production Orders,
- Dispense/Consumption of raw materials and critical consumables in Manufacturing,
- Recording of lot trace information during consumptions,
- Multi-Level Forward and Backward Lot Genealogy Reporting.

"POMS Corporation's truly web based POMSnet MES application with its out of the box SPEED project package and ability to be fully hosted in the Cloud allowed us to achieve our project goals for a validated material management and traceability MES application in 3 months."

-Customer, VP Finance and Project Management



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Why POMS

Our customer was looking for a long-term partnership with a leading MES solution provider that was capable of providing a turn-key solution that could deliver Customer's phase 1 MES requirements in a validated environment in 3 months and provide Customer's long term MES vision, goals and requirements.

Utilizing its 25+ years of industry experience, POMS consistently provides successful turn-key projects that include software license, design, implementation, testing, training, validation, maintenance, and 24x7 support.

The POMSnet SPEED (Streamlined POMSnet Enhanced Execution and Delivery) out-of-the-box project package was ideally suited to meet Customer's schedule, costs and the initial MES requirements while providing a foundation for full implementation in the future.

POMSnet's unique 100% web-based architecture allowed the system to be quickly deployed in a cloud hosting center which was required by Customer to meet their project schedule, costs, IT infrastructure, and ongoing maintenance and support business model.

POMSnet's ability to control and track all aspects of production from dispensing through packaging, secure predictable quality, enforce current Good Manufacturing Practices (cGMP) and provide a complete history for regulatory compliance will allow Customer to achieve additional MES benefits as their system and compliance needs expand.

To learn more about POMS solutions, please contact:

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POMSnet SPEED Project Package

The POMSnet SPEED (Streamlined POMSnet Enhanced Execution and Delivery) project package is a very robust highly pre-defined set of MES functionality, pre-packaged to the maximum extent possible, which allows POMSnet MES projects to be delivered at a significantly faster schedule, lower cost and lower risk than traditional MES projects.

The out of the box fixed initial defined scope includes the following functionality:

- Material Management,
- Weigh and Dispense Management,
- Inventory Management,
- Bar Code Labeling and Management,
- Equipment Management,
- Basic Process Control Integration,
- Recipes with Electronic Work Instructions,
- EBR,
- Full Forward and Reverse Material Genealogy,
- Standard Set of ERP Transactions.

To reduce the schedule, costs, risks and required documentation for validation, the SPEED package includes a complete package with User Requirements (URS), Functional Design (FDS), Trace Matrix, Risk Based Testing, and Validation Plan (IQ, OQ and PQ) for an MES project.

The prebuilt and validated system is available on virtualized environments that can be deployed to site hardware or cloud hosting centers. Hosting centers with experience in FDA regulated environments can also provide validation documentation for the system installation, maintenance and backup/restoration procedures.

The POMSnet MES SPEED package allows customers to start achieving ROI much sooner than the traditional MES deployments generating immediate MES returns that can then be used to fund the system to grow to a full paperless electronic batch record system.