Operations Management Solution For Life Sciences

MESTECH

Enabling the Real-time Factory

Pharmaceutical Manufacturing Challenges

- Increased need for regulatory compliance
- Too much paper
- Inefficiency in process due to redundancy
- Errors due to manual process
- Longer batch review cycle
- Audit Closures

Rockwell Automation FactoryTalk

Java JBoss Microsoft SQL Server eclipse

IBM ORACLE Apache Tomcat

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Rockwell Automation Recognized System Integrator Manufacturing Operations

Core Modules

Recipe Management

- Management of Master Recipe
  - Procedure
  - Unit procedures
  - Operations
  - Phases
  - Material Flow Control
- Graphical Interface
  - Multiple views with zoom levels and object levels
  - Sizing for usability
  - Dynamic search
  - Information flow
  - Fixed repetitive workflows
- Compliance
  - Versioning
  - Enforcement
- E-Signatures

Production Execution

- Predefined Workflows
  - Material Receipt and Issue
  - Scale Testing and Calibration
  - Room Cleaning
- Role-based by design
  - Intuitive and consistent user interface
  - Material tracking and enforcement
  - Equipment tracking and enforcement
  - Process guidance
  - Integration with Automation
- Compliant creation of exceptions
  - E-signature and comment
  - Multiple exception categories
- Label, Label History, re-print

Quality Review

- Real-time *Review by Exception*
- Role-based by design
  - Quality dashboard
  - Review by exception
  - Exception workflow
  - Workflow-driven review process
- Ease of integration
  - Batch record - aligned with S88/B2MML
  - XML-based reporting
  - Archiving with DMS

Standard Solutions

- MES Strategy and Roadmap
- Design, Implementation, Support for Rockwell's FactoryTalk PharmaSuite
  - MES standalone
  - ERP-MES integration
  - ERP-MES and MES-DCS integration
- Customization as per customer requirement
- Migration of legacy MES to newer platform
- Recipe Building support

Why MESTECH?

- Manufacturing Solution Focus
- Extensive Project experience
- Domain Expertise
- Client Driven Engagement Process
- Efficient Methodology that maintains quality, audit ability and transparency throughout the engagement
- Onsite-offshore model helps deliver projects on schedule and within budget

Systems Benefits

- Reduction of risk of non-compliance by enforcement of processes and specifications
- Elimination of paper in manufacturing
- Drastic reduction of manual entries
- Enforcement of material flow, equipment and related quality checks throughout the manufacturing process
- Providing controls that support right first time documentation
- Review of the batch records by exception
- Reduced time to market by speeding up batch review and release mechanism (near real-time)
- Real-time alerts on actions to be taken based on the intelligence of underlying automation systems
- Electronic batch record of steps executed by the user for inspections and regulatory submissions
- Ability to integrate MES system with ERP to avoid duplicate entry of master data and production data

Business Case