Proven Cost-Savings Using Manufacturing Execution Systems (MES) for BioPharm Manufacturers
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Speaker Information
Marco Lederle

- Home Country: Germany
- Master of Science in Business Information Systems
- 9 years experience large scale IT Automation, Manufacturing Execution Systems (MES) and PCS (Process Control Systems and SCADA) projects within the biopharm industry
- International experience from assignments in Europe, USA and Asia involving managing geographically distributed project teams working in a multi-cultural environment.
- Focus on Strategic Planning, EBR design and Project Management
- Currently serves as Operations Manager for the US office of i+o Industry Planning + Organization located in Bethlehem, PA.
- i+o (www.io-consultants.com) is an international consulting firm (established 1958) that provides services (IT Automation, SCM, Flight Catering) that are independent from software, hardware and solution providers
Facing continuing challenges to reduce manufacturing costs, Life Science companies are looking beyond departmental productivity improvements for cost saving solutions. MES is a technology that can improve the recording process, accuracy, timeliness and usability of data that manufacturing, quality, compliance and other departments rely on to achieve their business objectives. Departmental leadership routinely updates business processes to drive efficiency and address changing compliance requirements within their functional area. MES addresses cost savings opportunities that can only be captured by extending efforts across functional boundaries.

This presentation discusses planning for MES from evaluating the benefits of MES, defining goals, positioning MES within the IT infrastructure and aligning stakeholder requirements through development of a coordinated user requirements document. These activities provide the basis for MES software selection and implementation resources. Examples of cost savings available through an MES implementation are included in the presentation.

Manufacturing, Quality, Compliance, Automation and IT personnel will benefit from this presentation. Experience with Manufacturing Execution Systems (MES) or Paperless Manufacturing (EBR) is not required.
Content

- Understanding MES Concepts
  - Challenges in Manufacturing
  - MES in General Terms
  - MES in Your Organization (Benefits, Improvements)
  - MES in the Industry
  - Understanding Your MES Vision

- Establishing an MES Initiative
  - Strategic Considerations
  - MES Roadmap
  - Required Support and Resources
  - Factors for Success
  - Summary
Understanding MES Concepts

- Challenges in Manufacturing
- MES in General Terms
- MES in Your Organization (Benefits, Improvements)
- MES in the Industry
- Understanding Your MES Vision
- Summary / Conclusions
Challenges in Manufacturing

- Control and reduce costs in Manufacturing & the Supply Chain
- Prepare the business for future growth
- Continuous Quality Improvement
- Manage Inventories – Stock Level reductions
- Ensure successful capital investments
- Reduce production delays & downtime
- Improve Customer Service levels in changing economic climate
- Transparency and control of manufacturing process
- Ensure compliance and avoid errors during manufacturing
- Reduce review and approval cycles

⇒ **MES could be a solution to these problems**
MES in General Terms

Definition

The acronym MES stands for **Manufacturing Execution Systems**

[MES is a] production **scheduling and tracking system** used to analyze and report resource availability and status, schedule and update orders, **collect detailed execution data** such as **material usage**, **labor usage**, **process parameters**, **order and equipment status**, and other critical information. It accesses bill of material, routing and other data from the base ERP system and is typically the system used for **real-time shop floor reporting** and monitoring that **feeds activity data back to the base system**.

MES in General Terms

What is MES not

• A replacement for existing Enterprise Resource Planning (ERP) solutions
• A replacement for existing Warehouse Management (WMS) or Laboratory Management (LIMS) solutions
• Just another piece of software in your company
• The solution to all manufacturing related and production documentation issues
• Exactly the same for everyone in the company
• A universal solution which you can copy and paste in different companies
MES in General Terms
Positioning of IT Systems (With MES)

ERP
- Strategic functions
- Added Value
- Corporate focus
- Data evaluation

MES
- Operational functions
- Increase in efficiency
- Site focus
- Data gathering/management

PCS, PUC, PLC
- Automation functions
- Real time
- Process focus
- Data generation

ERP - Strategic functions - Added Value - Corporate focus - Data evaluation

MES - Operational functions - Increase in efficiency - Site focus - Data gathering/management

PCS, PUC, PLC - Automation functions - Real time - Process focus - Data generation

Event driven (Data)
Corporate focused (Data)
Second Minute Hour Shift Day Week Month Quarter Year

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MES in General Terms
MES in ISA-95 Context

Level 4
- Business Planning & Logistics
  - Plant Production Scheduling and Operational Management
  - Establishing the basic plant schedule
  - Production, material use, delivery and shipping;
  - Managing inventory levels

Level 3
- Manufacturing Operations Mgmt.
  - Area Supervision, Production Scheduling, Reliability Assurance
  - Work flow / recipe control to produce the desired end products;
  - Maintaining records and optimizing the production process

Levels 2, 1, 0
- Batch Control
- Continuous Control
- Discrete Control
  - Monitoring, supervisory control and automated control of the production process;
  - Sensing / manipulating the actual process

Source: ISA-95.00.03

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Benefits & Improvements
Operational View

• Reduce Batch Record Review Time
  – Identify & resolve exceptions during (not after) production
  – Make batch data available in an easily accessible format
  – Review by Exception

• Eliminate Manual Errors In Data Entry
  – Electronic data entry and verification

• Eliminate Manual Errors In Process Calculations
  – Automated calculations based on operator entry or system gathered information

• Eliminate Manual Errors In Reconciliation
  – Tracking of material consumptions/creations and consolidated reconciliation with plausibility checks
Benefits & Improvements Compliance View

• Ensure that only Qualified Manufacturing Resources are used
  – Equipment Status
  – Materials Status and Identity (material scanning prior to usage)
  – Staff Access Control (potential to link to training records)

• Ensure Use of Correct Work Processes
  – Enforce sequence of operations
  – Track step execution with timestamps
  – Enforce positive identification through electronic signatures

• Rigorously Control Materials
  – Automate weighing operation
  – Automate calculations and reconciliation of materials in real time

• Document Control Improvements (e.g. log books)
Your MES Vision
Overall Goals

• Improve manufacturing process for Operational Excellence
  – Increase productivity and lower manufacturing cost
  – Reduce quality related issues / Right First Time (RFT)
  – Faster release of products
• Minimize implementation risks and generate fast ROI
  – Modular Automation (MES) architecture:
    – Stepwise introduction and implementation
    – Seamless integration with ERP and process level applications
    – FDA compliant data storage and access
• Support state-of-the-art manufacturing concept using tailored IT (MES) solution
<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
<th>Advantages</th>
<th>Disadvantages and Possible Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No Implementation of MES</strong></td>
<td>Situation stays as is; manual/ organizational execution and documentation</td>
<td>No investments necessary</td>
<td>Inefficiencies; process and product quality issues, In transparency, Not state of the art</td>
</tr>
<tr>
<td><strong>Future Implementation of MES</strong></td>
<td>Preparation for future implementation; additional operations are implemented with future MES in mind</td>
<td>No significant investments now. Possible integration at a later point of time</td>
<td>See above</td>
</tr>
<tr>
<td><strong>Pilot Implementation of MES</strong></td>
<td>MES implementation limited to certain area/process/product =&gt; Hybrid solution</td>
<td>Proof of concept leads to reduced risk, Remaining operations not affected</td>
<td>Parallel operations of two systems. Impact on running operations when full roll out</td>
</tr>
<tr>
<td><strong>Full Implementation of MES</strong></td>
<td>Full MES implementation. =&gt; Paradigm shift to electronic batch recording and documentation</td>
<td>One fully electronic approach throughout operations. Parallel start up (without subsequent delays)</td>
<td>Major investment; Higher risk; major change in operations execution and documentation</td>
</tr>
</tbody>
</table>
Your MES Vision
MES Solution

• Three types of vendors offering MES functionality:
  – Dedicated MES solutions; e.g. Werum, Rockwell, Emerson
  – Vendors with ERP solutions offering MES functionality (downward integration), e.g. SAP, custom developed
  – Vendors with PCS / SCADA solutions offering MES functionality (upward integration); e.g. Rockwell, Siemens, Wonderware

• Traditionally dedicated vendors able to offer better functionality

• Improvement of solutions offered by ERP/PCS companies through higher level of integration

• Best fit dependent on the overall ERP and shop floor integration strategy
Establishing an MES Initiative

- Strategic Considerations
- MES Roadmap
- Required Support and Resources
- Factors for Success
- Summary
Use validated core as basis for localizations; in case new functions are added to core that require revalidation, localization will stay validated; each localization is based on the latest validated core.
Define and develop site specific MES solution; only leverage minor efforts between different localizations
MES Roadmap Overview

Project Management

1. Define MES Roadmap
2. Perform Area Assessment
3. Define MES Solution
4. Cost Estimation
5. Business Value Assessment
MES Roadmap
Area Assessment (Scorecard)

Summary
Manufacturing Area: xxx

Profile (lower score = lower risk, complexity)

Process (higher score = higher level of automation)

Financial Summary

Implementation Plan

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Main cost driver for an MES implementation:

- Services/Training
- Interfaces
- Automation (MES)
- External and Internal Resources
- Software and Licenses
- Infrastructure
- Hardware
## MES Roadmap Business Value Assessment

### Focus
- **Process Time**
  - MBR-Setup/Approval
  - Order Release
  - Process times
  - Execution
  - Approval/Release
  - Batch Record Scheduling

- **Staffing**
  - Optimization of resources (reduce one-over-one, reduce documentation on shop floor and for administration)

- **Quality**
  - Process integration/Reduction of error
  - Reduction of deviations / Rework
  - Process monitoring

- **Strategy**
  - Multiplier effects after successful implementation

### Tools
- **Time Study**
- **Staffing Plan**
- **Quality Reports**
- **Other Projects**

### Return
## Process Time

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>MES Improvement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Release / Batch Record Preparation</td>
<td>Time for order release incl. preparation of necessary order printouts and cross check; Reduction through less manual communication btw. planning and manufacturing</td>
<td>90%</td>
</tr>
<tr>
<td>Verification/Release Batch Record MFG</td>
<td>Cross check and release of batch record; estimation of preparation and release times for all departments</td>
<td>80%</td>
</tr>
<tr>
<td>Verification/Release Batch Record QA (In Process)</td>
<td>Cross check and release of batch record; estimation of preparation and release times for all departments</td>
<td>75%</td>
</tr>
<tr>
<td>Batch Records with errors (non conformance) / Returned EBRs</td>
<td>Maybe part of Deviations</td>
<td>100%</td>
</tr>
<tr>
<td>Scanning of BPR for Archiving data</td>
<td>Potential Labor Savings (RA group performs scanning); Data storage</td>
<td>100%</td>
</tr>
</tbody>
</table>
MES Roadmap Sequencing

Score Cards, Cost & Process Maps

Business Value & Overall Comparison

Sequenced & Prioritized Roadmap
MES Roadmap
Core Processes for Harmonization

- Operations/Detailed Scheduling
- Dispatching Production Unit
- Labor Management
- Resource Allocation and Status
- Document Control
- Process Management
- Performance Analysis
- Product tracking & genealogy
- Data Collection
- Quality Management
- Maintenance Management
Support and Resources

Key Resources and Responsibilities

- **Project Sponsor**
  Resource on an executive level to initiate, support and fund an MES program

- **Project Champion**
  Resource on a high level reporting to project sponsor, which drives the MES program.

- **Project Team**
  Resources which have access and knowledge to process area and key personnel

- **Subject Matter Experts (SME)**
  Resources which can provide knowledge, a sufficient level of detail to provide input for a BVA and to develop roadmap
Support and Resources
Example: Resource Loads

Detailed Engineering (13 weeks)
Development (16 weeks)
Implementation-StartUp (16 weeks)
Factors for Success Overview

• Master Data Management is essential
  – High quality of data

• Limit number of special functions
  – Minimize customization of standard MES system (leverage std.)

• Process owners need to understand the benefits
  – Discussions about process changes (business processes)

• Key users need to be able to drive the project
  – Reduces resistance against project

• State clearly that a Core MES cannot cover everything
  – Avoid frustration by giving the people realistic expectations

• Change Management (training etc….)
Factors for Success
Change Management – Overview

- Change Management is proactively managing the people side of change to achieve the desired business results
- Similar to Project Management except it is the people side of projects
- Research indicates Change Management is the #1 success factor for project teams
- Change ≠ Communication
- Change is NOT an event

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Factors for Success
Change Management – Risks

Example: MES Program Assessment
Size of Change = 72/100
Organizational Attributes = 58/100
Factors for Success Selling MES Internally

• Business Value Assessment
• Flexibility, e.g. using pilot implementation as proof of concept
• Improvements, Benefits for Compliance and Operations
• Case Studies of successful MES implementations in the pharmaceutical industry
• Long – term vision (operational excellence)
Summary

• Setup of actual MES program is important for solid foundation to successfully execute an MES implementation
• Using a tool and proper PM methodologies are important
• Change Management is a key factor for success and needs to be started early (expect significant changes)
• V-model provides a project approach following GAMP guidelines (specification, development, qualification)
• Importance of earlier conceptual stages to set stage right for the actual system implementation
• Independent approach supports a tailored solution for companies and is not limited by software specific functions