Manufacturing Execution Systems (MES): Overview and Case Study

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Agenda

• Manufacturing Execution Systems – Past, Present and Future
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• An MES Implementation at Novo Nordisk – Clayton, NC
  • Ray Boshold, Novo Nordisk
Characteristics

• Component-based structure
• High integration capability
• State-of the-art technologies
• Simple parameterization
• Access security
• Compliance
• Mobility and flexibility
ANSI/ISA 95 and ANSI/ISA 88 Standards

**Level 4**
- **ERP (e.g. SAP)**
  - Source, Plan, Manage Inventory, Delivery, etc.
- **What?**
  - Managing the end-to-end supply chain, establishing plans - production, material use, delivery, and shipping. Maintaining costs of operations.
- **Time Frame**: Months, weeks, days

**Level 3**
- **MES (e.g. PAS-X)**
  - Dispatch Production, Detailed Scheduling, Make product, Manage events / exceptions
- **What?**
  - Workflow/recipe control, stepping the process through states to produce the desired end products. Maintaining batch records and optimizing the production process.
- **Time Frame**: Shifts, hours, minutes, seconds

**Level 2**
- **DCS Batch Control**
- **Continuous Control**
- **Discrete Control**
- **What?**
  - Monitoring, supervisory control and automated control of the production process
- **Time Frame**: Milliseconds

**Level 1**
- **What?**
  - Sensing the production process, manipulating the production process
- **Time Frame**: Milliseconds
Integration

Level 4
ERP Systems

Level 3
LIMS
DMS

Level 2
DCS Systems
Historian
SCADA Systems

SAP Certified
Powered by SAP NetWeaver®
Based on ANSI/ISA 95 Standard
Based on ANSI/ISA 88 Standard

Standard Integration
Standard Integration
Standard Integration
Benefits

Batch Manufacturing Report Workflow Example after PAS-X Implementation

ISPE
An MES Implementation at Novo Nordisk – Clayton, NC

- PAS-X:
  - Background and Overview
- Implementation
  - Infrastructure & Deployment
  - Lessons Learned
Novo Nordisk

Novo Nordisk

- Global health care company with an 89-year history of innovation and achievement in diabetes care.
- Leader in the industry, providing a complete product portfolio of insulin and GLP-1 products and offers easy-to-use insulin delivery systems.

Novo Nordisk Pharmaceutical Industries, Inc (NNPII) - Clayton

- Employs over 540 local members of the community on a 264 acre property in Johnston County.
- Produces diabetes treatment products from formulation and aseptic filling to packaging and distribution.
- Only production site for diabetes products in North America.
Novo Nordisk Product Supply
PAS-X: One Global Harmonized MES System
For Discrete Production
PDS290 – “FlexTouch”

- Uses NovoTwist® for easy needle attachment
- Colour-coded
- Large dose display
- Max. dose of 80 units
- Audible click confirmation of dose delivery
- No push button extension at any dose
- Very low dose force

ISPE
PDS290 at DFP Site Clayton

- 1 packaging line
- 2 final assembly lines

The specific location of Packaging Line 4 is yet to be determined.
Paperless Electronic Workflow

Master Batch Record
- Bill of Material
- Process Definition
- Work Instructions
- Version

Electronic Batch Record
1. Order Number
2. Batch Number
3. Exact Work Center Routing
4. Right Sequence & Right First Time

Completed Batch Record
1. Actual Values
2. Exception Summary
3. Review by Exception
4. Signatures

Order & EBR Creation (ERP & MES)
Approve & Release EBR (MES & Operator)
PDS290 PAS-X

**Strategy**

- Goal is for PAS-X Core to become a global MES system including 95% of the MES functionalities that are required by the sites.
- To achieve this, focus on:
  - Functionality/processes
  - Technology.
- Streamline the business and manufacturing processes with as few variants as possible.

PAS-X Core is the standard MES software in Novo Nordisk. One solution for all sites will enable process standardisation in PS. Read more about the PAS-X Core project [here](#).
Business Objectives

- Harmonise MES and manufacturing processes through one central NN core – build on lessons learned from the current projects
- Reduce infrastructure operation costs
- Minimize licensing and maintenance cost on software
- Reduced ambiguity in validation costs
- Stabilize operation and maintenance costs
- Governance of functionality implemented will support harmonisation
Deployment

- 3 integral parties
  - Werum
  - PSIT
  - Clayton Site
    - Consultants (NNE Pharmaplan, etc.)
    - Site Automation
    - Site IT
Infrastructure

- Developed and qualified centrally.
- Local installations with local design (e.g. MBR) and settings validated by sites.
- DK sites will use the data centre for database and application services.
- Non-DK sites will use a locally placed server rack called “PAS-X in a box”.

![Diagram of infrastructure components: T, V and P Environment, NN PAS-X DB, NN PAS-X Application, Interface Software for PAS-X to: Taurus, CMES, MCS, NNTZW, SAP, OPC Client (PCS integration), Etc., Citrix Servers, Citrix Clients, Network / Switches, Other Systems Like: Taurus, CMES, MCS, NNTZW, SAP, OPC (PCS integration), Etc., Other System Devices: Printers, PDA, Barcode Scanners, Label Printers, Etc., Werum remote support.}

(*) In VMP Scope
Lessons Learned

• Planning
  • Gap analysis ~3 months
  • Involving stakeholders from LOB
    • Supply Chain
    • Quality
    • IT
• Ownership of system
• Customization
  • Programming
  • Validation
  • Associated costs
• Organizational Change Management
  • New processes, technologies for the site
  • Expertise