

Manufacturing Execution Systems (MES): Overview and Case Study

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Agenda

- Manufacturing Execution Systems Past, Present and Future
 - Gilad Langer, NNE Pharmaplan
- 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





Integration



Benefits



Batch Manufacturing Report Workflow Example after PAS-X Implementation



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"





PDS290 at DFP Site Clayton



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

and lost they have been



werum

Electronic Batch Record

- +
- Order Number
- Batch Number
- Exact Work Center Routing
- Right Sequence & Right First Time

PASIX WERUN

Completed Batch Record

- +
- Actual Values
- Exception Summary
- Review by Exception
- Signatures



Order & EBR Creation (ERP & MES)

Approve & Release EBR (MES & Operator)



PAS-X Product Description



SP

PDS290 PAS-X

PAS-X CORE One Core for all sites

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



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



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".











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

