Case Study: Journey Towards Pharma 4.0

Topics

- **Use Cases** on the Benefits of the Holistic Manufacturing Control Strategy with Pharma 4.0
- The **Business Benefits** to assure Quality for the Benefit of the Patient
- **Linking** Data Integrity, Process Maps and Data Flow with the Holistic Manufacturing Control Strategy
- **Questions & answers**
Use Cases

Benefits of the Holistic Manufacturing Control Strategy with Pharma 4.0

Pharma 4.0

Result
- highly automated production, newest technology
- control recipes manually from paper into HMIs
- process data printed for paper based release

Bottom line
- confidence in paper (recipes, release)
- individual projects
- structural capabilities

Paper kept

Use Case I:
Electronic batch record

Result
• perfectly validated systems and sub-systems
• structural challenges

Bottom line
• integration
• interests and responsibilities
• critical set points
• structural capabilities

Organization kept

Use Case II:

Improved

Result
• control of variability and availability of information
• identified data flows and communication means
• traceability

Bottom line
• management commitment
• knowledge from data integrity project
• interdisciplinary training
• design

Holistic view kept

Use Case III:
Business benefits
The Business Benefits to assure Quality for the Benefit of the Patient

Business benefit through data integrity project

Result
• less 4 eyes
• less redundancy
• faster data flow
• improved integrity

Bottom line
• a new experience for the team
• data flow, communication means and media breakages documented
• risk based improvement measures

Structural capabilities improved
Linking

Linking Data Integrity, Process Maps and Data Flow with the Holistic Manufacturing Control Strategy

Link holistic

**Architecture layers**
- description of structural properties of assets

**Hierarchy levels**
- recipes, equipment, material and personnel

**Life Cycle Value Stream**
- state and location of an asset

**RAMI4.0**
Reference Architecture Model Industrie 4.0

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Link structural capabilities

**Enablers**
- Management commitment
- Structural capability management
- Quality risk & knowledge management

**Tools**
- Master documentation (“one truth”)
- Risk classification of information
- Process maps (“unit operations”)
- Data flows (“from sender to recipient”)
- Communication means (“media breakages”)
- Information supply chain management

**Structural bottlenecks**

**Islands**
- equipment not connected
- information not shared
- media breakages
- data integrity issues
- organizational silos
- failures not discussed

Lessons learned:
Cross functional team

**Stages**
- management commitment
- same understanding (RAMI4.0, ICH, ISPE, etc.)
- structural capability management
  - resources
  - information systems
  - culture
  - organization
- holistic control strategy
  - structural capabilities
  - availability (information, resources, products)
  - variability (QTPP, CMA, CPP, CQA)

**Holistic control strategy**
along the product life cycle

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Questions & answers

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