Towards a Recipe Driven Organization

Presented by Terry Murphy, Strategic Operations Pharmaceutical Development & Manufacturing Sciences
Overview

• Introduction to Janssen and our challenges
• Defining the recipe based knowledge management strategy
• How the OSIsoft PI System enables that strategy
• Closing remarks
Janssen

Johnson & Johnson

Cardiovascular & Metabolism
Immunology
Infectious Diseases & Vaccines
Neuroscience
Oncology

80%
20%

Internal
External
Current State

REACTIVE ANALYSIS

- More time spent on aggregation than analysis
- Lack of knowledge management strategy
- Mix of paper/electronic
- Unstructured data
- Few standards
- Little built-in context
- Efforts mainly focused internally

Lab/Clinical/Commercial
**Future State**

**PROACTIVE ANALYSIS**

- Automated data aggregation
- More time spent on analysis than aggregation
- Common knowledge management strategy

- Electronic data capture
- Structured data
- Common standards
- Internal/external focus

**Recipe Based Knowledge Management**

**Lab/Clinical/Commercial**
S88 Recipe Based Knowledge Management Strategy

**Content**
Recipe Model
- Process
- Process Stage
- Process Operation
- Process Action

**Execution**
Recipe Based Workflow
- Operation
- Operation
- Operation
- Operation

**Visualization**
- Process
- Process Stage
- Process Operation
- Process Action

Consistent S88 Structure
S88 Recipe KM Strategy: Content

![Recipe KM Strategy Diagram]

- **Recipe Model**
- **Process**
  - Stage
  - Operation
  - Action

![Platform Operating Conditions: 3L Bioreactor Process]

- **Platform Operating Conditions**
  - Medium: M199 + 8% FBS
  - Cells: CCL-134

![Recipe Step Risks]

- **Recipe Step**
  - Solution Preparation/Add Materials and Mx/Additions
  - Risk Asset: 5
  - Severity T: 7
  - Likelihood T: 15
  - Impact T: 19%
S88 Recipe KM Strategy: Execution

Execution

ERP

Material Requirements & reconciliation

Recipe Data & Events

Process Data & reconciliation

OSIsoft PI System

MES

Process and Batch Data Historian

ERP

Material Requirements & reconciliation

Recipe Data & Events

Process Data & reconciliation

OSIsoft PI System

PCS

Process and Batch Data Historian
Contextualized data to enable:

- Real time process monitoring
- Quality reporting and review
- Reliability monitoring and analysis
- Continuous Process Verification
- Process optimization
S88 Recipe KM Strategy: Link to the Regulatory Filing

Regulatory Filing = General Recipe

CONTENT
Critical Parameters and Steps
Structured in S88 Format

VISUALIZATION
Critical Parameters and Steps
Context rich data

EXECUTION
Data generated in S88 Format
Contains additional site details
Value of the OSIsoft PI System

- Very disparate systems landscape
  - ranging from distributed process control systems with inherent historian capability to stand-alone instruments with paper printouts
- Require capability to capture and aggregate data for visualisation, reporting & analysis

OSIsoft PI System ~ System Independent Enterprise Data Presentation Layer
Value of the OSIsoft PI System: Future

- Very disparate systems landscape – now including MES, ELN, Manual Data Entry...
- Ability to share contextualized process data with external partners is critical
- Require capability to capture and aggregate data for visualisation, reporting & analysis
Conclusions

• Janssen is actively driving forward on S88 KM Strategy:
  – Content: Defining platform recipes
  – Execution: Aligning systems to S88 Platform definitions
  – Visualization: Building advanced analytical and modeling tools to help scientists and engineers gain advanced understanding of our processes

• A solution is required for a source independent data aggregation layer to include contextualized data from multiple enterprises.

• Collaboration with other companies would help drive this solution.
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Terry Murphy

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