Combining Laboratory and Process Data on the PI System

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Agenda

Introduction

- Janssen Pharmaceutical PI System
- Defining Requirements/ Creating Solutions
- Supporting Elements
- Benefits and Next Steps
Introduction - Janssen Pharmaceutical – Cork Facility

• Multi Product Facility

• Support Structure
  • CNS
  • Virology
  • Internal Medicine
  • Support Group

• API/ Aseptic Processing
  • Reactors
  • Centrifuges
  • Dryers
  • Centrifuge Dryers
  • Powder Handling
Agenda

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Janssen Pharmaceutical PI System

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Janssen Pharmaceutical PI System – OSI Products & Services

- Janssen & OSIsoft Enterprise Agreement
  - Managed PI
  - Performance Monitoring
  - Unrestricted Tag Count
- PI Server (High Availability/Reliability)
- PI Asset Framework
- PI Interfaces
- RtReports
- PI ProcessBook
- PI Notifications
- PI Batch/PI Event Frames

As Standard we embrace S88 standard within our source systems and with the PI System deployment.
Janssen Pharmaceutical PI System Architecture

- Standard Architecture
  - PI Collective
  - PI AF
  - PI RtReports
  - API Nodes

- Multiple Sources
  - Separate VLANS
  - DCS
  - PLCs
  - Chart Recorders
Janssen Pharmaceutical PI System – Source Data

- ABB 800xa and Sattline
- Fedegari, Chart Recorders and RSLinx
- ABB 800xa and Sattline
- ELIMS
- ABB 800xa

- OPC Continuous Process Data
- Alarm and Event Data
- Batch Context Data
- PI System
Agenda

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• Janssen Pharmaceutical PI System

Defining Requirements/ Creating Solutions

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Defining Requirements – Process Validation

FDA: Process Validation
General Principles and Practices (Jan 2011)

Stage 1
Process Design
- Build Process Knowledge
- Establish Process Control Strategy

Stage 2
Process Qualification
- Design and Qualify Installation
- Process Performance Qualification

Stage 3
Continued Process Verification
- Ongoing Program/Process Data
- Process Analysis/Product Data

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Creating Solutions – Connecting Data

**Process Data:**
- **Batch Data:** From multiple source Control Systems – batch/ unit batch / step start and end times, durations, interactions, events, etc
- **Continuous Data:** From multiple source Control Systems – Reactor Temperature, Agitation Speed, etc

**Product Data:**
- **Lab Sample Test Result Data:** Critical Quality Attributes (CQAs) – Loss in Drying, HPLC Results, Assays, etc

**Data NOW acquired and in Required Context**
Creating Solutions – PI System

FDA’s Process Validation guidance calls for continuous process verification.

**PROCESS DATA**
Multiple Production Control Systems

**PRODUCT DATA**
ELIMS Database

PI System
Multiple Sources – One System

Historical and real time process/equipment performance data

Historical and up to date Lab Data
Creating Solutions – One System/ One View

VIEW PROCESS DATA
Batch Search
Batch Step Duration
Max Tag Value
Min Tag Value
Average Tag Value

VIEW PRODUCT DATA
Batch Search
Parameter List
CQA
Creating Solutions – One System/One View

VIEW PROCESS DATA
Batch Search
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Creating Solutions – Data Retrieval, Review, Export

**Data Selection And Retrieval**

- Material ID
- ELIMS Parameters
- Linked Process Parameter
- Search Start and End Time
- Batch Search
- Batch List Populated
Creating Solutions – Linking out to Detailed Analysis

- Batch Data Analysis
  - Batch Search
  - Multiple Levels
  - Multiple Steps
  - Cycle Times
  - Export Facility

- Processing Data
  - Tag Search
  - Link to Batch Gantt
  - Multiple Batch Data
  - Overlay Analysis
  - Export Facility
Agenda

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Supporting Elements

• Benefits and Next Steps
Supporting Elements - Foreword

- PI Interface Configuration Utility
- PI AF
- PI ACE
- Microsoft SQL Server 2008
- LivePoint from Mirabo Systems
Supporting Elements – PI Asset Framework

• Element Created for Process - S88 Model

• Sub element for each CQA

• Attributes represent linked process phases/ steps (S88 Procedural Model)

• Child elements represent CPPs: PI tags – temperature, pressure, etc
Supporting Elements – PI Advanced Computing Engine

- ACE Module executed
- PI AF Configuration inputs to ACE
- Code Retrieves Process Data-Batch events and tag values
- Retrieved Process Data written to SQL Database in structured format
Supporting Elements – SQL Server

SQL Server 2003

- Interaction with source DB too slow
- Intermediate Data Cache created

Structured
- Product Data from ELIMS Interface/DB
- Process Data from PI ACE
Agenda

• Introduction

• Why MES in API

• Solution Architecture

• Supporting Elements

Benefits and Next Steps
Benefits and Next Steps - Building Solid Foundations

- **CPV Capability to Broad End User Spectrum.**
  - “Validation is an ongoing continuum of process design, process qualification and Continued Process Verification”

- **Linking Product Data and Process Data**
  - “Recognition that more knowledge will be gained during commercial production than is present at the time of initial process qualification”

- **Scalability**
  - S88 unified structure implemented. The system is structured so that we can add ALL materials. No limit to linked processing parameter elements in AF.

- **Enhancing PI System**
  - “with the additional data, traditionally not available on the PI System, other useful data can be made available to the everyday user”
Benefits and **Next Steps**

- **Complete roll out to Business Units**
  - Current focus on certain products. Expand the material list.

- **RtReports for Annual Product Review**
  - Product Data on PI. Visualization complete but what about reporting?

- **Continue to Expand the PI System**
  - EA, AF and ACE. A good foundation for *Event Frames* deployment.

- **Bridge the Gaps**
  - Connect with Process Development following Data Analysis Incentives like modelling, predictive tools.
  - Cross discipline knowledge sharing/ link with other groups.
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