Implementation of a OSIsoft PI System in support of advanced pharmaceutical manufacture

Presented By:
Breakthroughs that change patients’ lives
Bold Moves & Big Ideas

**Deliver first-in-class science**
- Double our innovation success rate
- Bring medicines to the world faster

**Win the digital race on pharma**
- Digitize drug discovery and development
- Make our work faster and easier
Pharmaceutical Sciences
Small Molecule

- Groton, Connecticut
- Drug Product Supply
- Process Development, Clinical Manufacturing
- Home of PCMM
  - 1\textsuperscript{st} Continuous OSD Technology at Pfizer
  - Highly automated
  - ~2000 Tags
  - Local process historian
Data Utilization Challenges

- Local access only
- Raw .csv values
- Manual Excel or Spotfire analysis
- Manual duplication and sharing with stakeholders
- Retrospective only
Objectives

1. Aggregate and Contextualize BMS & Process Data
2. Create Collaborative Enterprise Environment
3. Implement visualizations and analytics to empower decision makers
Emerson Impact Partner

- 30 years providing Life Science solutions
- 150+ employees in 4 locations in MA, CT, ME, NH
- Automation, MES, Data Services, and Instrumentation
- Locations supported locally & globally
Details of Solution

• Utilize the OSIsoft PI Enterprise Agreement – Robust Dev/Test/Prod Environment

• Collect BMS and Process Data from Manufacturing System Environment

• Create Contextualized Asset Framework Data Models

• Published Data Models to Amazon Web Services for visualization in Spotfire
Asset Framework Approach – Data Models

- **Interview End Users and Create Asset Framework Data Models** which provide immediate access to context previously gathered through manual effort.

- Utilize both a Process and Equipment Level Asset Framework Hierarchy
  - **Process Level Hierarchy** for Tablet Generation Process
  - **Equipment Level** for Building Management Data
Data Model Elements

- Facility and Environmental Monitoring
- Anteroom
- Disassembly Room
- Material A/L
- Material Handling
- Multipurpose Room
- PAL 02
- PAL 03
- Production
- Tech Space 01
- Tech Space 02
- Tech Space 03
- Tech Space 05
- Wash Room

Tech Space 3
- PI-97 Diff Press: 0.4530 inH2O
- PI-15 Diff Press: 0.4530 inH2O

Tech Space 2
- TS-3 Temp: 67.71°F
- Material Handling
  - MH Space Humidity: 56.9073% RH
  - MH Diff Pressure: 0.09136 inH2O
  - MH Abs Pressure: 0.05805 inH2O

Tech Space 1
- PI-08 Diff Press: 0.36766 inH2O
- Clean Room Space Humidity: 45.8708% RH
- PAL2 Corridor DP: 0.02951 inH2O
- PAL2 Pressure: 0.04216 inH2O
- PAL3 Pressure: 0.03292 inH2O
- D/A Room
  - PI-11 Diff Press: 0.01885 inH2O

Anteroom
- Corridor Abs Pressure: 0.0301 inH2O
- PAL2 Corridor DP: 0.0300 inH2O
- PAL3 Corridor DP: 0.05372 inH2O

Wash Room
- PI-21 Abs Pressure: 0.03518 inH2O
- WD1 Pressure: -0.01805 inH2O

Multipurpose
- PAL4 Pressure: 0.03518 inH2O
Asset Framework Approach – AF Analytics

- Event Frame Creation Triggers
- Yield Calculation Analytic
- Batch Pause Filter
- Carriage Return Removal
PI Integrator for Business Analytics

- **Published Contextualized Data Models** to Amazon Web Services via the **PI Integrator for Business Analytics** for consumption in Redshift and visualization in Spotfire

- Asset & Event Views by Process Type
  - Wet Granulation Asset + Event View
  - Direct Compression Asset + Event Views
  - Contextualized summary data for each associated Event Frame (Etc. Lot/Batch).
PI Integrator for Business Analytics

• **Data Flow**
  • Four views are generated and published to flat text files.
  • SDC Agent migrates files each evening for Redshift consumption in AWS.
  • End users can visualize process data contextualized for batch/lot in Spotfire.
  • Asset Views have interpolated data every 1 second.
  • Event Views have event frame summary data for batches that have closed since last publishing.
Pfizer PI System Use Case 1
Groton Site BMS Management
## Site PI System Advantages

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Site OSI PI Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data Accessibility</strong></td>
<td>Provides a single process to access data. “Self-serve” data mining made practical.</td>
</tr>
<tr>
<td><strong>Root Cause Analysis</strong></td>
<td>Data consolidated and modeled in system when collected. Cause and effect easier to discern.</td>
</tr>
<tr>
<td><strong>User Access</strong></td>
<td>Access simplified by putting the consolidated data on the enterprise network. Risks reduced.</td>
</tr>
</tbody>
</table>
Pfizer Groton PI Architecture Rollout

Existing SDC
- PCMM Historian

Connection to SDC
- Non-regulated Historian

Site system
- OSI PI Connector

Future build-out
- 

Future

In Progress
Pfizer PI System Use Case 2
PCMM Process Support
PCMM Process Support

- Data model created highly contextualized data set
  - PIAF
- PI Vision enabled live view-only process monitoring separate from process control system
- Calculated event frame values to streamline analyses
- Automated batch summary analytics
  - Previously done on a tag by tag basis
- Remote process troubleshooting
Feeder Emptying  
Hopper Level ↓  
Screw Speed ↑

Refill Event  
Hopper Level ↑  
Screw Speed ↓

*Screw speed ramp rate and lag critical to maintaining consistent mass flow during refills*
Pfizer PI System Use Case 3

Scientific Data Cloud Connectivity
Liberating Process Data… to the cloud

• Utilizing BI and AWS to create enterprise wide accessible data lake
• Batch Summary Data
• Common high resolution data source
• Enables cross-line collaboration
• Acceleration of technology
• Automated dashboarding surfaces relevant outcomes to upper leadership.
# PCMM Analytics Dashboards

## General Information

<table>
<thead>
<tr>
<th>Tag</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot Number</td>
<td>20180320-13h40m</td>
</tr>
<tr>
<td>Product</td>
<td>Placebo Tablet</td>
</tr>
<tr>
<td>Recipe ID</td>
<td>GR-PCM-16705-IOQ-0122#004</td>
</tr>
<tr>
<td>Recipe Description</td>
<td>RTD Study</td>
</tr>
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<td>Recipe Name</td>
<td>GR-PCM-16705-IOQ-0122</td>
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<tr>
<td>Start Date and Time</td>
<td>3/20/2018 4:03:35 PM</td>
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<td>Process Type</td>
<td>Direct Compression</td>
</tr>
<tr>
<td>PAT Method</td>
<td>2.00000</td>
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## Summary Information

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<td>1.2</td>
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<tr>
<td>PAT 5 Batch Potency</td>
<td>96.1000</td>
</tr>
<tr>
<td>No. Good Tablets</td>
<td>59877.0000</td>
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<td>Rejected Tablets</td>
<td>397.0000</td>
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<tr>
<td>No. of Tablets Manual Mode</td>
<td>15150.0000</td>
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<tr>
<td>Yield(%)</td>
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PCMM Analytics Dashboards

1) Filter for batch

Time Series Query

Select Data

Predefined Template:
  Blending Data (Blend Co.)
  Blending Data (Wall Granule)
  Compression Data
  Drying and Milling Data
  Feeders Data (Oven Count)  
  Feeders Data (Wall Granule) 
  Unspecified
  Wet Granulation Data

Select Individual Tags

Tags:
  Feeder 05 Feed Factor 50
  Feeder 06 Feed Factor 50
  Feeder 08 Mass Flow PV
  Feeder 08 Mass Flow SPS
  Feeder 08 Netweight
  Feeder 08 Portal
  Feeder 08 Screen Spend
  Feeder 08 Volumetric Mode
  Feeder 07 %Comp:High Limit
  Feeder 07 %Comp:High Warning Limit
  Feeder 07 %Comp:Low Alarm Limit
  Feeder 07 %Comp:Low Warning Limit
  Feeder 07 Avg Feed Factor
  Feeder 07 Feed Factor 50

2) Select Tags

Manufacturing Site
  Groton, CT

PCMM Analytics Dashboards

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  Feeder 08 Volumetric Mode
  Feeder 07 %Comp:High Limit
  Feeder 07 %Comp:High Warning Limit
  Feeder 07 %Comp:Low Alarm Limit
  Feeder 07 %Comp:Low Warning Limit
  Feeder 07 Avg Feed Factor
  Feeder 07 Feed Factor 50

2) Select Tags

Manufacturing Site
  Groton, CT
Overall Business Impact

• No manual data collection or analysis
  • Spend time analyzing
  • Compliance Reporting – 50% faster

• Productivity Improvement
  • Automated process summary reporting
  • Remote access for troubleshooting
  • 5-10 SME hours per week reduction from routine data collection and analysis

• Quality Improvements – improved response to process upsets.
  • Batch-Batch variation – extensive assessment due to data availability
  • Root cause identification up to 30% faster
  • SDM often 90% faster alarm cause identification
  • Segregation from control systems
  • Data integrity
Pfizer

Implementation of a OSIsoft PI System in support of advanced pharmaceutical manufacture

**CHALLENGE**

- Isolated raw data sets, poor analytical tools, and the lack of a collaborative environment made data utilization inefficient and ineffective.
- Process understanding and troubleshooting
- Enable portfolio acceleration through advanced manufacturing
- Digital manufacturing initiative

**SOLUTION**

- Implementation of a 3 stage PI system architecture to effectively structure and liberate processing data for the PCMM continuous manufacturing line.
- Cross-functional team within Pfizer R&D & NECI
  - PI Business Integrator
  - PI Vision

**RESULTS**

- Processing and facility data is structured and readily available to stakeholders. Liberation and analysis of data enables stakeholders to make faster, more accurate decisions.
- BMS: 20% faster RCA & 50% reduction in reporting times
- PCMM: 90% faster alarm resolution
- Liberate data for collaborate drug development
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©2019 OSIsoft, LLC
1) Filter for batch

2) Select Tags

3) Export to Excel

Time Series Query

Select Data

Predefined Template:
- Blending Data (Silico Co.)
- Blending Data (Wet Gran)
- Composition Data
- Driving and Mixing Data
- Feeder Data (Wet Gran)
- Feed Concentrations
- Unspecified Wet Granulation Data

Select Individual Tags

Tags:
- Feeder 01 Feed Factor (% of Dev)
- Feeder 08 Feed Factor % (of Dev)
- Feeder 09 Feed Factor (% of Dev)
- Feeder 06 Mass Flow PV
- Feeder 05 Mass Flow SP
- Feeder 05 Netweight
- Feeder 06 Parcial
- Feeder 06 Screw Speed
- Feeder 06 Volumetric Mode
- Feeder 07 %Comp-Recip
- Feeder 07 %Comp-Recip High Alarm Limit
- Feeder 07 %Comp-Recip Low Alarm Limit
- Feeder 07 %Comp-Recip Low Warning Limit
- Feeder 07 Avg Feed Factor
- Feeder 07 Feed Factor %

Manufacturing Site:
Groton, CT
Pfizer

• David Eisenberg
• Manufacturing Engineer
• Pfizer
• David.Eisenberg@Pfizer.com

• David Rabon
• Team Lead, Automation Services
• Pfizer
• David.Rabon@Pfizer.com
NECI

• Chris Beaupre
  • Data Integration Manager
  • NECI
  • cbeaupre@neci.com

• Wyatt Ling
  • Data Integration Engineer
  • NECI
  • wling@neci.com