



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

Presented By:



Emerson Impact Partner



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

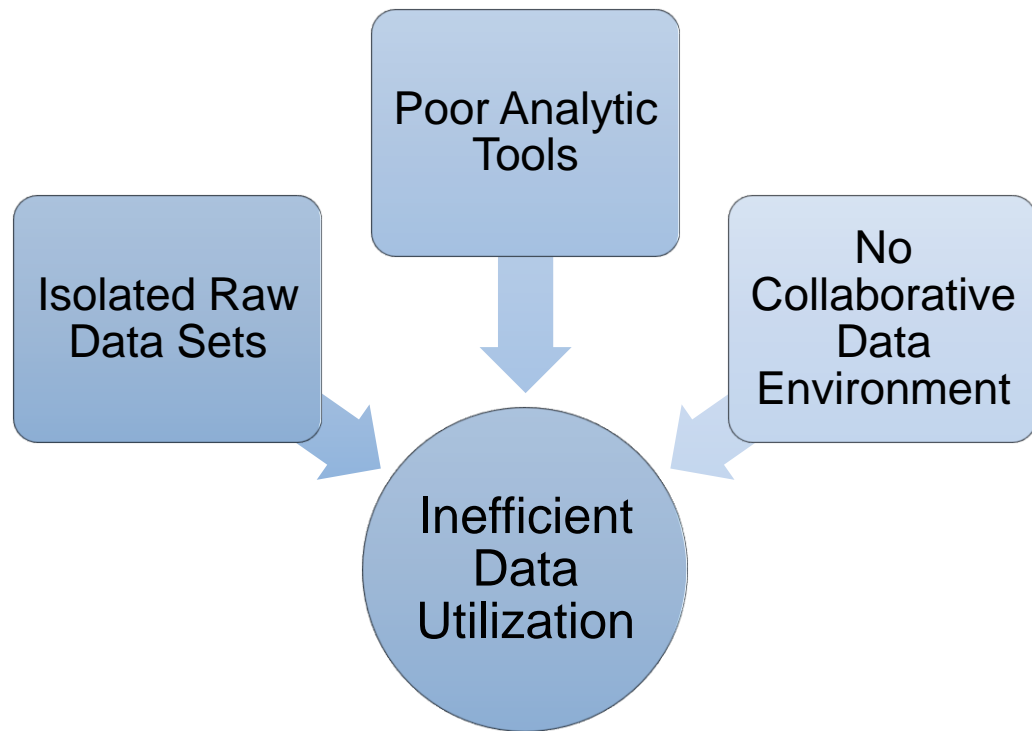
Pharmaceutical Sciences Small Molecule

- Groton, Connecticut
- Drug Product Supply
- Process Development, Clinical Manufacturing
- Home of PCMM
 - 1st 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



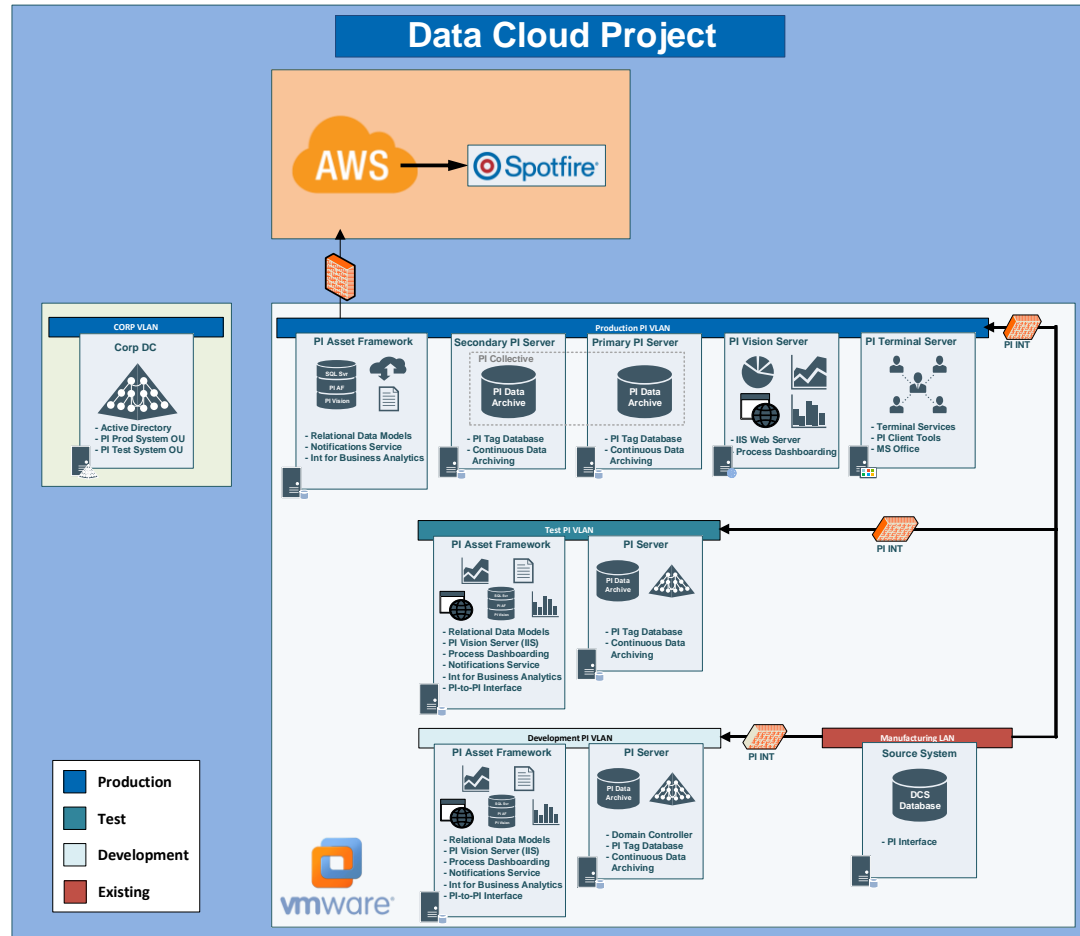


Emerson Impact Partner

- 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

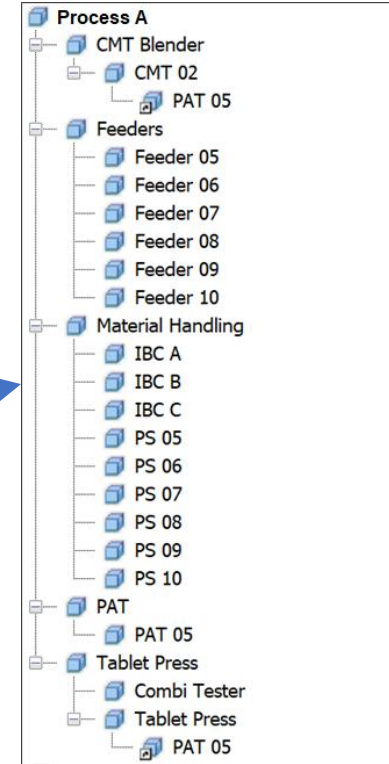
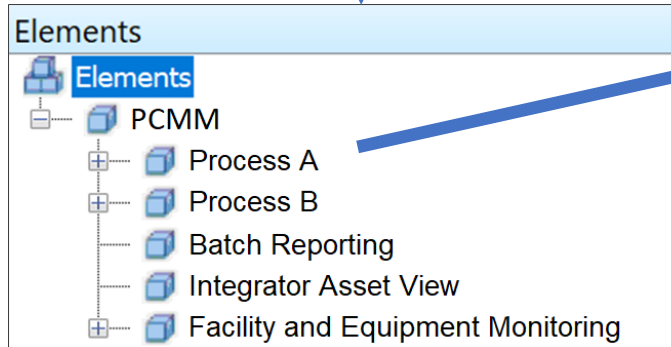
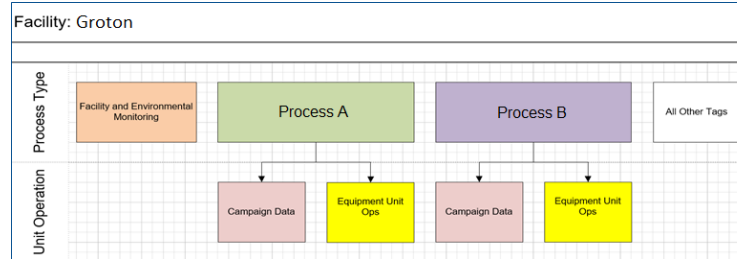
Details of Solution

- **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

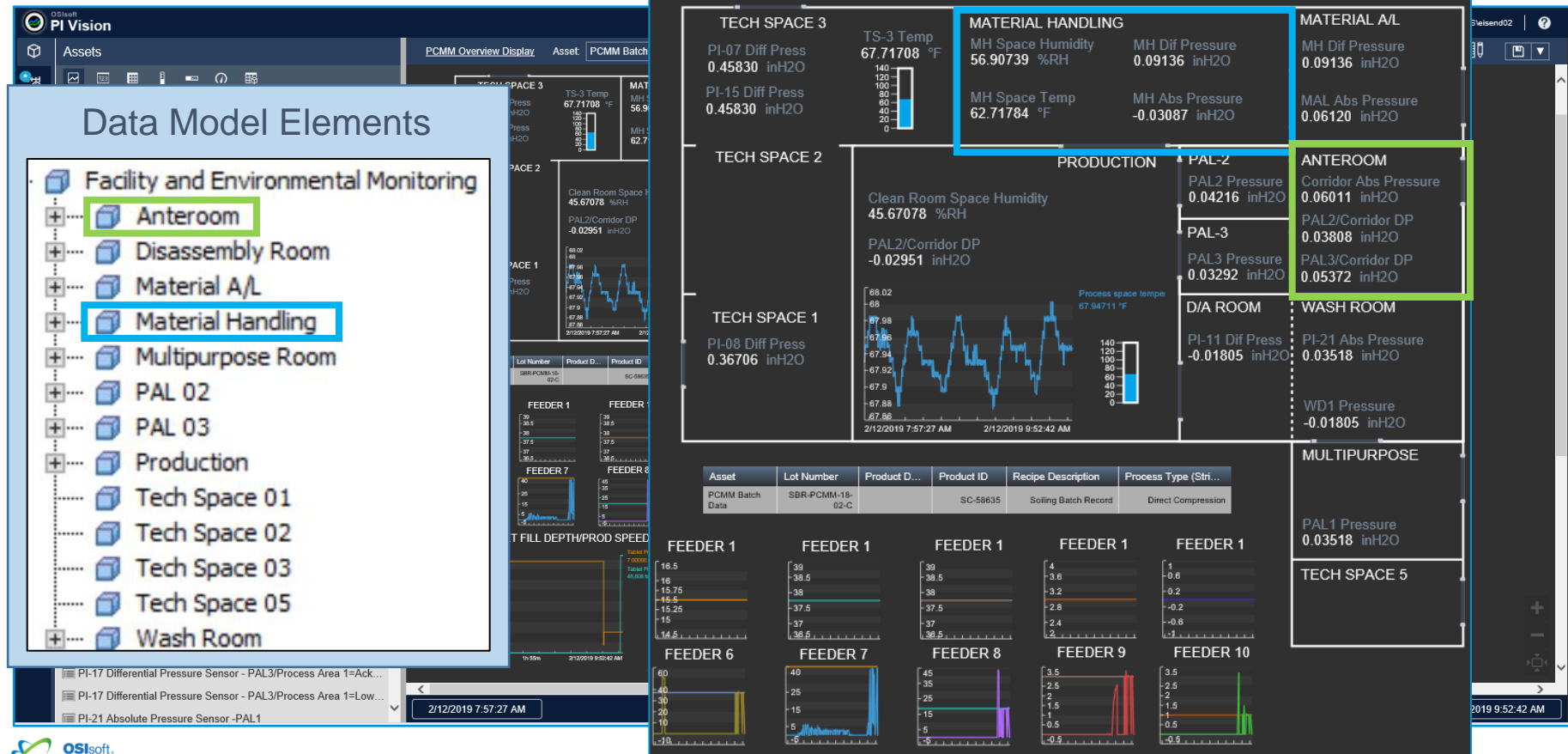


Asset Framework Approach – Data Models

- ***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

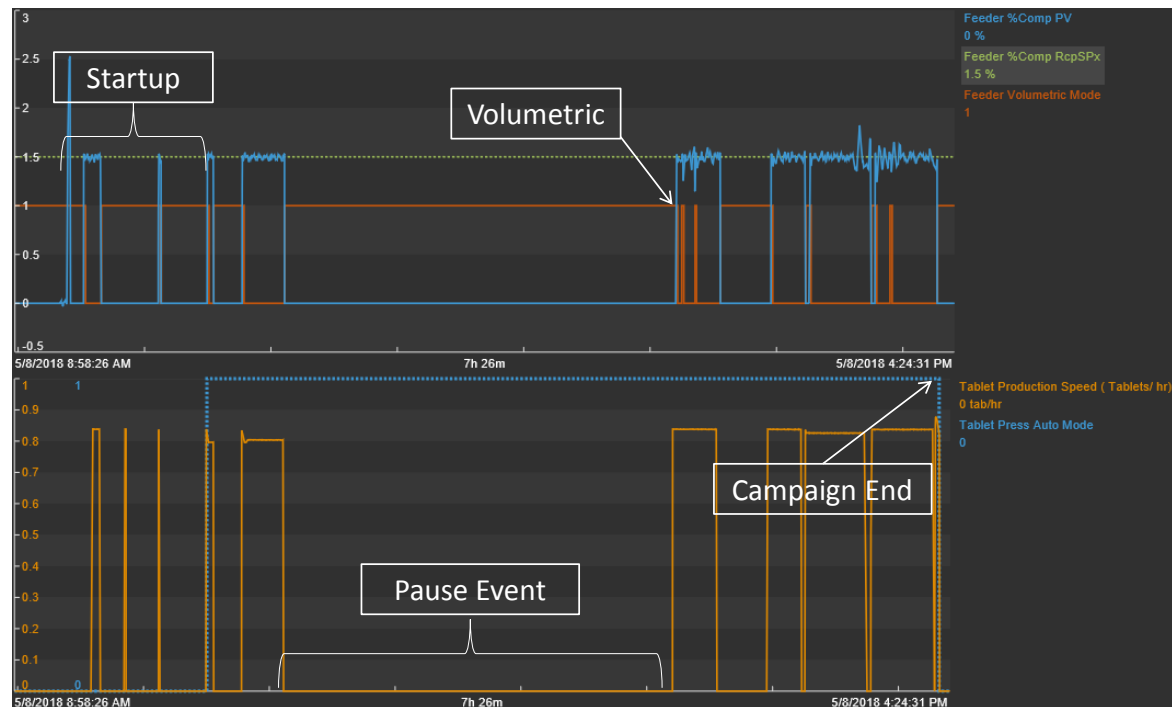


Asset Framework Approach - Visualization



Asset Framework Approach – AF Analytics

- Event Frame Creation Triggers
- Yield Calculation Analytic
- Batch Pause Filter
- Carriage Return Removal



PI Integrator for Business Analytics

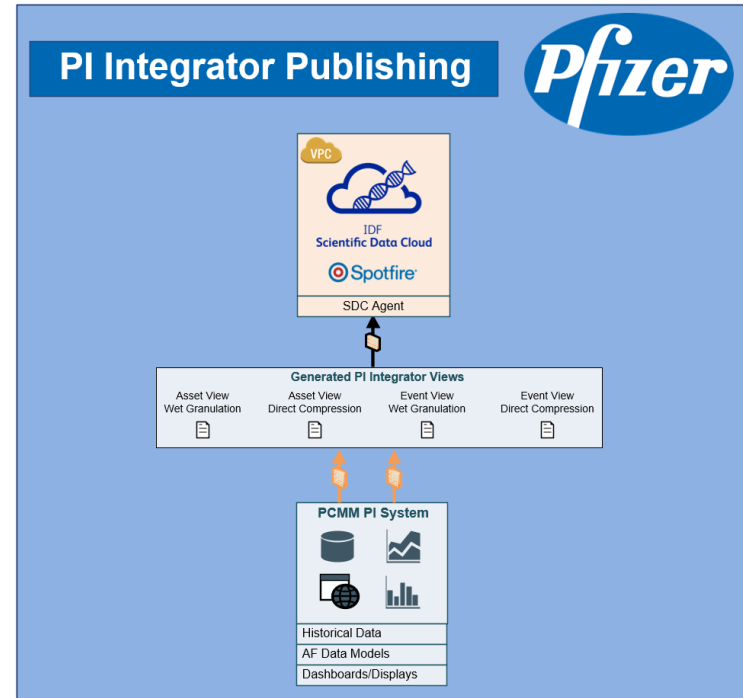
- **Published Contextualized Data Models** to Amazon Web Services via the **PI Integrator for Business Analytics** for consumption in Redshift and visualization in Spotfire
- **Asset & Event Views by Process Type**
 - Wet Granulation Asset + Event View
 - Direct Compression Asset + Event Views
 - Contextualized 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.



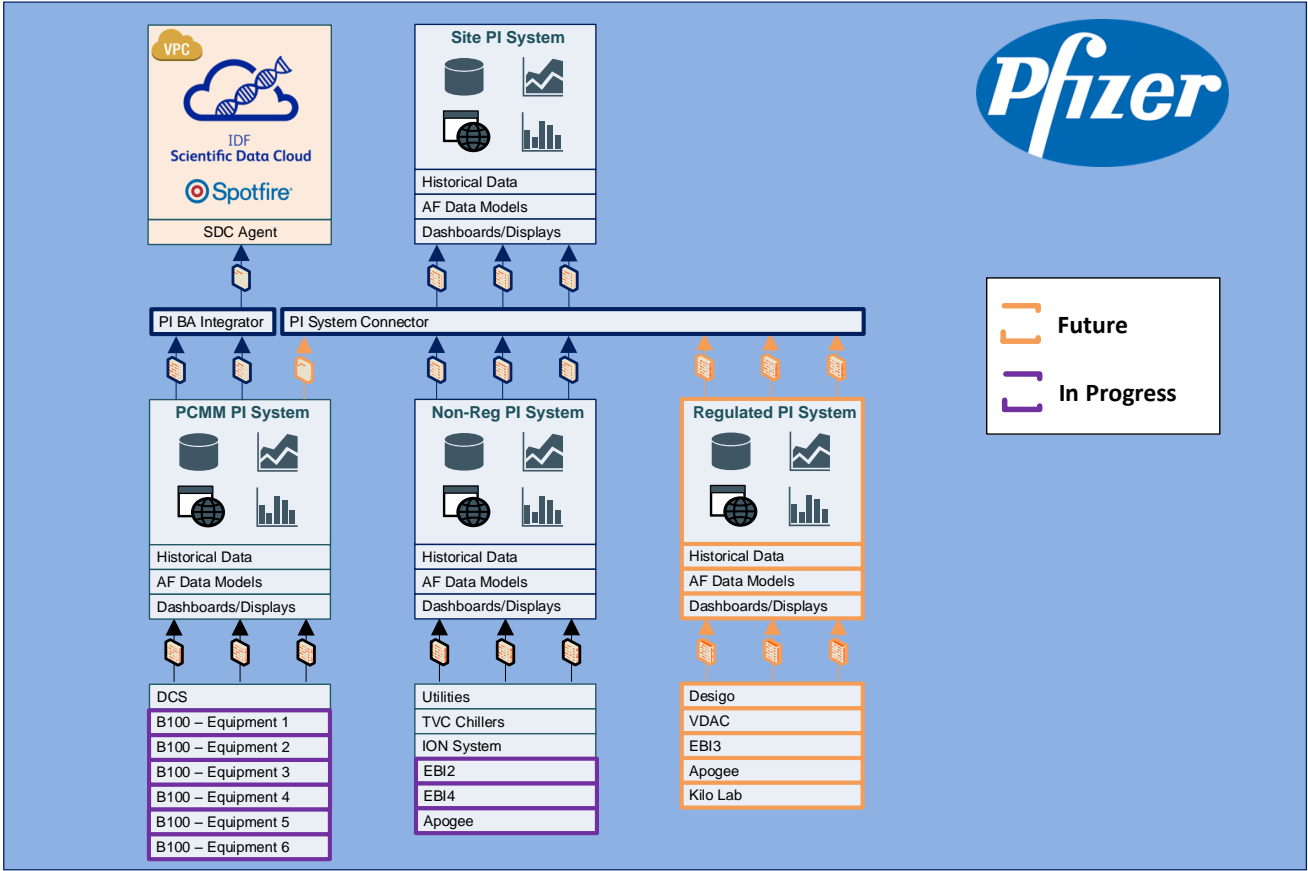
Pfizer PI System Use Case 1 Groton Site BMS Management

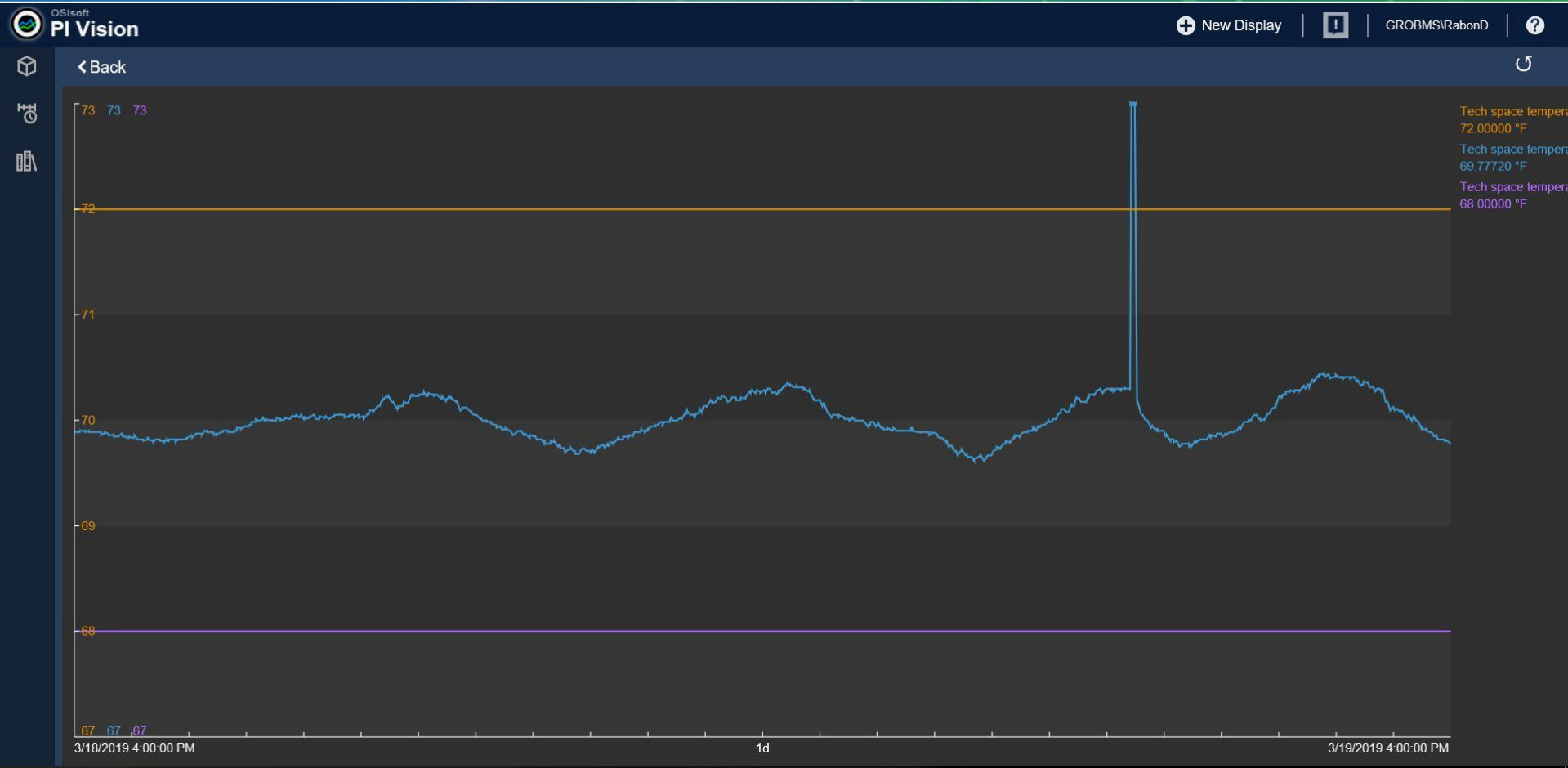
Site PI System Advantages

	Challenge	Site OSI PI Solution
Data Accessibility	Data has to be consolidated from multiple systems. Requires knowledge different systems. Experts required to obtain data	Provides a single process to access data. “Self-serve” data mining made practical.
Root Cause Analysis	Data requires third party software to consolidate and model data. Cause and effect difficult to determine	Data consolidated and modeled in system when collected. Cause and effect easier to discern.
User Access	Current systems are deployed on internal networks isolated by firewalls. Access require multiple passwords. Access creates security risks.	Access simplified by putting the consolidated data on the enterprise network. Risks reduced.

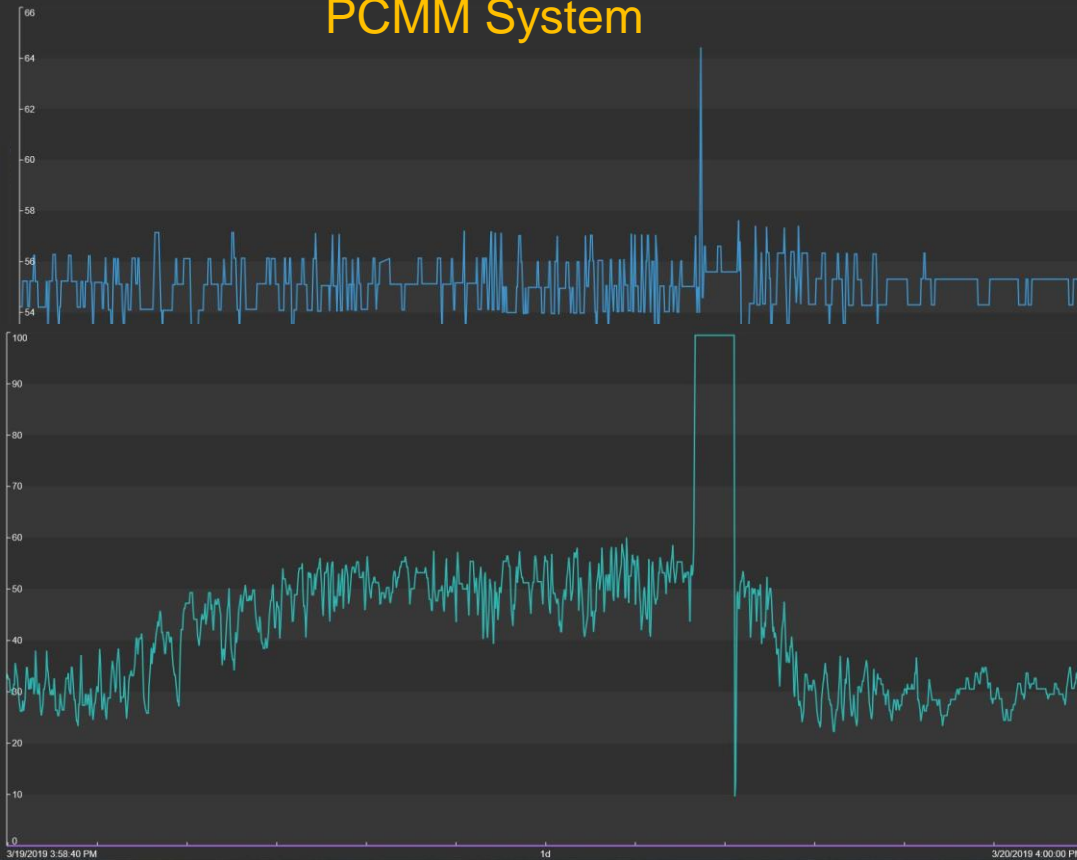
Pfizer Groton PI Architecture Rollout

- Existing SDC
- PCMM Historian
- Connection to SDC
- Non-regulated Historian
- Site system
- OSI PI Connector
- Future build-out





PCMM System



Preheat Temperature
55.31 °F
Preheat Temperature
No Data °F

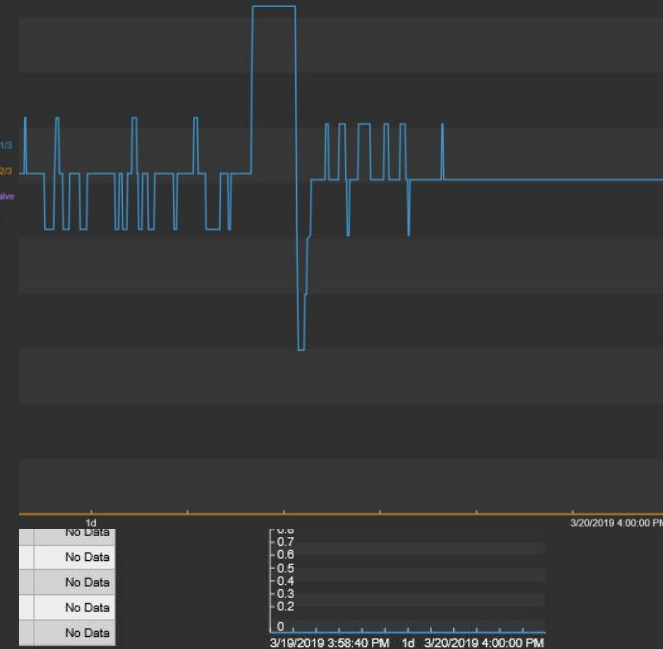
BAS System

Mode

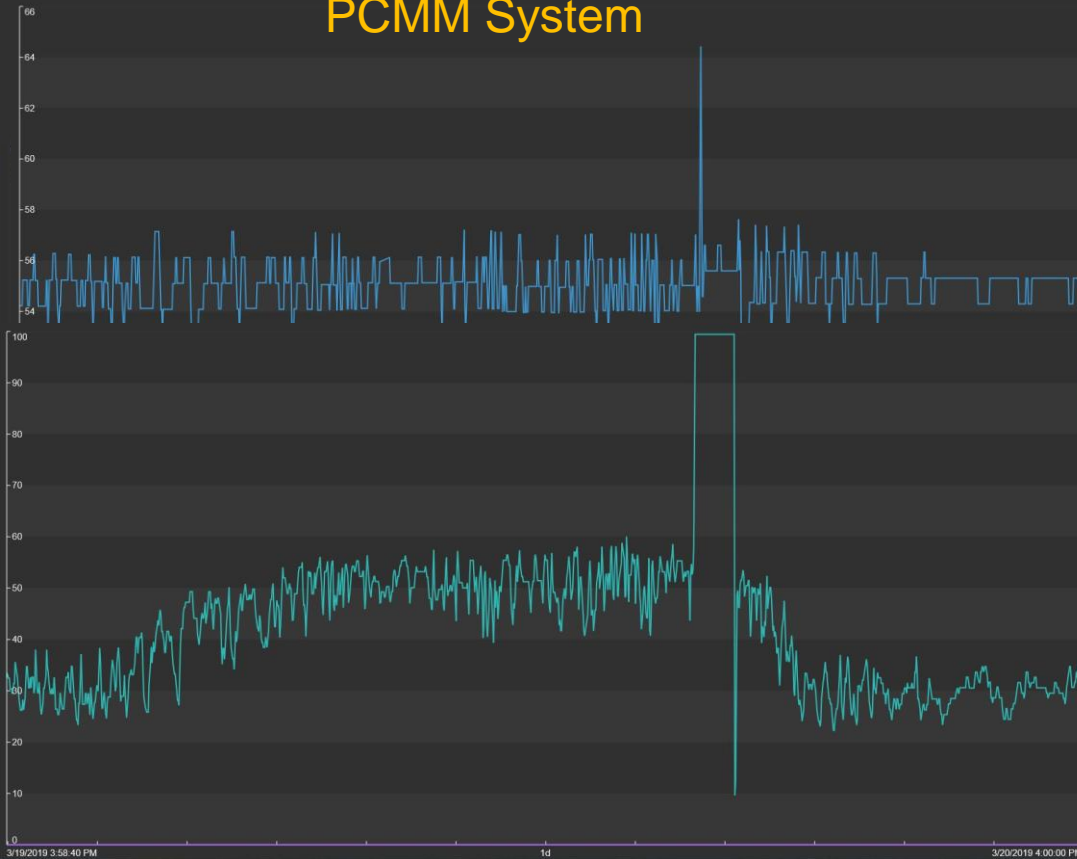


Heating Valve 1/3
N/A
Heating Valve 2/3
N/A
Cooling Coil Valve
0 %
Heating Valve
30.748 %

Discharge Air Temp
72.065 °F
Discharge Air Temp
66 °F



PCMM System



Preheat Temperatu
55.31 °F
Preheat Temperatu
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BAS System

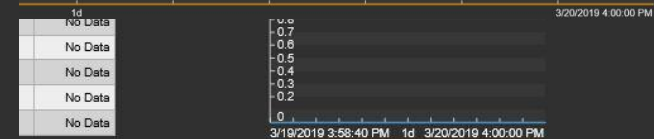
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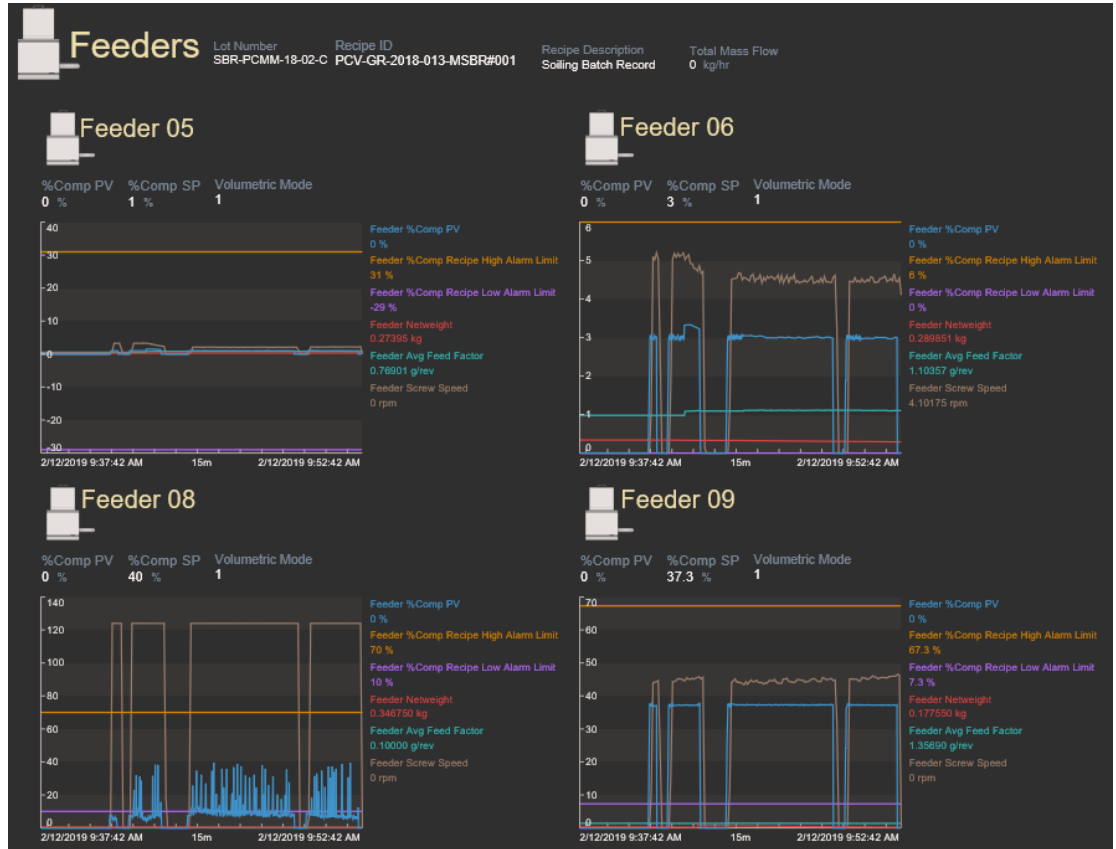


Pfizer PI System Use Case 2

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





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

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

Summary Information

Tag	Values
PAT Batch Standard Deviation	1.2
PAT 5 Batch Potency	96.10000
No. Good Tablets	59877.00000
Rejected Tablets	397.00000
No. of Tablets Manual Mode	15150.00000
Yield(%)	79.00000
No. of Critical Alarms	

Product Information

Tag	Values
Tablet Shape	
Tablet Diameter	
Tablet Length	

PAT Batch Standard Deviation	1.2
PAT 5 Batch Potency	96.10000
No. Good Tablets	59877.00000
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No. of Tablets Manual Mode	15150.00000
Yield(%)	79.00000
No. of Critical Alarms	

Filters

Reset Filters

Start Date and Time

12/15/2017 2:00:00 PM

Manufacturing

☒ Groton, CT

Product:

Type to search in

(All) 5 values

Process Type:

Type to search in

(All) 2 values

☒ Direct Compression

☐ Wet Granulation

DMID:

Type to search in list

GR-PCM-16705-IOQ-0122
QTS-2126785V1
QTS2233497-1
StartupandShutDownJune17

Lot Number:

Type to search in list

(All) 29 values
20180320-12h51m
20180320-13h40m
20180320-16h4m
20180411-11h0m

Ready

36 of 112 rows 0 marked 137 columns batch_summary_report

PCMM Analytics Dashboards

3) Export to Excel

Landing Batch Report DC Feeders Composition WG-DC Feeders Time Series Query Feeder Trends Tablet Press Trends CMT Trends Definitions

Edit

1) Filter for batch

Time Series Query

Filters

Reset Filters

Product

Type to search in list

(All) 1 values

Placebo Tablet

Process Type

Type to search in list

(All) 1 values

Direct Compression

DMID

Type to search in list

(All) 2 values

Start Date

Type to search in list

(All) 3 values

8/27/2018 8:09:27 PM

8/28/2018 7:35:27 PM

8/28/2018 7:43:27 PM

Lot Number

Type to search in list

(All) 2 values

NC-05918a

NC-05918B

Select Data

Predefined Template:

- Blending Data (Direct Com...
- Blending Data (Wet Gran...
- Compression Data
- Drying and Milling Data
- Feeder Data (Direct Com...
- Feeder Data (Wet Granul...
- Unspecified
- Wet Granulation Data

Select Individual Tags

Tags:

- Feeder 06 Feed Factor #8 St.Dev
- Feeder 06 Feed Factor #9
- Feeder 06 Feed Factor #9 St.Dev
- Feeder 06 Mass Flow PV
- Feeder 06 MassFlow SPx
- Feeder 06 Netweight
- Feeder 06 PertVal
- Feeder 06 Screw Speed
- Feeder 06 Volumetric Mode
- Feeder 07 %Comp PV
- Feeder 07 %Comp RcpSPx
- Feeder 07 %Comp Recipe High Alarm Limit
- Feeder 07 %Comp Recipe High Warning Limit
- Feeder 07 %Comp Recipe Low Alarm Limit
- Feeder 07 %Comp Recipe Low Warning Limit
- Feeder 07 Avg Feed Factor
- Feeder 07 Feed Factor #1

Manufacturing Site

☒ Groton, CT

2) Select Tags

Details

Lot Number	Date Time	feeder 06 feed factor #1	feeder 06 feed factor #7	feeder 06 mass flow pv	feeder 06 feed factor #5 st.dev	feeder 06 feed factor #10	feeder 06 feed factor #5	feeder 06 feed factor #8	feeder 06 feed factor #9 st.dev	feeder 06 feed factor #9 st.dev	feeder 07 % comp recipe high alarm limit	feeder 06 pertval	feeder 06 scr... speed	feeder 06 netweight	feeder 06 massflow spx	feeder 07 % comp recipe high warning limit	feeder 06 volumetric mode	feeder comp
NC-05918B	8/27/2018 10:06:22 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:23 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:24 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:25 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
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	8/27/2018 10:06:36 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
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	8/27/2018 10:06:38 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
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Ready

External data HistorianData

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.

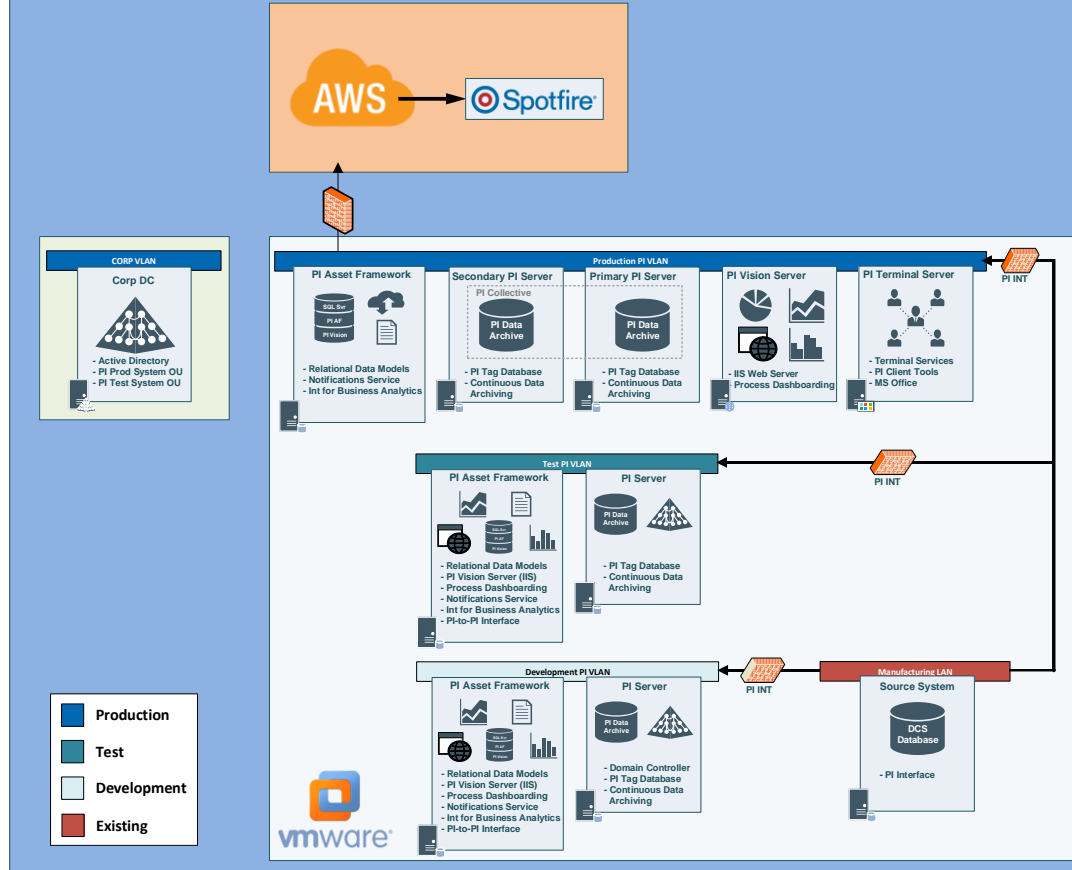
- Cross-functional team within Pfizer R&D & NECI
- PI Business Integrator
- PI Vision

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

Data Cloud Project



Existing SDC

PCMM Historian

Connection to SDC

Non-regulated
Historian

Site system

OSI PI Connector

Future build-out



PCMM Analytics Dashboards

Filters

Reset Filters

Start Date and Time

12/15/2017 2:00 PM

Manufacturing

☒ Groton, CT

Product:

Type to search in

(All) 5 values

Process Type:

Type to search in

(All) 2 values

☒ Direct Compression

☐ Wet Granulation

DMID:

Type to search in list

GR-PCM-16705-IOQ-0122

QTS-2126785V1

QTS223497-1

StartupandShutDownJune17

Lot Number:

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(All) 29 values

20180320-12h51m

20180320-13h40m

20180320-16h4m

20180411-11h0m

General Information

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

Summary Information

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No. of Critical Alarms	

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Tag	Values
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Tablet Length	

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Landing Batch Report DC Feeders Composition WG-DC Feeders Time Series Query Feeder Trends Tablet Press Trends CMT Trends Definitions

Edit       

1) Filter for batch

Time Series Query

Filters

Reset Filters

Product

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(All) 1 values

Placebo Tablet

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Lot Number

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NC-05918

(All) 2 values

nc-05918a

NC-05918B

Select Data

Predefined Template:

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- Feeder 07 Feed Factor #1

Manufacturing Site

☒ Groton, CT

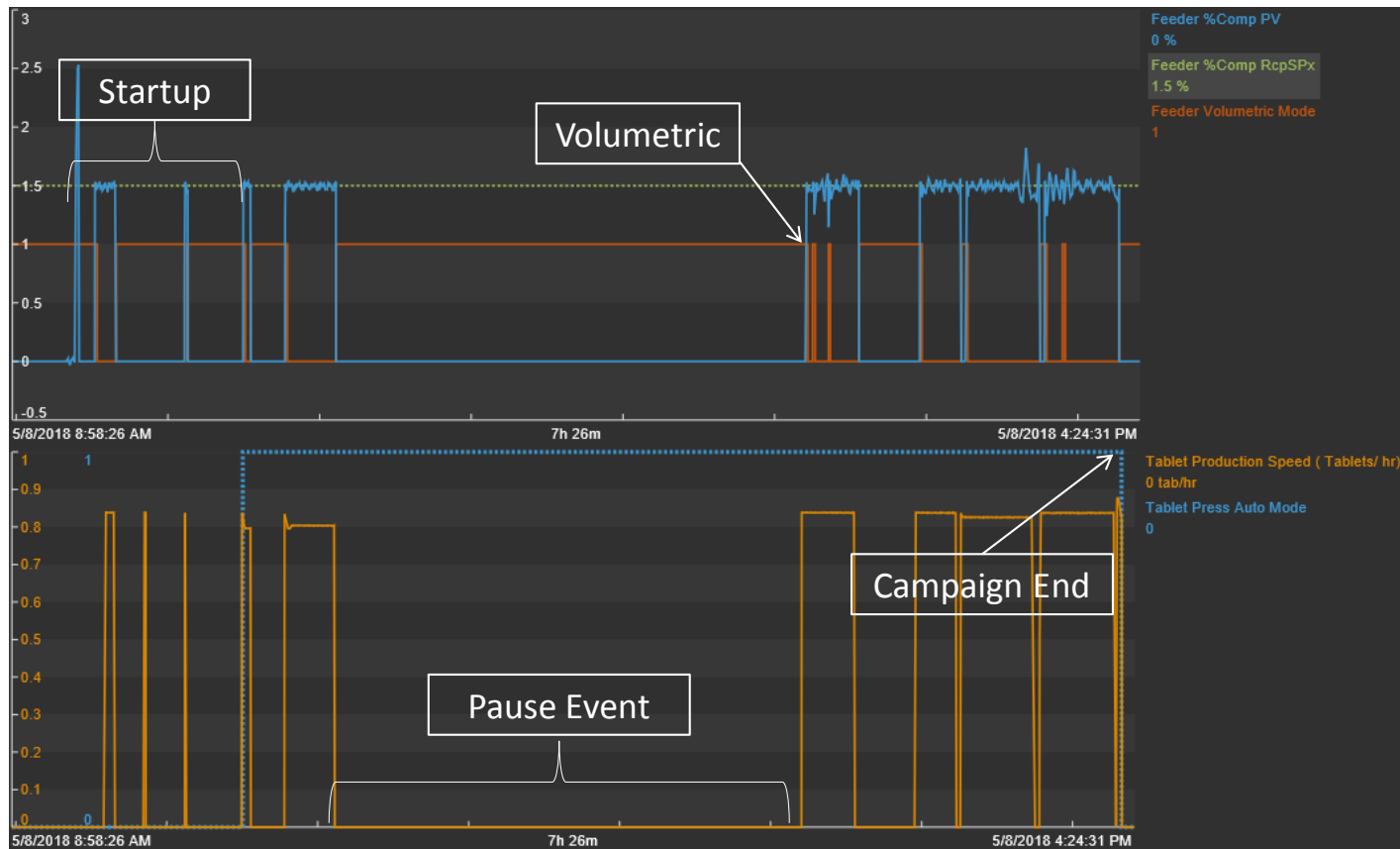
2) Select Tags

Details

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	8/27/2018 10:06:34 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:35 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:36 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:37 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:38 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	
	8/27/2018 10:06:39 AM	1.43	1.54	0.00	1.00	1.56	1.51	1.54	1.00	1.00	51.84	0.00	0.00	0.55	4.91	23.84	1.00	

Ready

External data HistorianData





Feeders

Lot Number: SBR-PCMM-18-02-C
Recipe ID: PCV-GR-2018-013-MSBR#001

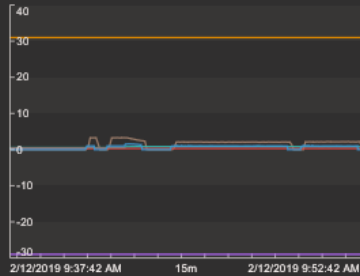
Recipe Description:
Soiling Batch Record

Total Mass Flow:
0 kg/hr



Feeder 05

%Comp PV: 0 %
%Comp SP: 1 %
Volumetric Mode: 1

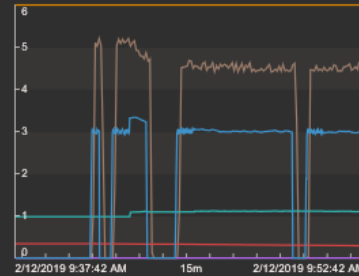


Feeder %Comp PV: 0 %
 Feeder %Comp Recipe High Alarm Limit: 31 %
 Feeder %Comp Recipe Low Alarm Limit: -29 %
 Feeder Netweight: 0.27395 kg
 Feeder Avg Feed Factor: 0.76901 g/rev
 Feeder Screw Speed: 0 rpm



Feeder 06

%Comp PV: 0 %
%Comp SP: 3 %
Volumetric Mode: 1

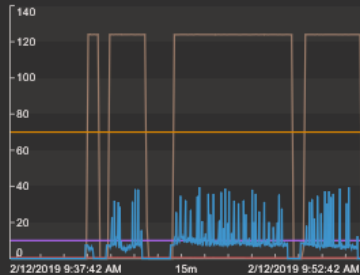


Feeder %Comp PV: 0 %
 Feeder %Comp Recipe High Alarm Limit: 6 %
 Feeder %Comp Recipe Low Alarm Limit: 0 %
 Feeder Netweight: 0.289851 kg
 Feeder Avg Feed Factor: 1.10357 g/rev
 Feeder Screw Speed: 4.10175 rpm



Feeder 08

%Comp PV: 0 %
%Comp SP: 40 %
Volumetric Mode: 1

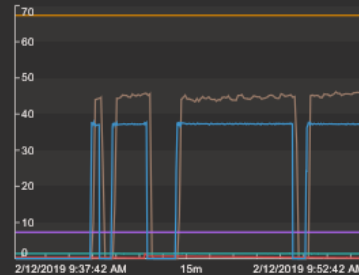


Feeder %Comp PV: 0 %
 Feeder %Comp Recipe High Alarm Limit: 70 %
 Feeder %Comp Recipe Low Alarm Limit: 10 %
 Feeder Netweight: 0.346750 kg
 Feeder Avg Feed Factor: 0.10000 g/rev
 Feeder Screw Speed: 0 rpm



Feeder 09

%Comp PV: 0 %
%Comp SP: 37.3 %
Volumetric Mode: 1



Feeder %Comp PV: 0 %
 Feeder %Comp Recipe High Alarm Limit: 67.3 %
 Feeder %Comp Recipe Low Alarm Limit: 7.3 %
 Feeder Netweight: 0.177550 kg
 Feeder Avg Feed Factor: 1.35690 g/rev
 Feeder Screw Speed: 0 rpm

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