

“It’s the DATA, Stupid!”



How PI Asset Analytics Rescued Our Real-time Multivariate Process Monitoring

Presented by: Matthew Morrow and Bing Zhang



Bristol-Myers Squibb Company

Agenda

- **Company Overview**
- Business Problem
- Multivariate Modeling Overview
- SIMCA-online/PI System Integration Challenges
- Business Benefits
- Future Capabilities

Our Mission



To **discover, develop** and **deliver**
innovative **medicines** that help patients
prevail over serious diseases.

WHO ARE *you* WORKING FOR?

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How does real-time multivariate process monitoring benefit the business?

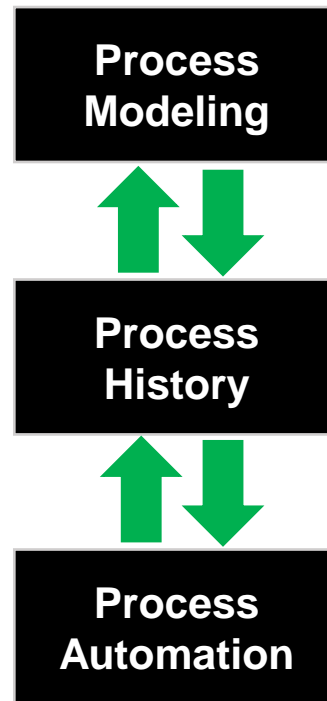
• Business Benefits:

- Optimize process performance
- Proactively monitor multivariate process against historical performance
- Empower operators with real-time fault detection
- Reduce risk of batch loss



How does real-time multivariate process monitoring benefit the business?

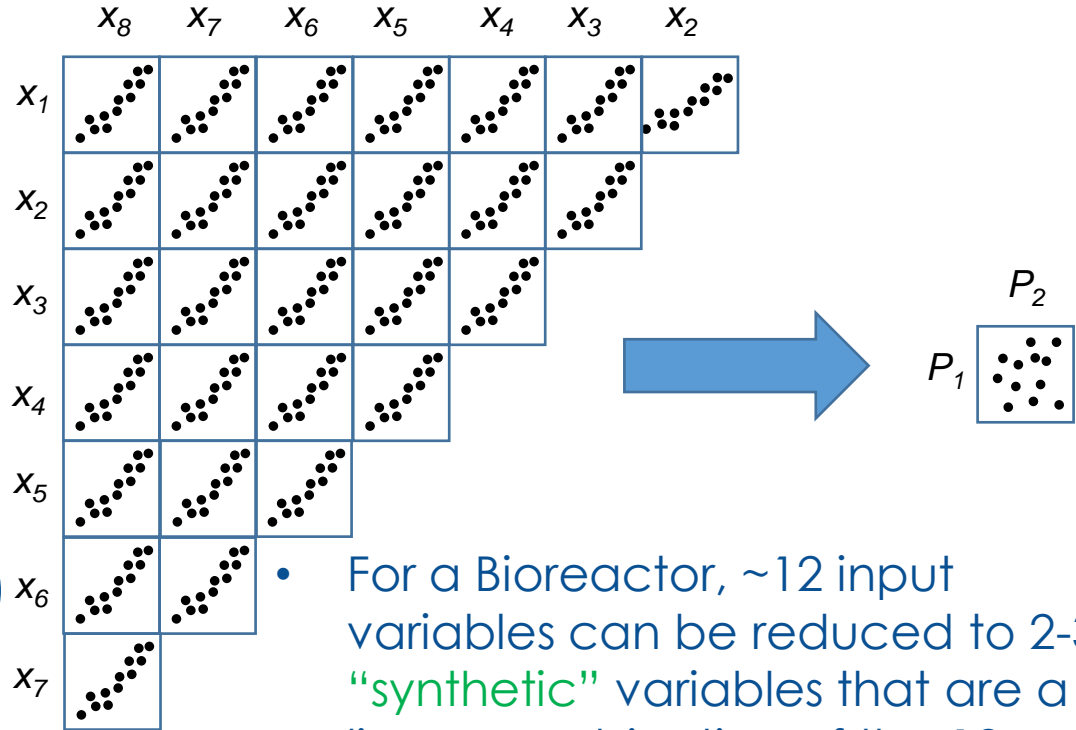
- **Opportunity:** Leverage data infrastructure and data availability in data sources to enable new capability
- **Problem:** Data latency and lack of data context **did not enable** real-time multivariate monitoring of manufacturing process



Multivariate Process Analysis Background

- **What is it?**

- Transform a large number of highly correlated process variables into a small number of uncorrelated “synthetic” variables (principal components) that still fully describe the process



- For a Bioreactor, ~12 input variables can be reduced to 2-3 “synthetic” variables that are a linear combination of the 12 process variables

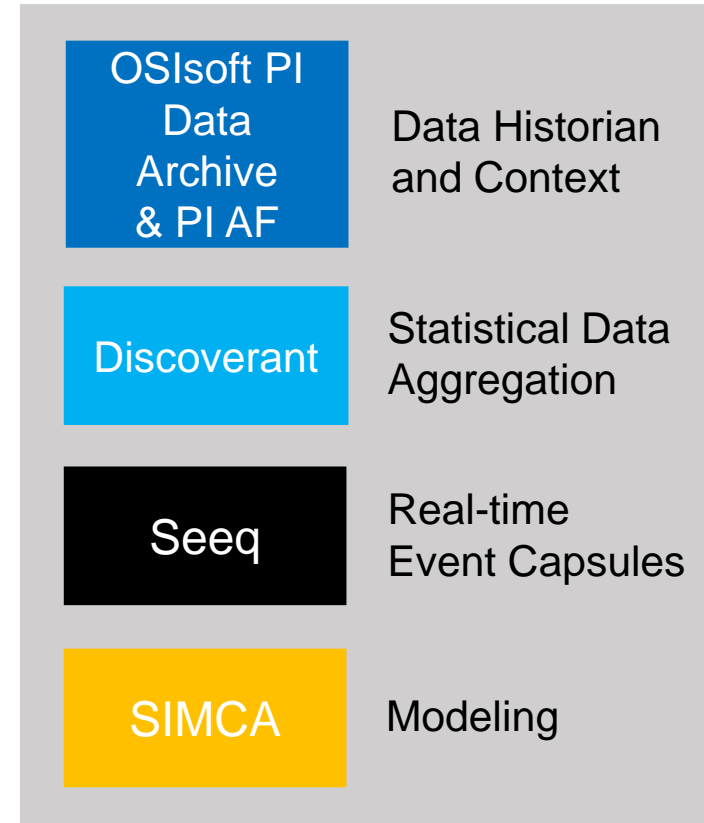
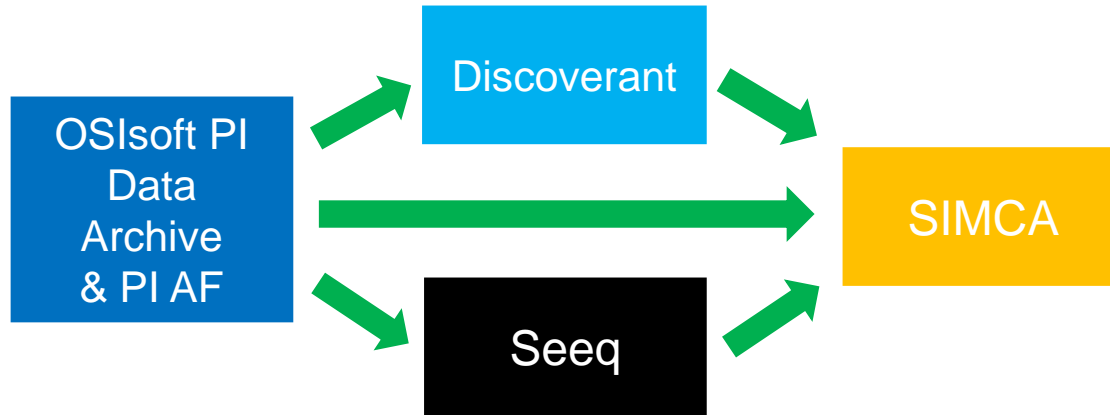
Multivariate Process Analysis Background

- **Why is it useful?**

- Can monitor a process using 1 or 2 “synthetic” variables instead of a dozen or more process variables
 - vs...** operator overload with individual trends/alarm banners/graphics
- Past experience can be used to define a multivariate batch tunnel with high and low limits that specify normal process operation

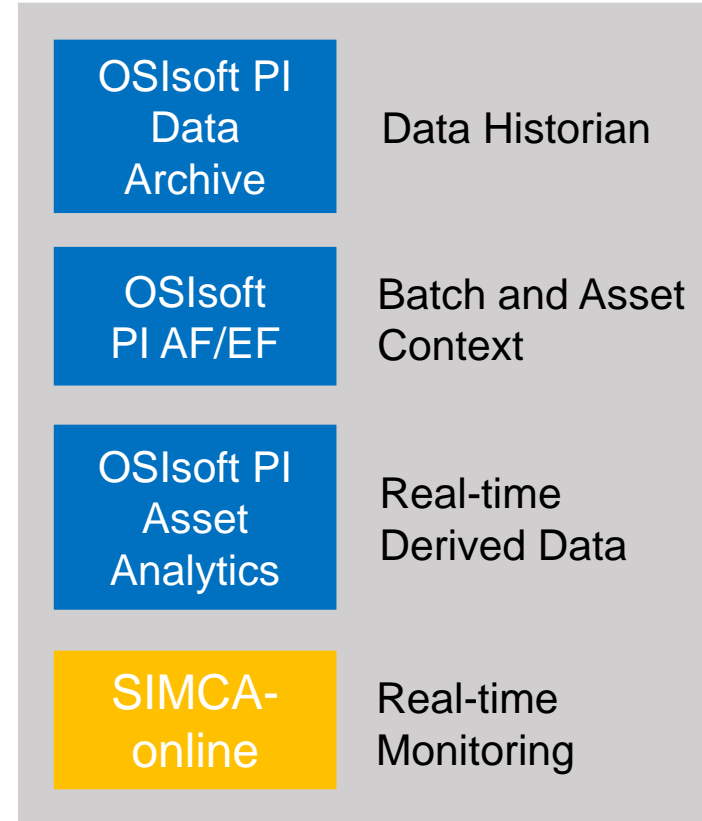
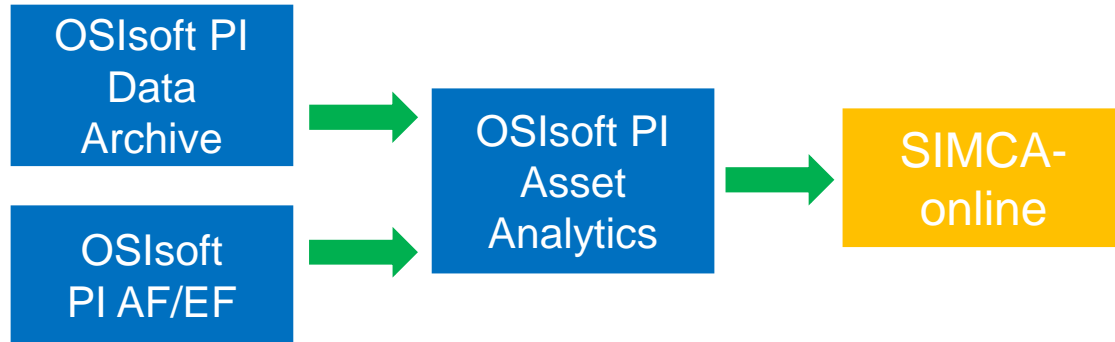
Domain Knowledge

(1) Process Modeling



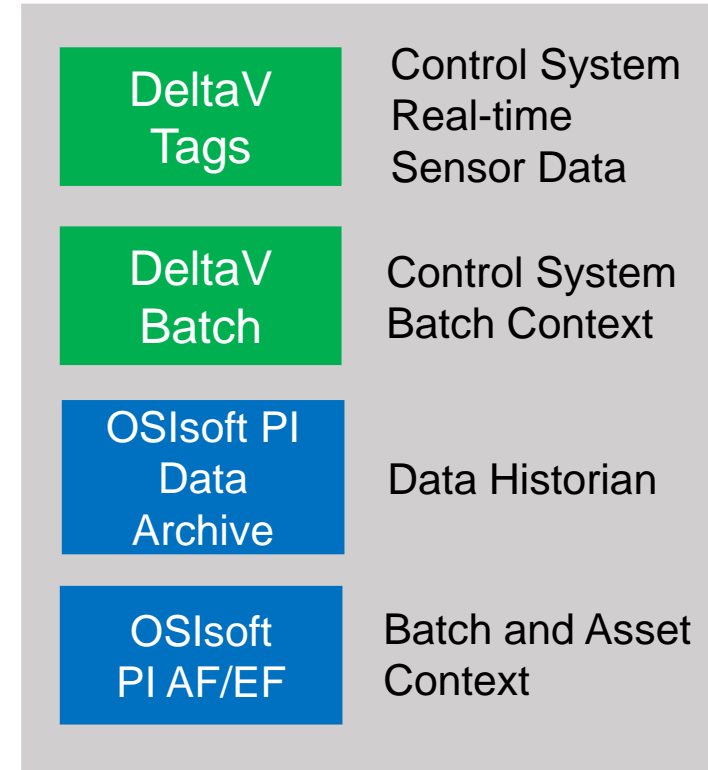
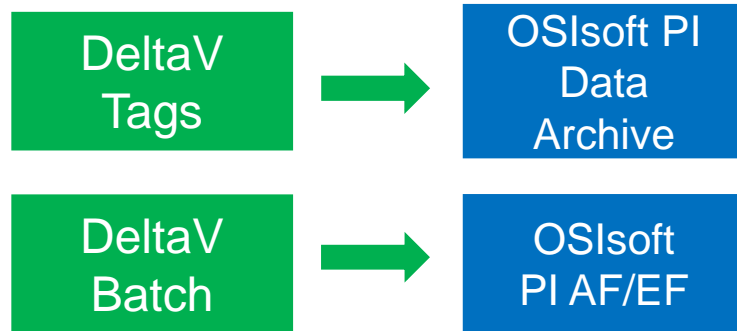
Domain Knowledge

(2) Process History



Domain Knowledge

(3) Process Automation



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How are multivariate models developed and deployed?

SeeQ[®]
/SIMCA_exporter



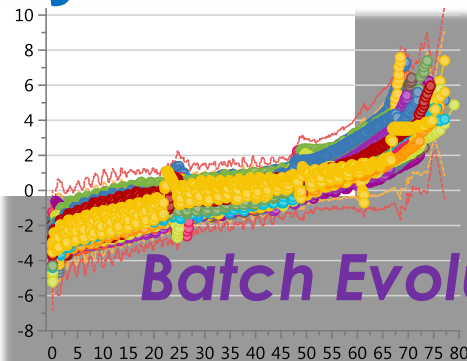
SIMCA[®]
BY MKS UMETRICS



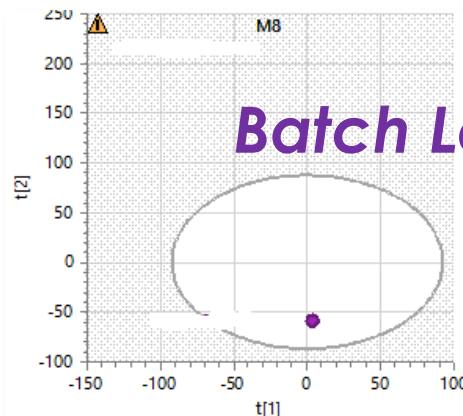
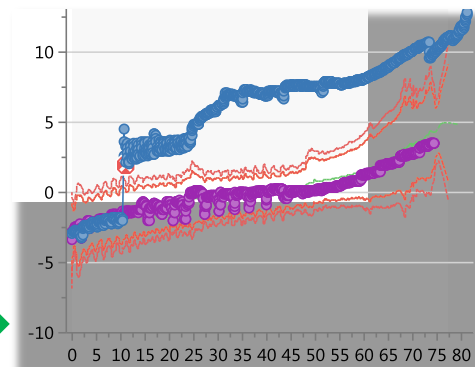
CHALLENGE: Configuring Offline Models to Real-time Monitoring



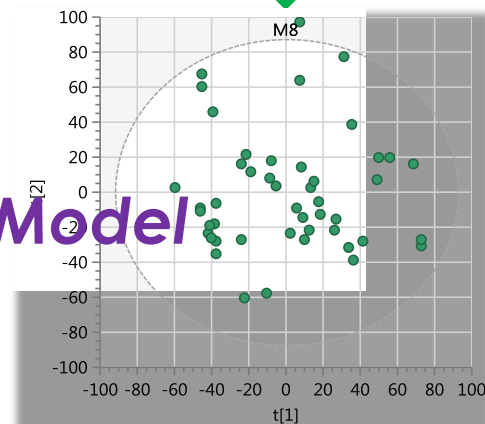
SIMCA[®]-online



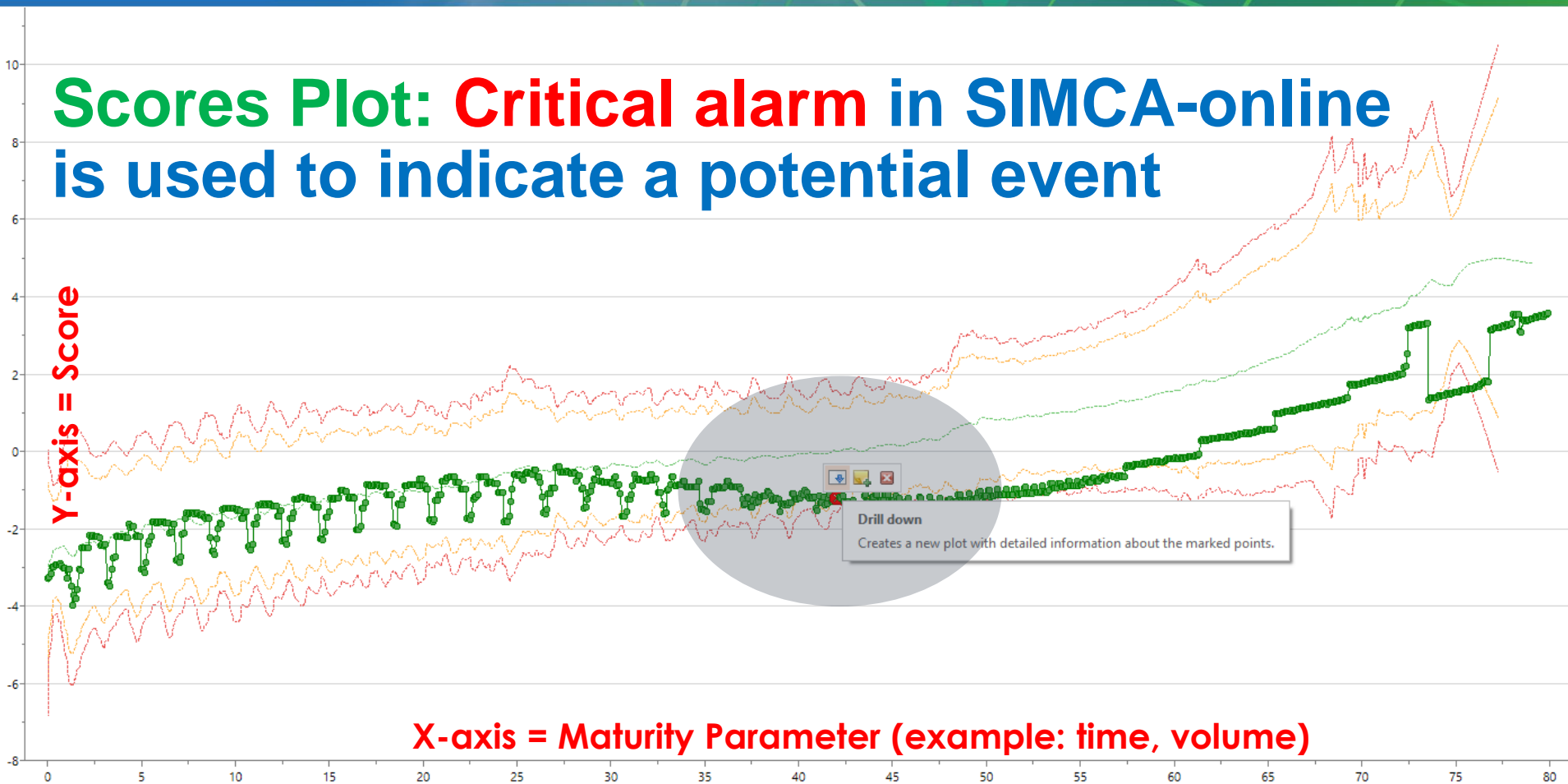
Batch Evolution Model



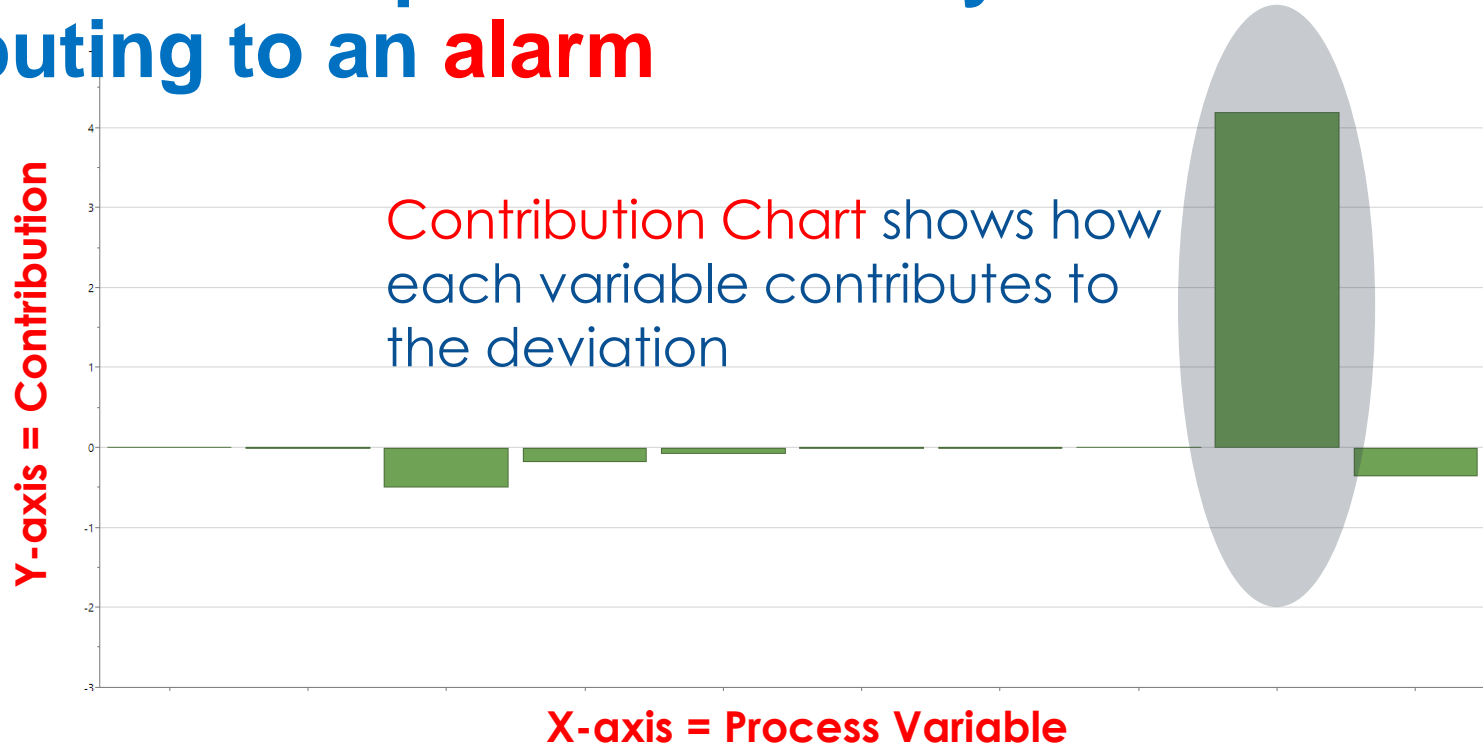
Batch Level Model



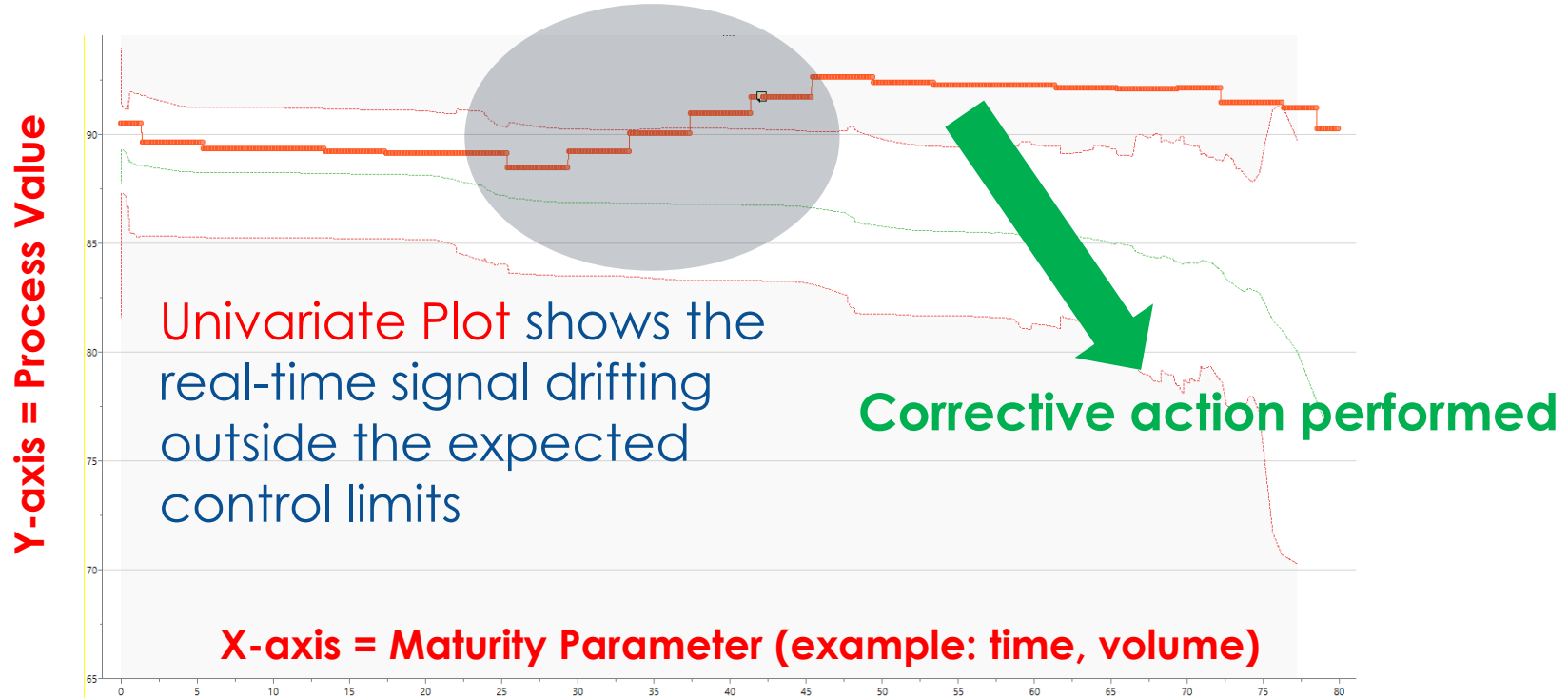
Scores Plot: Critical alarm in SIMCA-online is used to indicate a potential event



Contribution Chart: Used to determine which parameters may be contributing to an **alarm**



Univariate Plot: Zooming in to look at single parameter performance



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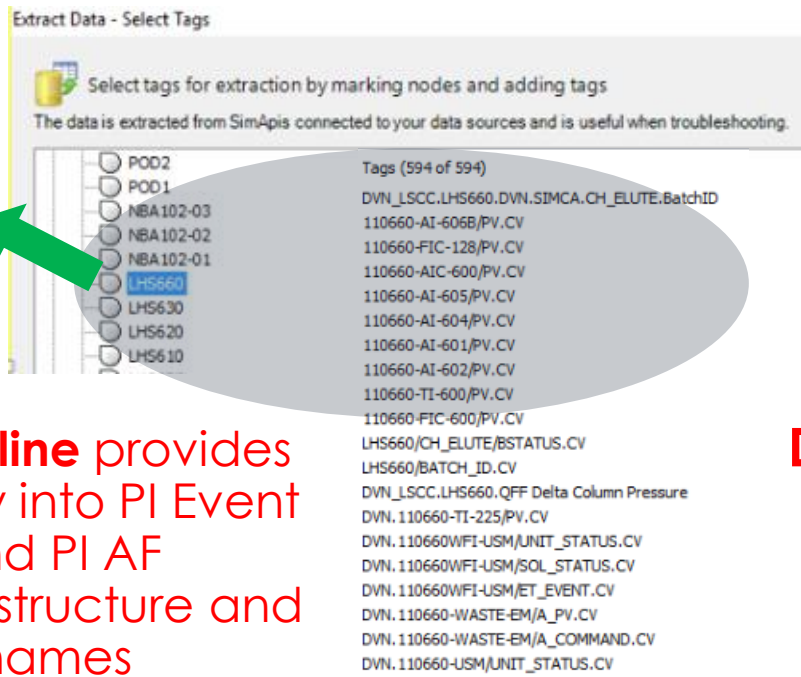
Challenge: Provide Real-time Batch Context to SIMCA-online

- SIMCA-offline models – data manually sourced from PI System, Seeq and Discoverant
- IPC and release testing data guide batch selection for process model
- Batch time context is implicitly built into the data sets that feed the models
- **Challenge:** Transitioning from static model development to real-time data and batch context for process monitoring



Challenge: Provide Real-time Batch Context to SIMCA-online

SIMCA-online shows flat PI AF hierarchy structure with links to PI tags



SIMCA-online provides no visibility into PI Event Frames and PI AF hierarchy structure and attribute names



Data latency

- PI Interface for Emerson DeltaV Batch (PI EMDVB)
- Continuous data if sourced from Enterprise PI System

SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics



Specify the conditions for phase execution

The batch identifier tag and the phase execution condition determine when a phase is executed.

QFF:QFF	
Batch identifier tag	:EnterprisePIAF:LHS660:DVN_LSCC.LHS660.DVN.SIMCA.CH_ELUTE.BatchID
Sleep condition	ValueTag(":EnterprisePIAF:LHS660:DVN_LSCC.LHS660.QFF CH_ELUTE Process Phase Active and Running") == 0
Phase execution conditions	
M3, QFF_Elution_BEM	ValueTag(":EnterprisePIAF:LHS660:DVN_LSCC.LHS660.QFF CH_ELUTE Phase Active") == 1

Real-time batch context triggers in SIMCA-online

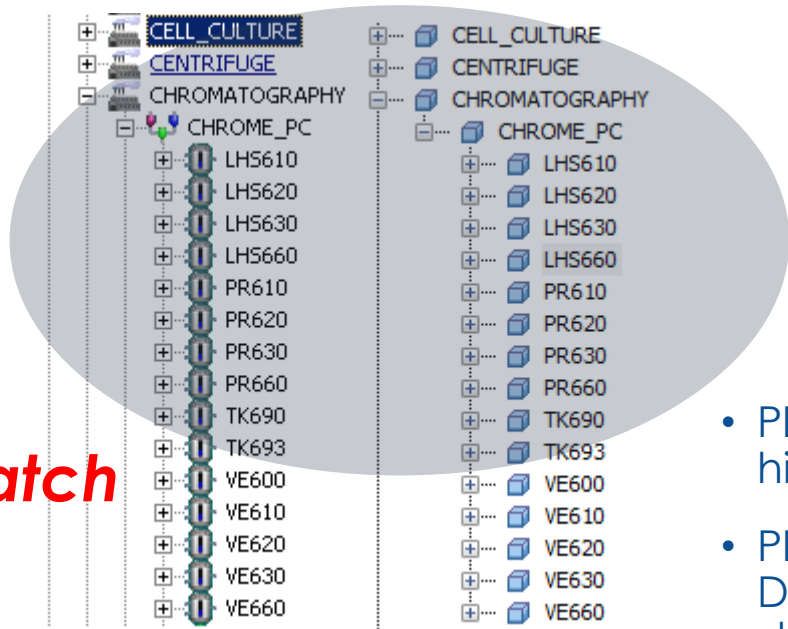
- Phase execution condition: Phase Active == 1
- Sleep condition: Process Phase Active and Running == 0
- Batch identifier tag: Batch ID

This looks so simple!!!

**What the \$@#%!
Is this a joke?!?**

**Why are you wasting
my time???**

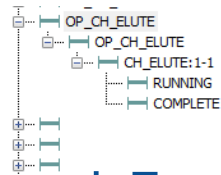
SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics



Ability to find batch data is key!

- PI AF and DeltaV equipment hierarchies are **aligned**
- PI Interface for Emerson DeltaV Batch and user-defined metadata write to **identical** PI AF equipment hierarchy

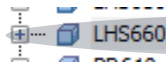
SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics



Name	Duration	Start Time	End Time	De...	Category	Severity	Template	Primary Element
OP_CH_ELUTE	1:37:07.46	2/5/2019 7:30:37.369 AM	2/5/2019 9:07:44.83 AM		OSIBatch;OSIBatchDB	None	Operation	LHS660
CH_ELUTE:1-1	1:35:18.024	2/5/2019 7:32:23.619 AM	2/5/2019 9:07:41.643 AM		OSIBatch;OSIBatchDB	None	Phase	LHS660
RUNNING	1:35:18.023	2/5/2019 7:32:23.619 AM	2/5/2019 9:07:41.642 AM		OSIBatch;OSIBatchDB	None	PhaseState	LHS660
COMPLETE	0:00:00.001	2/5/2019 9:07:41.642 AM	2/5/2019 9:07:41.643 AM		OSIBatch;OSIBatchDB	None	PhaseState	LHS660

PI Event Frame

Primary Element



PI AF Attribute - BatchID

Enterprise PI | DVN_LSCC:LHS660:CH_ELUTE:BatchID

BatchID PI tag – PI EMDVB interface

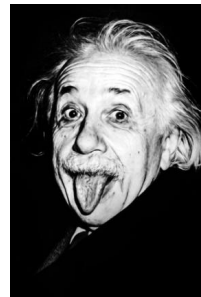


PI AF Attribute - Phase State

Enterprise PI | DVN_LSCC:LHS660:CH_ELUTE:State Changed::State Change

Phase State PI tag – PI EMDVB interface

**Batch data latency
issue identified!**



**"It's the DATA,
Stupid!"**

SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics

CHROMATOGRAPHY

- CHROME_PC
 - LHS610
 - LHS620
 - LHS630
 - LHS660
 - PR610
 - PR620
 - PR630
 - PR660
 - TK690
 - TK693
 - VE600

Name	Express	Value at Evaluation	Value at Last Trigger	Output Attribute
PhaseActive	IF Ba			QFF CH_ELUTE Process Phase Active and Running QFF CH_ELUTE Phase Active

```
IF BadVal('CH_ELUTE:State Changed::State Change') THEN NoOutput() ELSE(IF(Contains (UCase (TagVal('CH_ELUTE:State Changed::State Change')), "RUNNING")) THEN 1 ELSE(IF(Contains (UCase (TagVal('CH_ELUTE:State Changed::State Change')), "COMPLETE")) OR (Contains (UCase(TagVal('CH_ELUTE:State Changed::State Change')), "IDLE")) OR (Contains (UCase(TagVal('CH_ELUTE:State Changed::State Change')), "NOT LOADED")) THEN 0 ELSE NoOutput()))
```

Add a new variable

Scheduling: ☐ Event-Triggered ☒ Periodic

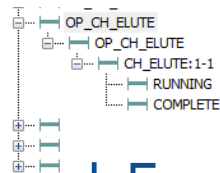
Period: 00h 00m 01s

Connected to the PI Anal

Example PI Asset Analytics with data latency

- Equation inputs sourced from PI EMDVB tags
- Periodic scheduling: 1 second period
- **Observation:** Equation provides desired phase stage change with a **undesired delay** versus DeltaV
- Can tolerate offset in slower upstream phases but not faster downstream phases

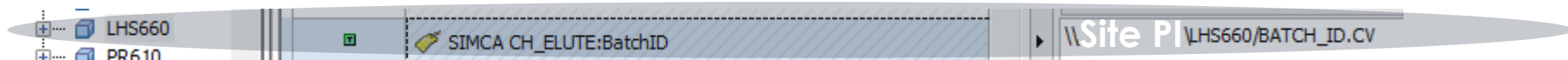
SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics



PI Event Frame

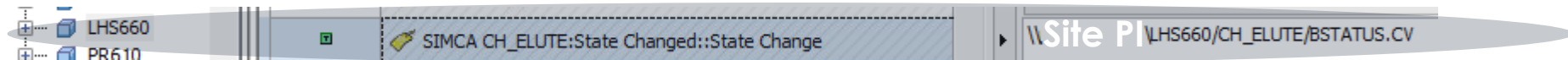
Name	Duration	Start Time	End Time	De...	Category	Severity	Template	Primary Element
OP_CH_ELUTE	1:37:07.46	2/5/2019 7:30:37.369 AM	2/5/2019 9:07:44.83 AM		OSIBatch;OSIBatchDB	None	Operation	LHS660
CH_ELUTE:1-1	1:35:18.024	2/5/2019 7:32:23.619 AM	2/5/2019 9:07:41.643 AM		OSIBatch;OSIBatchDB	None	Phase	LHS660
RUNNING	1:35:18.023	2/5/2019 7:32:23.619 AM	2/5/2019 9:07:41.642 AM		OSIBatch;OSIBatchDB	None	PhaseState	LHS660
COMPLETE	0:00:00.001	2/5/2019 9:07:41.642 AM	2/5/2019 9:07:41.643 AM		OSIBatch;OSIBatchDB	None	PhaseState	LHS660

Primary Element



PI AF Attribute - BatchID

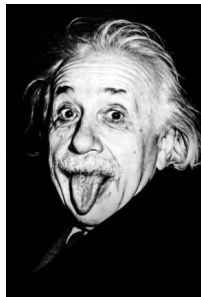
BatchID PI tag – historized DeltaV
BatchID tag



PI AF Attribute - Phase State

Phase State PI tag – historized DeltaV
BSTATUS tag

**Batch data latency
issue resolved!**



**"It's the DATA,
Stupid!"**

SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics

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- CHROME_PC
 - LHS610
 - LHS620
 - LHS630
 - LHS660
 - PR610
 - PR620
 - PR630
 - PR660
 - TK690
 - TK693
 - VE600

Name	Express	Value at Evaluation	Value at Last Trigger	Output Attribute
PhaseActive	IF Ba			QFF CH_ELUTE Process Phase Active and Running QFF CH_ELUTE Phase Active

```
IF BadVal('SIMCA CH_ELUTE:State Changed::State Change') THEN NoOutput() ELSE(IF(Contains (UCase (TagVal('SIMCA CH_ELUTE:State Changed::State Change')), "RUNNING")) THEN 1 ELSE(IF(Contains (UCase (TagVal('SIMCA CH_ELUTE:State Changed::State Change')), "COMPLETE")) OR (Contains (UCase(TagVal('SIMCA CH_ELUTE:State Changed::State Change')), "IDLE")) OR (Contains (UCase(TagVal('SIMCA CH_ELUTE:State Changed::State Change')), "NOT LOADED")) THEN 0 ELSE NoOutput()))
```

Add a new variable

Scheduling: ☐ Event-Triggered ☒ Periodic

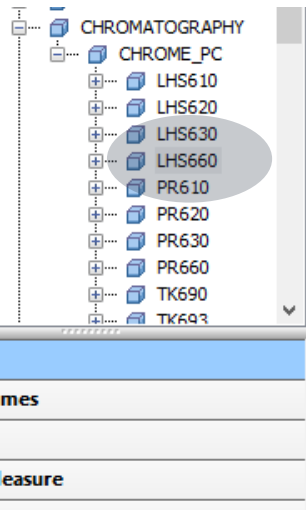
Period: 00h 00m 01s

Connected to the PI Anal

Example PI Asset Analytics without data latency

- Equation inputs sourced from historized DeltaV tags
- Periodic scheduling: 1 second period
- **Observation:** Equation provides desired phase stage change with **near-zero delay** versus DeltaV

SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics



Name	Expressic	Value at Evaluation	Value at Last Trigger	Output Attribute
DeltaVolume	IF Bad\	0	0	QFF CH ELUTE Process Phase Active and Running QFF CH ELUTE Delta Volume
ODA	IF Bad\	0	0	QFF CH ELUTE Process Phase Active and Running QFF CH ELUTE ODA
PhaseActive	IF Bad\	0	0	QFF CH ELUTE Process Phase Active and Running QFF CH ELUTE Phase Active
PhaseRunning	IF Bad\	0	0	QFF CH ELUTE Process Phase Active and Running QFF CH ELUTE Phase Running
PhaseActiveRunning	IF Bad\	0	0	QFF CH ELUTE Process Phase Active and Running QFF CH ELUTE Phase Active and Running
ProcessPhaseActiveRunning	IF Bad\	0	0	QFF CH ELUTE Process Phase Active and Running

[Add a new variable](#)

Evaluation Time: 2/12/2019 1:51:19 PM Last Trigger Time: 2/12/2019 1:51:19 PM

**Example PI Asset
Analytics showing
Boolean outputs**

Phase Active and **Process Phase
Active Running** are triggered in
real-time by PI Asset Analytics

SIMCA-online/PI System Integration Workaround: Created Real-time Batch Context using PI Asset Analytics



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The batch identifier tag and the phase execution condition determine when a phase is executed.

QFF:QFF

Batch identifier tag	:EnterprisePIAF:LHS660:DVN_LSCC.LHS660.DVN.SIMCA.CH_ELUTE.BatchID
Sleep condition	ValueTag(":EnterprisePIAF:LHS660:DVN_LSCC.LHS660.QFF CH_ELUTE Process Phase Active and Running") == 0
Phase execution conditions	
M3, QFF_Elution_BEM	ValueTag(":EnterprisePIAF:LHS660:DVN_LSCC.LHS660.QFF CH_ELUTE Phase Active") == 1

1	2	3
TIME	:EnterprisePIAF:LHS660:DVN_LSCC.LHS660.QFF CH_ELUTE Process Phase Active and Running	:EnterprisePIAF:LHS660:DVN_LSCC.LHS660.QFF CH_ELUTE Phase Active
2019-01-28 14:01:50	0	1
2019-01-28 14:01:55	0	1
2019-01-28 14:02:00	0	1

**Real-time batch
context triggers
in SIMCA-online**

Phase Active and **Process Phase Active
and Running** are read as Booleans from
PI Asset Analytics in real-time

SIMCA-online/PI System Integration Workaround: Sourced Real-time Data using PI Asset Analytics

Name	Expression	Value at Evaluation	Value at Last Trigger	Output Attribute
PostColumnBypassPressure	'SIMCA Post-Column Bypass Pressure PV'	-73.001 mbar	-73.001 mbar	SIMCA RT Post-Column Bypass Pressure
ColumnTopPressure	'SIMCA Column Top Pressure PV'	-247.89 mbar	-247.89 mbar	SIMCA RT Column Top Pressure
ODA1	'SIMCA Outlet UV Probe A PV'	0.037308 OD	0.037308 OD	SIMCA RT Outlet Optical Density 1
ODA2	'SIMCA Outlet Optical Density 2'	0.039836	0.039836	SIMCA RT Outlet Optical Density 2

[Add a new variable](#)

Evaluation Time: 2/12/2019 2:01:57 PM Last Trigger Time: 2/12/2019 2:01:57 PM

Scheduling: ☐ Event-Triggered ☒ Periodic [Advanced...](#)

Period: 00h 00m 01s [Configure](#)

**CAUTION: Only use
for signals that will
feed SIMCA-online**

Data latency

- Cannot source archive data from Enterprise PI System (via PI to PI interface)

**SIMCA-online
real-time data
needs**

- Need to source high-frequency snapshot data
- PI Asset Analytics provides **centralized, flexible solution** to replicate snapshot data from Site to Enterprise PI System

SIMCA-online/PI System Integration Workaround: Best Practices

- Use PI Asset Analytics equations to define real-time batch context
- Source phase state/batch ID from historized DeltaV tags

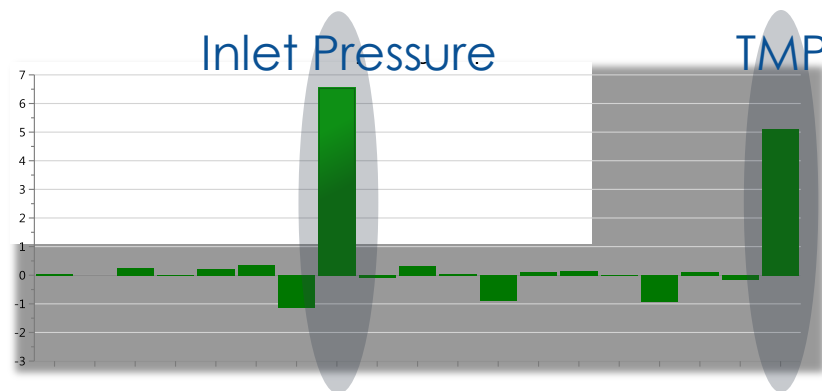
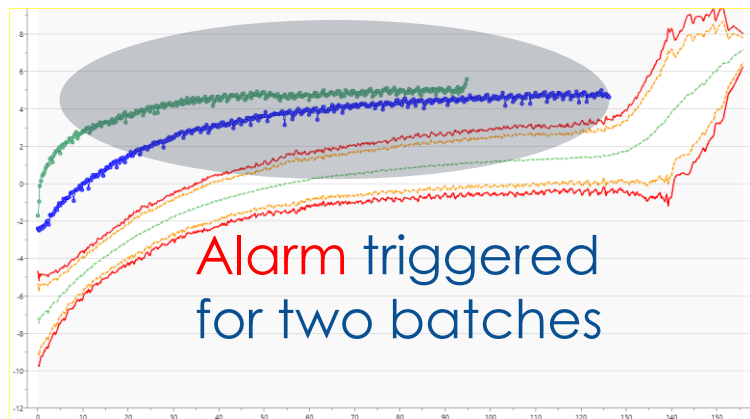


- Use DeltaV equipment modules to simplify equations
- Build solution at Site PI System and not Enterprise PI System
- Source real-time continuous data from snapshot data

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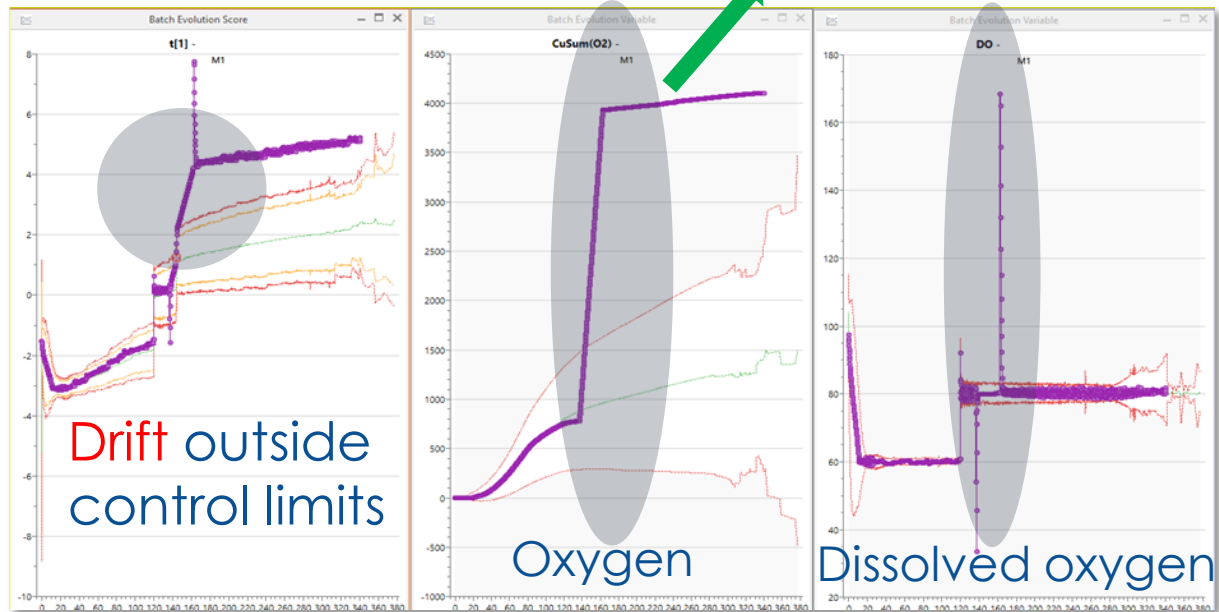
Business Benefit Example #1: UF Diafiltration – Adjusted Transmembrane Pressure to Comply with Allowable IPC Limit



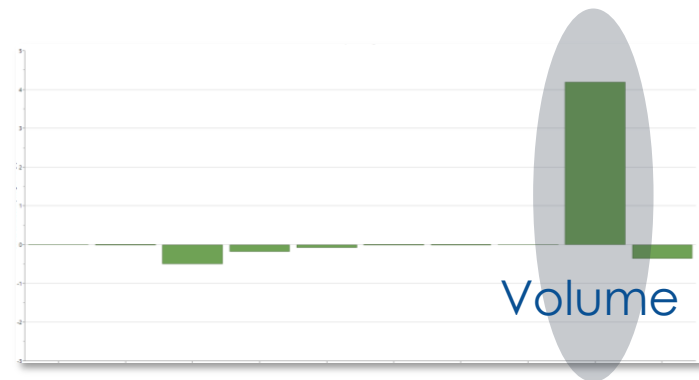
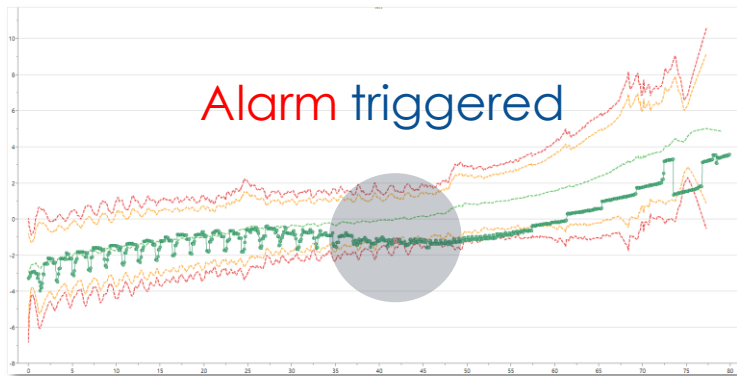
- High TMP was detected during a UFDF step
- New protocol was implemented to reduce TMP within IPC limits
- Prevented potential deviations

Business Benefit Example #2: Bioreactor – Fixed Open Oxygen Valve

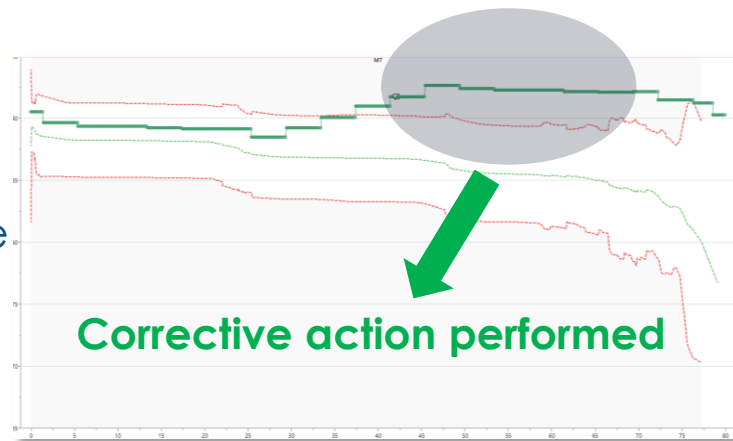
- Abnormally high usage of O₂ in a bioreactor was identified
- Cause was O₂ escaping through an room
- Valve was closed which prevented waste of O₂ (an expensive utility)
- Early fault detection averted maintenance issue by enabling the leak to get fixed promptly



Business Benefit Example #3: Bioreactor – Leaking Steam Valve

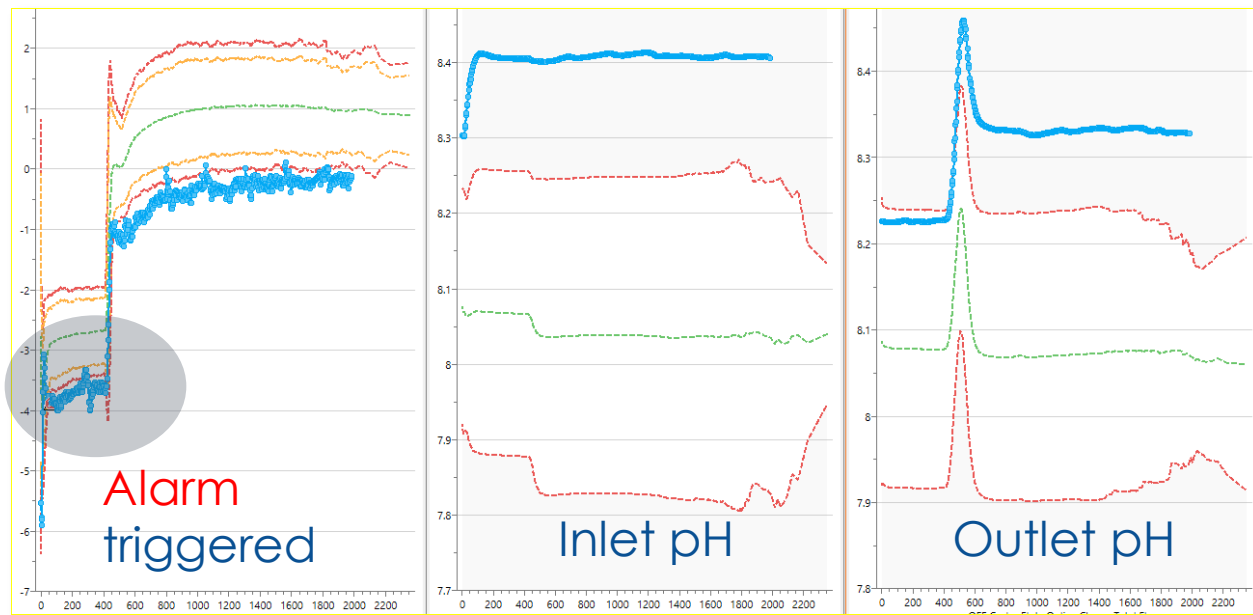


- Increasing volume trend detected in a bioreactor
- Investigation identified the cause as a leaking valve
- Proactive identification and correction of this leak prevented potential impact to the process



Business Benefit Example #4: Chromatography – Drifting pH

- High Inlet pH and Outlet pH on the skid were detected
- Recipe for transition to next process phases did not proceed due to “high” pH
- Root cause was drifting pH probes
- More frequent replacement of pH probes was implemented to ensure accurate pH reading and **streamline recipe execution**



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- **Future Capabilities**

Future Capabilities

- Upgrade to SimAPI 3.0.0.7271 (released Feb 2019)
- Expand multivariate modeling:
 - Additional biologics process stages
 - Equipment Monitoring
 - Pharmaceutical products
 - Other biologics sites

Acknowledgements: A Great Collaborative Effort



Data Systems, Monitoring and Analytics

GPS IT Process Robustness

GPS IT PI Build/Run

Manufacturing Technology Process Engineering – Upstream

Manufacturing Technology Process Engineering – Downstream

Manufacturing Operations

Manufacturing Science & Technology

IT/Automation

Quality Assurance

Deadline Solutions

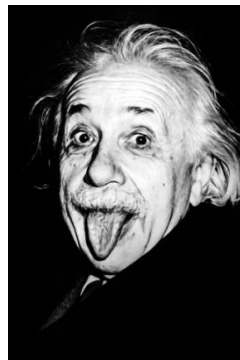
OSIsoft Tech Support

Sartorius Stedim

Seeq

Bristol-Myers Squibb

"It's the DATA, Stupid!" How PI Asset Analytics Rescued Our Real-time Multivariate Process Monitoring



CHALLENGE

Transitioning from offline model building to real-time multivariate monitoring requires batch time triggers to frame the dataset of interest

- Our real-time Multivariate Process Monitoring tool is not PI Event Frame aware – no direct way to mark batch time triggers to instruct multivariate monitoring when to start/stop

SOLUTION

Identified substitutes for PI Event Frames within the raw batch data brought into PI via PI Interface for Emerson DeltaV Batch (PI EMDVB)

- Created PI Asset Analytics to transform raw batch data into Boolean batch time markers that SIMCA-online could easily parse

RESULTS

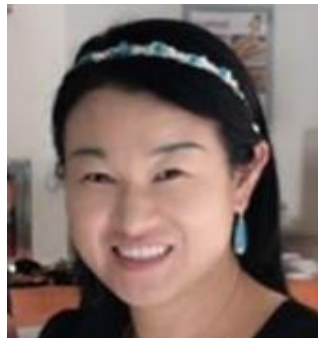
Real-time Multivariate Monitoring enabled across the company provided Operations a tool to monitor the process against historical performance and enable real-time fault detection

- Prevented potential batch impact
- Averted maintenance issue
- Prevented potential deviations
- Streamlined recipe execution

“It’s the DATA, Stupid!” How PI Asset Analytics Rescued Our Real-time Multivariate Process Monitoring



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- Bristol-Myers Squibb
- bing.zhang@bms.com

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the **microphone**

State your
name & company



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