

Integrating Disparate Platforms for Consistent Analysis and Batch Reporting

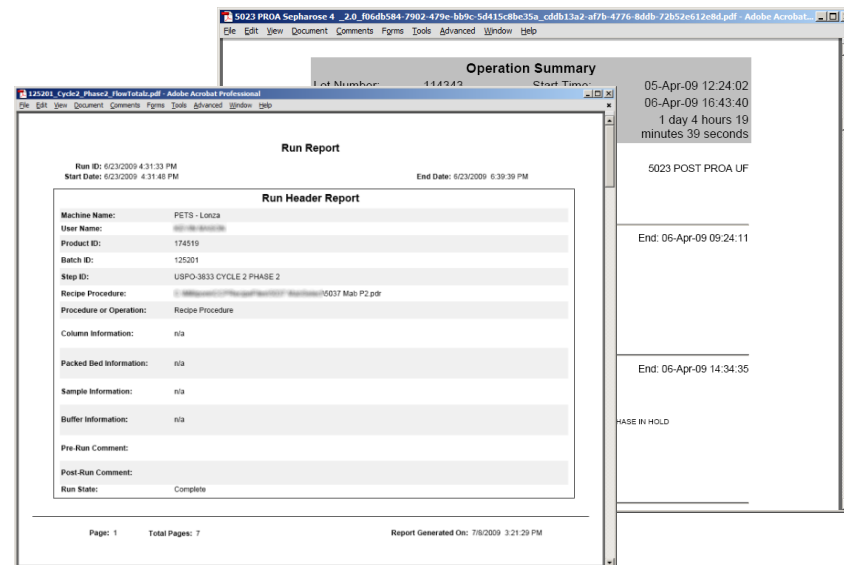
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Controls Engineer

Lonza

The Challenge: Consistent Batch Reporting across disparate systems

“We use the PI system to provide our customers with a consistent batch record review process which includes a review of the process alarms summary and critical process data trends for our DeltaV systems. The reports and the review process should be the same despite the production area or the equipment used.”



Customer Business Challenge

- Provide our Customers with a consistent report format regardless of the process equipment used
- Reduce the workload of operators
- Create exception based reporting to improve the efficiency of lot review
- Reduce the opportunities for errors during the batch release processes

Solution

- Leverage the RtReports installation already in use with the site PI system
- Utilize the existing investment in our site system which had PIBaGen and the batch sub system installed
- Propagate information already available in the existing HMI database

Customer Results / Benefits

- Consistent batch reporting format
- Transfer the responsibility of report generation from the operators to the Quality group
- Report by exception which translates to less time for product release
- Eliminates the manual method for identifying exceptions

Lonza Portsmouth

Custom Manufacturing
of Biopharmaceuticals

Size: 350,000sq ft

Employees: ~642

Technology: Mammalian cell culture

Equipment:

- Four 20,000-liter bioreactor trains
- Three 5,000-liter bioreactor trains
- Two 1,500-liter perfusion bioreactor trains



Facility Design

- The Portsmouth facility is divided into two plant areas
 - 101A
 - Built in 1995
 - Two 1,500L and three 5,000L trains
 - Automated with a Provox DCS and numerous PLC's
 - 101B
 - Built in 2004
 - Four 20,000L trains
 - Automated by two DeltaV systems with a limited number of PLC's

Our History with OSIsoft

- The first PI in Portsmouth was installed in 1998 to replace an existing historian
- Embedded PI Historians were installed with DeltaV for the 101B
- A site historian and RtReports were installed in 2005 to provide Part 11 compliant batch reporting for the DeltaV systems
- The PIOPC, PitoPI, CHItoPI, OPC Alarms and Events, and the DeltaV batch interface utilized for data gathering

The 101A Purification Equipment

- A new chromatography skid was recently purchased to replace older equipment
- The new system greatly expanded the flexibility of the purification suite
- The system is automated with Allen Bradley's Control Logix PLC and GE's iFix HMI
- Operational data is stored within the Microsoft SQL Server 2000 Desktop Engine (MSDE)
- Continuous instrument data is already collected by the PI OPC interface

Run Report

Run ID: 6/23/2009 4:31:33 PM
Start Date: 6/23/2009 4:31:48 PM

End Date: 6/23/2009 6:39:39 PM

Run Header Report

Machine Name:	PETS - Lonza
User Name:	602186-8402248
Product ID:	174519
Batch ID:	125201
Step ID:	USPO-3833 CYCLE 2 PHASE 2
Recipe Procedure:	C:\MSI\ossoft\11\Process\Recipe\1037_Recipe\M5037 Mab P2.pdr
Procedure or Operation:	Recipe Procedure
Column Information:	n/a
Packed Bed Information:	n/a
Sample Information:	n/a
Buffer Information:	n/a
Pre-Run Comment:	
Post-Run Comment:	
Run State:	Complete

Run Report

Run ID: 6/23/2009 4:31:33 PM
Start Date: 6/23/2009 4:31:48 PM

End Date: 6/23/2009 6:39:39 PM

Process Data Tabular Log

Confusing descriptions

Date Time	FI01	FQ01_OP	FQ01_PR	FQ01_US			
6/23/2009 4:31:48 PM	0.0	0.0	0.0	0.0			
6/23/2009 4:32:48 PM	0.0	0.0	0.0	0.0			
6/23/2009 4:33:48 PM	0.0	0.0	0.0	0.0			
6/23/2009 4:34:48 PM	0.0	0.0	0.0	0.0			
6/23/2009 4:35:48 PM	-0.6	0.0	0.0	0.0			
6/23/2009 4:36:48 PM	1.8	0.1	0.1	0.1			
6/23/2009 4:37:48 PM	6.9	8.6	8.6	8.6			
6/23/2009 4:38:48 PM	9.1	18.2	18.2	18.2			
6/23/2009 4:39:48 PM	9.0	27.3	27.3	27.3			
6/23/2009 4:40:48 PM	9.0	36.3	36.3	36.3			
6/23/2009 4:41:48 PM	9.0	45.5	45.5	45.5			
6/23/2009 4:42:48 PM	9.0	54.7	54.7	54.7			
6/23/2009 4:43:48 PM	9.0	63.8	63.8	63.8			
6/23/2009 4:44:48 PM	9.0	72.9	72.9	72.9			
6/23/2009 4:45:48 PM	9.0	81.8	81.8	81.8			
6/23/2009 4:46:48 PM	9.0	90.9	90.9	90.9			
6/23/2009 4:47:48 PM	9.1	100.0	100.0	100.0			
6/23/2009 4:48:48 PM	9.1	109.2	109.2	109.2			
6/23/2009 4:49:48 PM	9.1	118.3	118.3	118.3			
6/23/2009 4:50:48 PM	9.1	127.4	127.4	127.4			
6/23/2009 4:51:48 PM	9.1	136.3	136.3	136.3			
6/23/2009 4:52:48 PM	9.1	145.4	145.4	145.4			
6/23/2009 4:53:48 PM	9.1	154.5	154.5	154.5			
6/23/2009 4:54:48 PM	9.0	163.5	163.5	163.5			
6/23/2009 4:55:48 PM	9.0	172.9	172.9	172.9			
6/23/2009 4:56:48 PM	9.1	182.0	182.0	182.0			
6/23/2009 4:57:48 PM	9.1	190.9	190.9	190.9			
6/23/2009 4:58:48 PM	9.0	200.0	200.0	200.0			

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4 more pages

Report Generated On: 7/8/2009 3:21:29 PM

The Path to the Problem

- The chromatography equipment contained its own reporting package
- This was initially sufficient for lot release requirements and shortened the startup period
- It became apparent that the report configuration was inflexible to changes, was not exception based, and was very different from other reports provided to our customers
- Batch or event framing for continuous data did not exist

Operation Summary			
Lot Number:	89175	Start Time:	27-Oct-08 12:43:10
Unit:	X-26100	End Time:	27-Oct-08 13:15:52
		Duration:	32 minutes 42 seconds

Operation: O-PC6-COL-EQ Formula: 5052 QFF CLEAN-1
 Batch ID: USPO-5851/Lot89175/Step8.9

Phase: P-COL-EQ:1-1 Start: 27-Oct-08 12:43:23 End: 27-Oct-08 13:15:49

Holds:

Time.	Duration:	Reason:
27-Oct-08 12:45:20	3 minutes 51 seconds	CONDUCTIVITY OUT OF RANGE
27-Oct-08 12:50:40	2 minutes 15 seconds	CONDUCTIVITY OUT OF RANGE

Alarms:

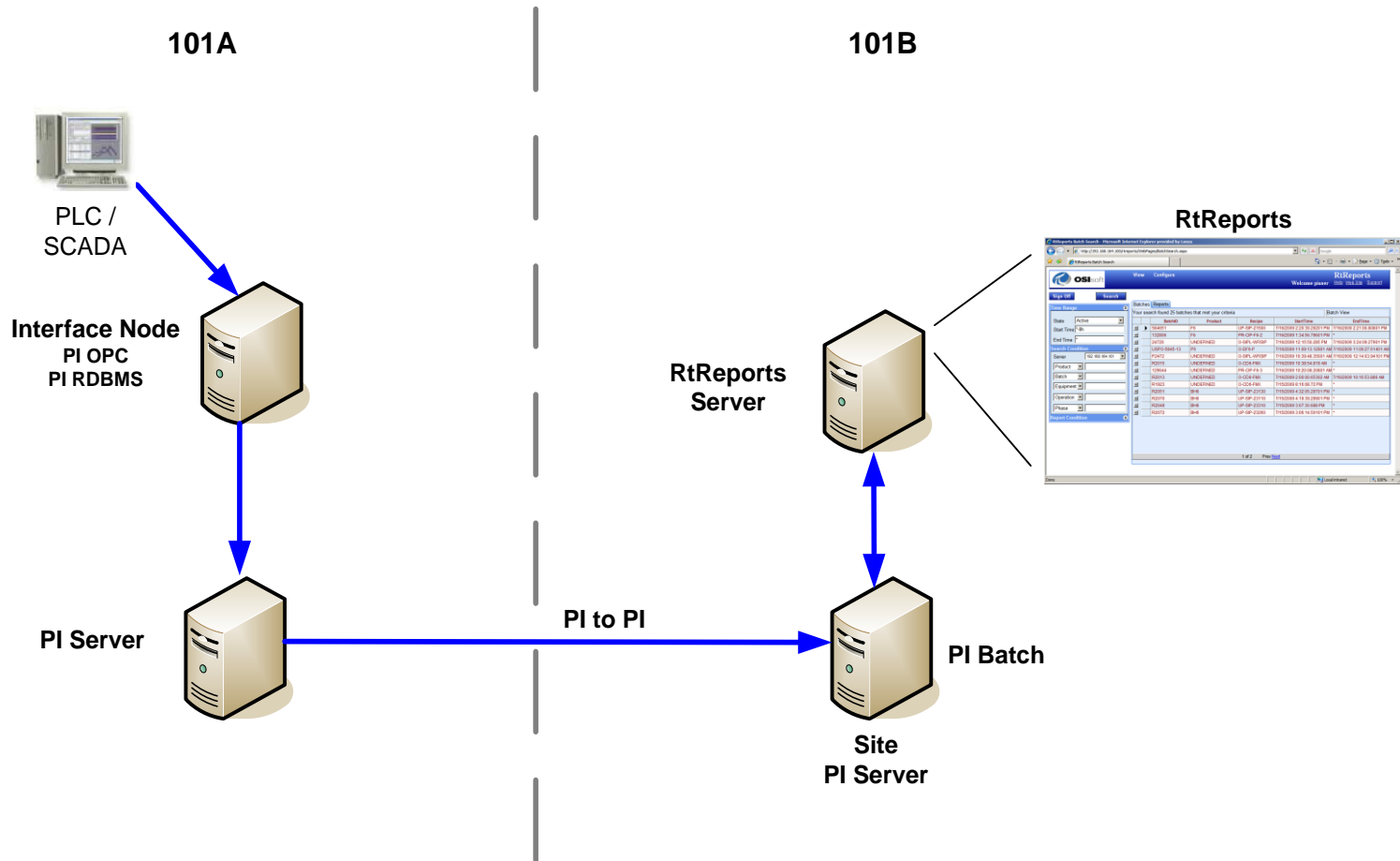
Conductivity	AI-349230	
	27-Oct-08 12:45:08	High High Alarm Value 89.4167 Limit 24
	27-Oct-08 12:50:31	High High Alarm Value 68.6057 Limit 24
Pressure	PI-349212	
Flow	FIC-349222	

Exception based

The Solution

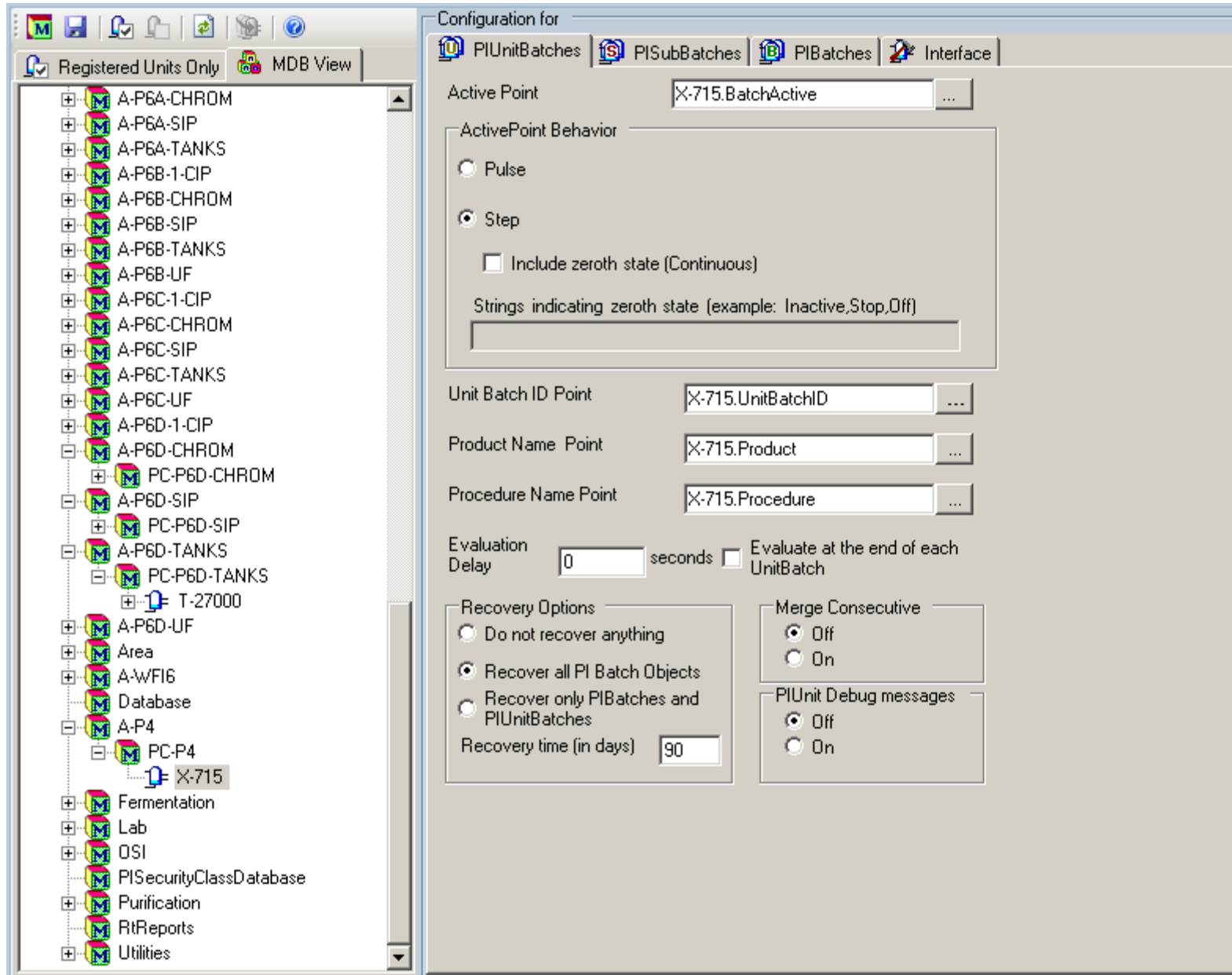
- Purchase the PI RDBMS (Relational Database Management System) interface
- Utilize the existing RtReports installation that provides reporting for DeltaV operations
- Configure the PIBaGen (PI Batch Generator) that was installed but had not been used

How Does It Work?



How Hard Was It To Configure?

1. Survey the data available in the database
2. Create SQL queries to retrieve the data for each tag
3. Create the tags for the RDBMS interface (the first one is the hardest!)
4. Configure the unit in the module database
5. Associate the RDBMS tags in PIBaGen
6. Build the RtReport!



The screenshot displays the OSIsoft software interface. On the left is a tree view titled 'Registered Units Only' in 'MDB View' mode. The tree lists various units such as A-P6A-CHROM, A-P6A-SIP, A-P6A-TANKS, A-P6B-1-CIP, A-P6B-CHROM, A-P6B-SIP, A-P6B-TANKS, A-P6B-UF, A-P6C-1-CIP, A-P6C-CHROM, A-P6C-SIP, A-P6C-TANKS, A-P6C-UF, A-P6D-1-CIP, A-P6D-CHROM, A-P6D-SIP, PC-P6D-CHROM, PC-P6D-SIP, A-P6D-TANKS, PC-P6D-TANKS, T-27000, A-P6D-UF, Area, A-WFI6, Database, A-P4, PC-P4, X-715, Fermentation, Lab, OSI, PISecurityClassDatabase, Purification, RptReports, and Utilities. The 'X-715' unit is selected.

On the right is the 'Configuration for' dialog box for the selected unit. It has four tabs: 'PIUnitBatches' (selected), 'PISubBatches', 'PIBatches', and 'Interface'. The configuration includes:

- Active Point:** X-715.BatchActive
- ActivePoint Behavior:**
 - Pulse
 - Step
 - Include zeroth state (Continuous)
 - Strings indicating zeroth state (example: Inactive,Stop,Off)
- Unit Batch ID Point:** X-715.UnitBatchID
- Product Name Point:** X-715.Product
- Procedure Name Point:** X-715.Procedure
- Evaluation Delay:** 0 seconds
- Evaluate at the end of each UnitBatch
- Recovery Options:**
 - Do not recover anything
 - Recover all PI Batch Objects
 - Recover only PIBatches and PIUnitBatches
 - Recovery time (in days): 90
- Merge Consecutive:**
 - Off
 - On
- PIUnit Debug messages:**
 - Off
 - On

Technical Benefits

- Data is “backed up” in a real-time fashion to the PI server
- Report generation is paperless since RtReports permits saving to PDF
- Most importantly, data is no longer isolated within the HMI and is available to anyone using ProcessBook, DataLink or RtReports

The Return on Investment

- The responsibility of report generation shifts from the production floor to the Quality department saving time for Operators
- Batch review time is reduced from hours to minutes
 - Reviewing the current report requires and a sharp eye for anomalies
 - Time is wasted reviewing the tabular data to determine if exceptions were encountered
 - Once an exception is discovered, the investigation begins
 - The new format identifies the exceptions reducing the opportunities for error

Return on the Investment

- The greatest returns are created by the time savings for a lot release!

Batch Record / Report Review

	101A	101B
Review Time (hrs) X	2:30	0:20
Reports per Week	15	15
	37:50	5:00

- Also resulting in a shortened product release period!

Solution Challenges

- The SQL database within the HMI does not store information in an S88 format
- The SQL database is undocumented
- Difficult to determine triggers for S88 style framing of batch data (this is overcome with more sophisticated queries)
- Improving the data collection requires the vendor's assistance since the functionality is hidden within DLL's

Rewards

- No more report printing by the operators
- All batch reporting for the site is consolidated within the site PI system
- Data is now available to everyone with PI access
- Easier to determine when the equipment was run for analyzing data
- Customers are provided with a common exception based report format
- Leveraged value from existing functionality that was not being used!

Next Steps and Future Opportunities

- Work with the vendor to produce more data
- Replicate our success to other equipment with reporting needs
 - Older chromatography equipment
 - Autoclaves
 - Bench-top Lab Equipment
- Tie in data from the Building Automation System
 - What were the environmental conditions during production?
- Tie in additional data from utilities to determine energy usage

Questions?