



Use of RtReports in the Pharmaceutical Environment

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Empowering Business in Real Time
PI Infrastructure for the Enterprise

Disclaimer

- Disclaimer
 - The opinions and ideas expressed in this presentation are strictly my own.
 - Everything said and presented is strictly my personal opinion and does not necessarily represent the views of sanofi pasteur.

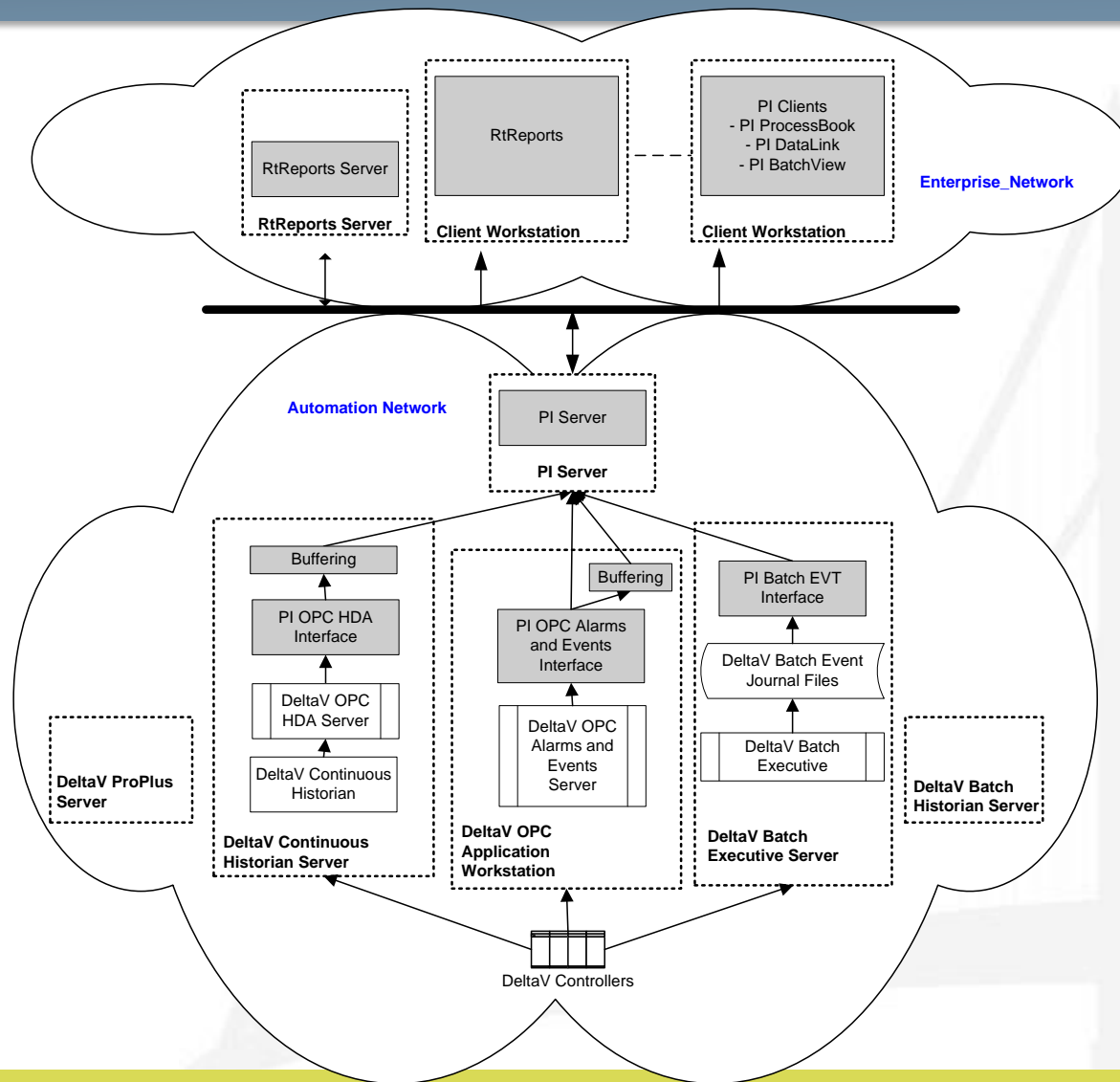
Introduction

- Sanofi Pasteur, the vaccines division of sanofi-aventis Group, is the largest company in the world devoted entirely to human vaccines. Our driving goal is to protect people from infectious diseases by creating safe and effective vaccines.
- Sanofi Pasteur offers the broadest range of vaccines in the world, providing protection against 20 bacterial and viral diseases. We distribute more than 1.6 billion doses of vaccine each year, making it possible to vaccinate more than 500 million people across the globe.

PI and RtReports Introduction

- New PI system at sanofi pasteur released for use Jan 2009
- Data Sourced from Emerson DeltaV Control System – vaccine process
- Batch Reporting used to monitor process parameters

DeltaV Integration to PI



Use of RtReports

- Exception Based Report Elements
 - Supplemental information to batch record
 - Header / Footer / Batch Information
 - Process Parameters
 - DeltaV Alarms
 - Exception Details

Use of RtReports - Header

Report Name: PREP
Batch ID: 036496_MPREP

Version: 1.0 Generation Date: dd-MMM-yy hh:mm:ss AP
Last Official Print: dd-MMM-yy hh:mm:ss AP

Batch Start: 28-Feb-08 01:24:08 PM
Batch End: 28-Feb-08 03:58:44 PM

Prep Batch Report

Batch Summary

Batch ID: 036496_MPREP

Recipe: PREP

Unit: 6496

Start Time: 28-Feb-08 01:24:08 PM

End Time: 28-Feb-08 03:58:44 PM

Cycle Time: 2 hours 34 minutes 36 seconds

Use of RtReports – Parameter Check

Process Parameter Summary

Batch Summary

Expected Status: Sanitized Actual: Sanitized
Formula and Batch Size Setpoint: M55 SODIUM 50L
Batch Size Actual: 55.8 Kg

Amount Manually Added: 5 Kg

WFI

Temperature Setpoint: 35.0 °C Range 10.0 - 45.0 °C Exceptions: 0

Mix

Agitation Rate Setpoint: 400 RPM Range 350-450 RPM Exceptions: 0
Mix Time: 20 min Exceptions: 0

Parameter Check

Final pH: 4.8 Range 4.0 - 5.0 Exceptions: 0
Final Conductivity: 290 mS/cm Range 300-500 mS/cm Exceptions: 0

Use of RtReports - Exception Details

Transfer Temperature High Limit

-No Exceptions Found-

Transfer Agitation Rate Low Limit

Exception: Transfer Agitation Rate Low Limit Exceeded (27 SIC001.PV)

Limit: 100 RPM

Start Time: 27-Sep-08 10:43:03 PM

Speed: 70 RPM

End Time: 28-Sep-08 12:31:52 AM

Speed: 0 RPM

Min Speed: 0 RPM

Use of RtReports -Critical Alarms

DeltaV Alarms

Tag	Alarm	State	Timestamp
ZY-20\PT001.HI_HI_ALM	High High Alarm Value 80 Limit 40	INACT/ACK	29-Sep-07 08:43:37 AM
ZY-20\TIC004.PVBAD_ALM	General Failure	ACT/UNACK	29-Sep-07 08:43:37 AM
ZY-20\TT002.HI_HI_ALM	High High Alarm Value 148.8272 Limit 140	INACT/ACK	29-Sep-07 08:43:38 AM

Template Options

Process Parameter Summary

Batch Summary

Expected Status: Clean Actual: Clean
Formula and Batch Size Setpoint: M 65 WATER 650L
Batch Size Actual: 650.3 Kg

WFI

Temperature Setpoint: 75.0 °C Range 65.0 - 85.0 °C Exceptions: 0

--- Exception Detail ---

DeltaV Alarms

-No Exceptions Found-

Temperature Limit

-No Exceptions Found-

--- End of Exceptions ---

Use of RtReports - Footer

Reviewed By: _____ Date: _____

Notes: _____

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- Paper Approval for Initial Implementation
- Electronic Signature – Future

Validation of RtReports

- Follows GAMP for Computer Validation
- Builds Quality from Beginning – Quality can not be “tested into the system”
- Lengthy Process due to amount of documentation
- Not a custom system – Testing of “configured” software significantly less than “custom” software

Validation of RtReports - Deliverables

- Starts with User Requirements
 - 21 CFR Part 11 Requirements
- Vendor Audits – OSIsoft and Integrator RoviSys
- Validation Plan – sets out testing methodology
- Functional Specification – Defines system functions
- Design Specifications – System Design, Server Application Design and Configuration, Interface Design, Report Design
- Risk Analysis – focuses testing to critical items

Validation of RtReports - Deliverables

- User Testing – FAT – Factory Acceptance, SAT – Site Acceptance Testing
- Installation Qualification – PI Server, Interfaces, Reports
- Operational Qualification- PI Server, Interfaces, Reports, Client Tools – PI DataLink, PI ProcessBook, PI BatchView
 - Tested Part 11 Requirements – Audit Trail, Security etc.
- Reports for each protocol to summarize testing and deviations
- SOPs for System Operation, Disaster Recovery, Maintenance, Back-Up and Recovery, and Security Administration
- System Released then Process Performance Evaluation

Exception Based Report Testing

- Verify data transfer to PI points - Operational Testing
- Report journal actions based on aliases stored in module database
- To verify exception monitoring:
 - Replace alias in Module DB with test PI point
 - Enter data before, during, and after exception in SMT data archive editor for PI test point
 - Verify exception on report
 - Return alias to original point
 - Repeat for each exception for every parameter – very time intensive

Exception Based Report Benefits

- Exception Bases Reporting Focuses information down to what is critical
- Reduces review time
- Easy to understand format –
 - Deviations from ideal process easy to see

PI Benefits

- The power of PI information can not be overlooked in BIO/Pharm
 - Unexplained batch deviations = loss of entire batch
- Shown to reduce start-up time
 - PI data used to troubleshoot start-up issues
- PI Data used to reduce CIP cycle time
- Used to optimize Water For Injection (WFI) usage
- Used to monitor utilities and reduce water usage

Lessons Learned

- The PI Event File Interface (EVT) can create a large number of tags depending on phase and recipe parameters
- Emerson DeltaV requires additional OPC HDA license for OPC HDA interface
- Changes will be necessary to control system for Reporting
 - Example: Reporting across multiple unit procedures and phases

Future PI System Use

- Quick adoption by sanofi pasteur organization
 - PI Client Tools – easy to use
 - RtReports Interface – small learning curve
 - PI Consolidates Data
- Initial Expansion Favorable – approved for expansion
- Lower validation costs for expansion
 - Test only changes to the PI / RtReports system

Wrap-up

- RtReports – Exception Based Reports focus information and reduces review time
- PI – DeltaV – RtReports
- The Power of PI Information – Favorable Initial Implementation – PI System approved for expansion
- Questions?