

Combining Laboratory and Process Data on the PI System

Presented by **Kevin Crean**

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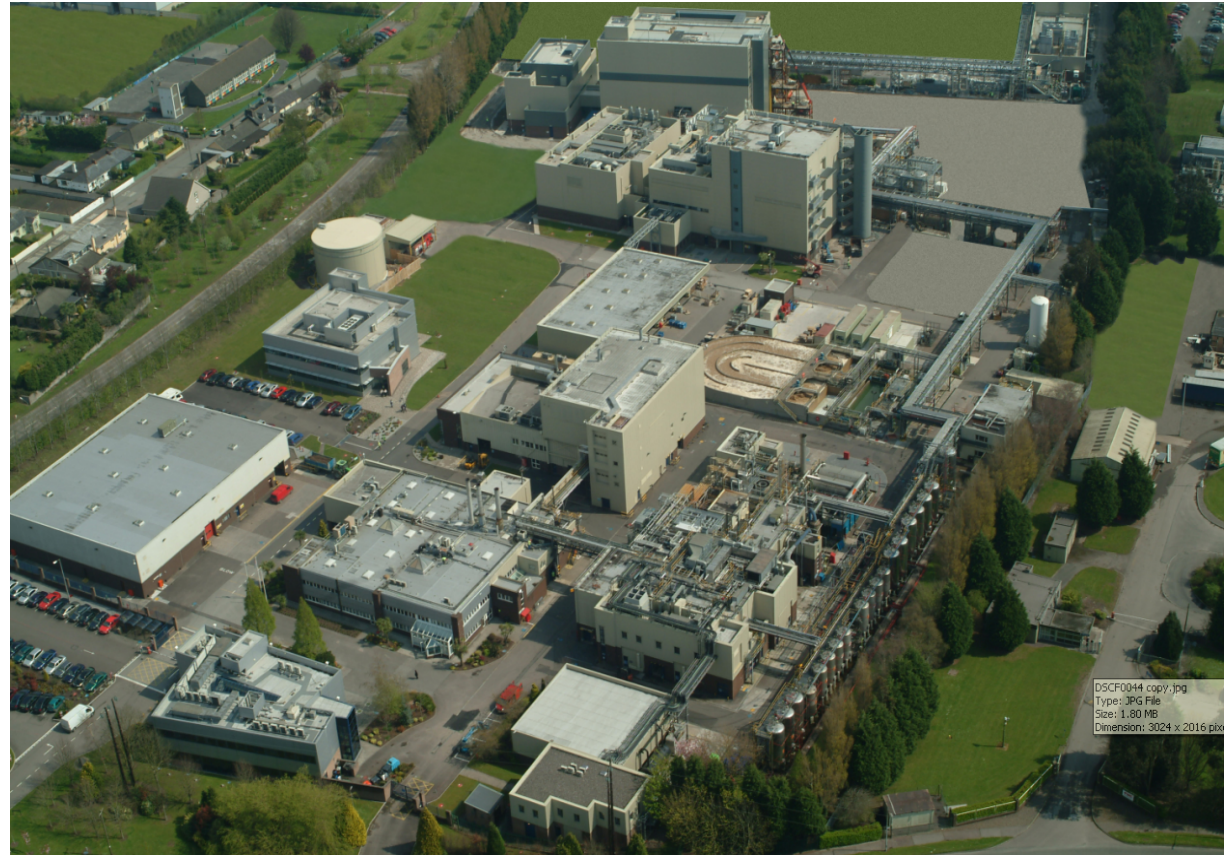
Agenda

Introduction

- Janssen Pharmaceutical PI System
- Defining Requirements/ Creating Solutions
- Supporting Elements
- Benefits and Next Steps

Introduction - Janssen Pharmaceutical – Cork Facility

- Multi Product Facility
- Support Structure
 - CNS
 - Virology
 - Internal Medicine
 - Support Group
- API/ Aseptic Processing
 - Reactors
 - Centrifuges
 - Dryers
 - Centrifuge Dryers
 - Powder Handling



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Janssen Pharmaceutical PI System

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Janssen Pharmaceutical PI System – OSI Products & Services

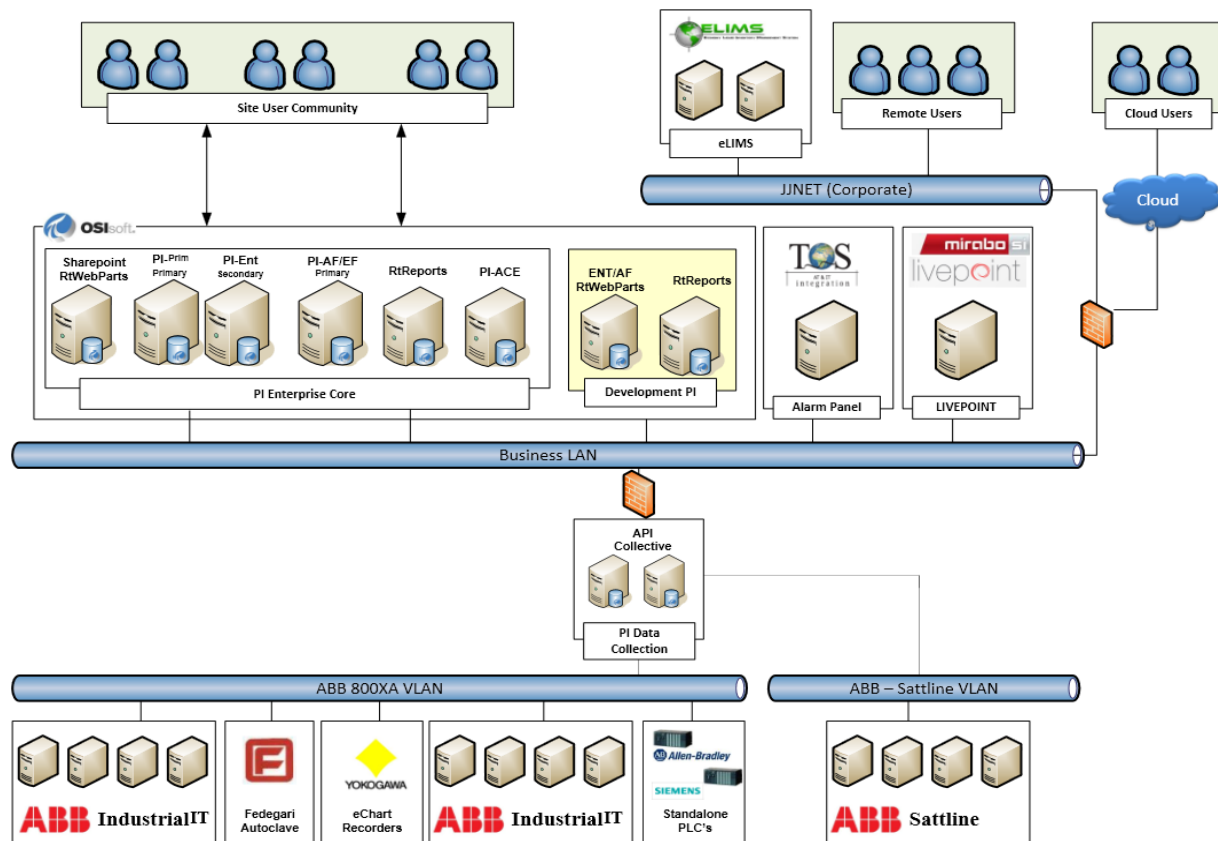
- Janssen & OSIsoft Enterprise Agreement
 - Managed PI
 - Performance Monitoring
 - Unrestricted Tag Count
- PI Server (High Availability/ Reliability)
- PI Asset Framework
- PI Interfaces
- RtReports
- PI ProcessBook
- PI Notifications
- PI Batch/ PI Event Frames



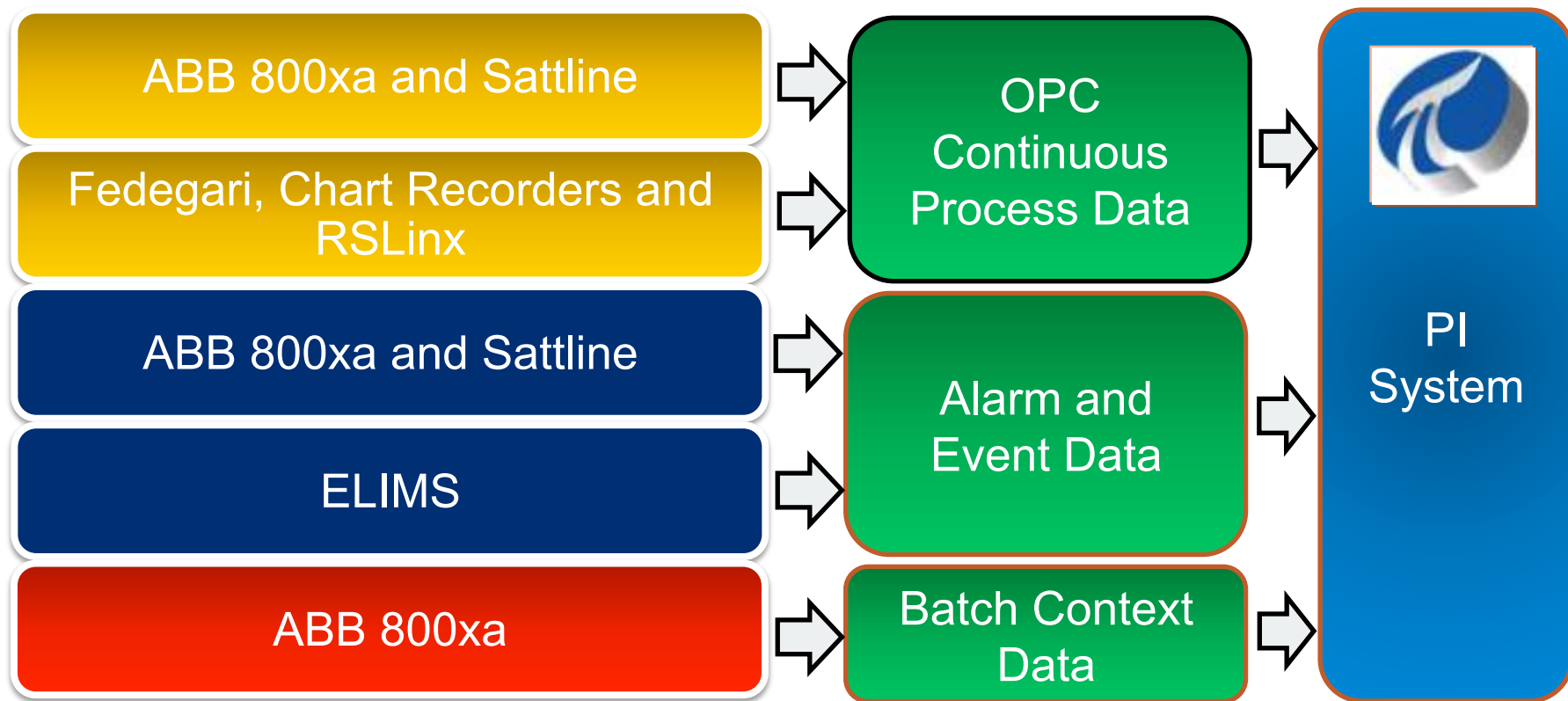
As Standard we embrace S88 standard within our source systems and with the PI System deployment.

Janssen Pharmaceutical PI System Architecture

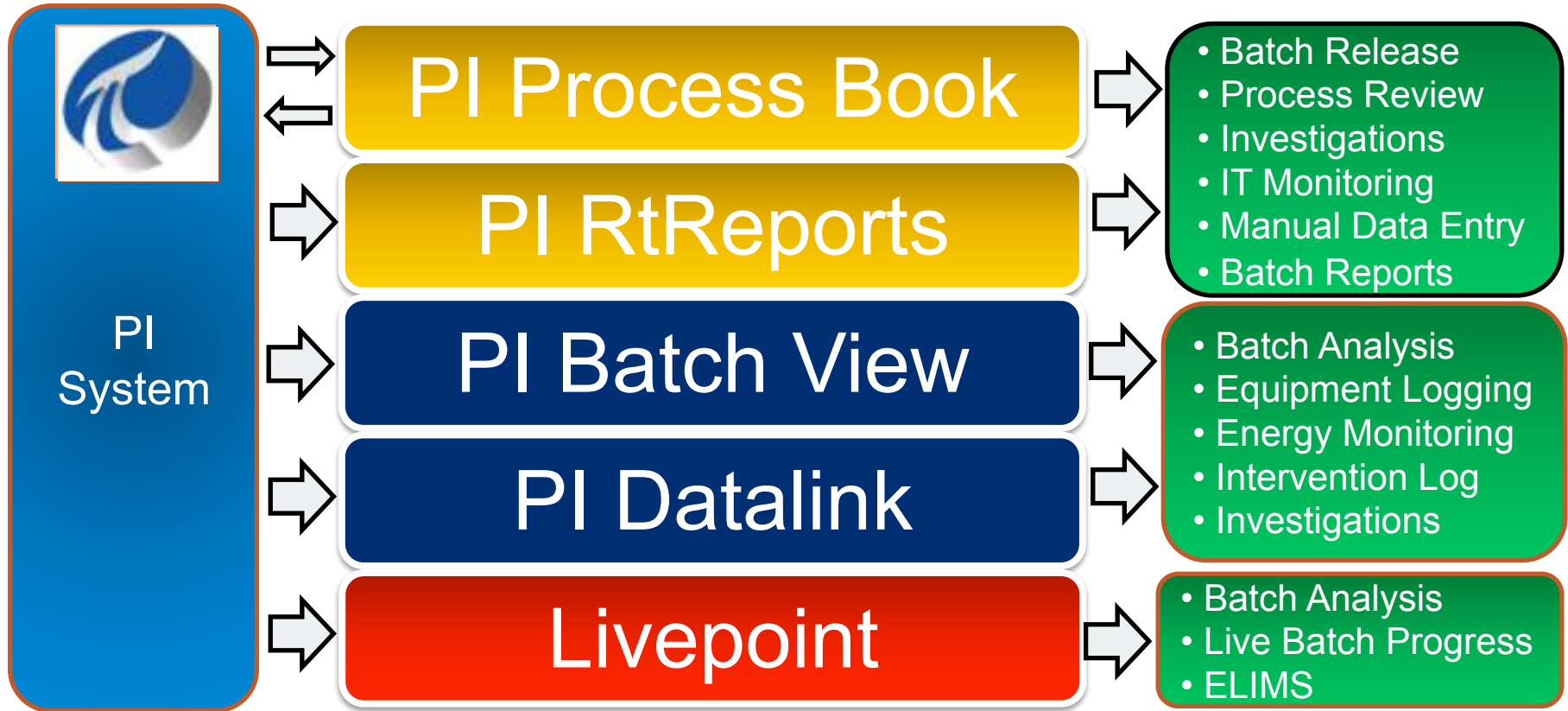
- Standard Architecture
 - PI Collective
 - PI AF
 - PI RtReports
 - API Nodes
- Multiple Sources
 - Separate VLANs
 - DCS
 - PLCs
 - Chart Recorders



Janssen Pharmaceutical PI System – Source Data



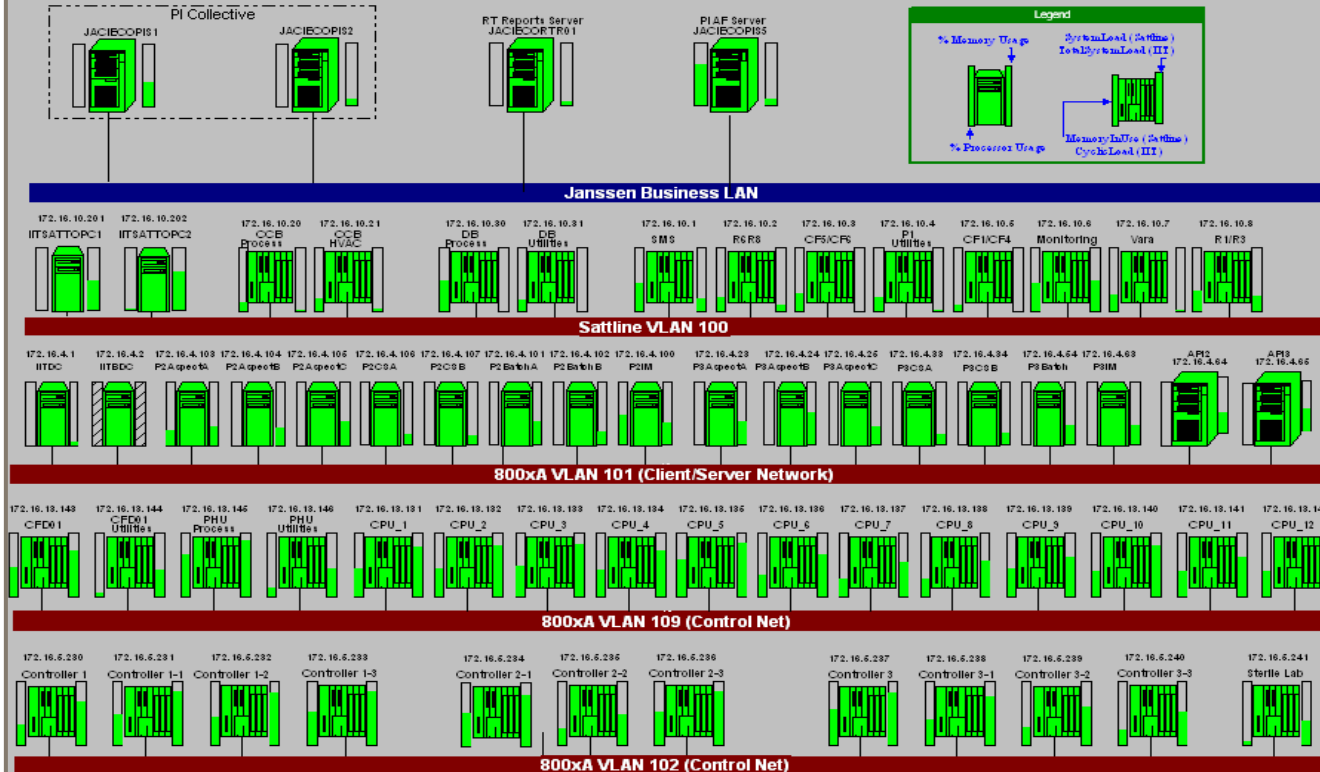
Janssen Pharmaceutical PI System – Client Tools



Janssen Pharmaceutical PI System – Client Tools

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AUTOMATION NETWORK AND PI SYSTEM MONITORING



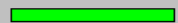
INTERFACES ON JACIECOAPI2

INTERFACE	MODE	STATUS
P2 IIT	Primary	INTERFACE OKAY
P3 IIT	Primary	INTERFACE OKAY
SATT	Primary	INTERFACE OKAY
N2SKID	Primary	INTERFACE OKAY
QCM016	Primary	INTERFACE OKAY
YOKA	Primary	INTERFACE OKAY
BATCH	N/A	Good
RDBMS1	N/A	Good
RDBMS2	N/A	Good

INTERFACES ON JACIECOAPI3

INTERFACE	MODE	STATUS
P2 IIT	Backup	INTERFACE OKAY
P3 IIT	Backup	INTERFACE OKAY
SATT	Backup	INTERFACE OKAY
N2SKID	Backup	INTERFACE OKAY
QCM016	Backup	INTERFACE OKAY
YOKA	Backup	INTERFACE OKAY
BATCH	N/A	Good
RDBMS1	N/A	Good
RDBMS2	N/A	Good

Sattline ECS Status:



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Defining Requirements – Process Validation

FDA: Process Validation

General Principles and Practices (Jan 2011)

Stage 1
Process Design

Stage 2
Process Qualification

Stage 3
Continued Process
Verification

Build
Process
Knowledge

Establish
Process
Control
Strategy

Design and
Qualify
Installation

Process
Performance
Qualification

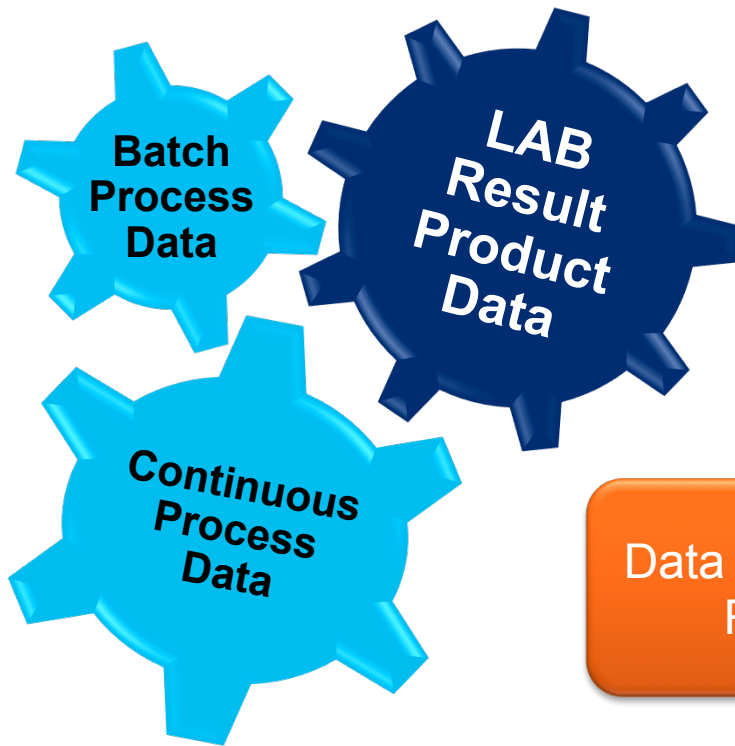
Ongoing
Program/
Process
Data

Process
Analysis/
Product
Data

Creating Solutions – Connecting Data

Process Data:

- **Batch Data:** From multiple source Control Systems – batch/ unit batch / step start and end times, durations, interactions, events, etc
- **Continuous Data:** From multiple source Control Systems – Reactor Temperature, Agitation Speed, etc



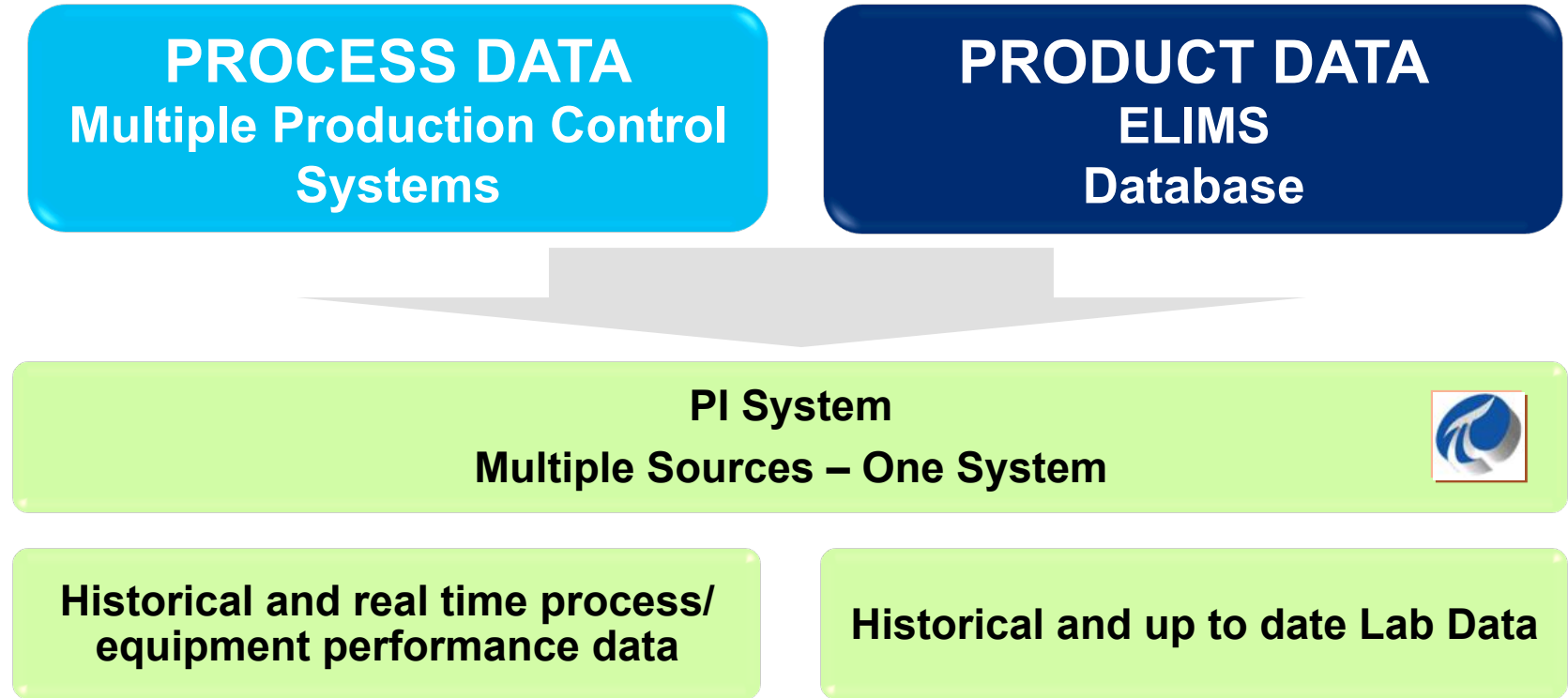
Product Data:

- **Lab Sample Test Result Data:** Critical Quality Attributes (CQAs) – Loss in Drying, HPLC Results, Assays, etc

Data NOW acquired and in Required Context

Creating Solutions – PI System

FDA's Process Validation guidance calls for continuous process verification.



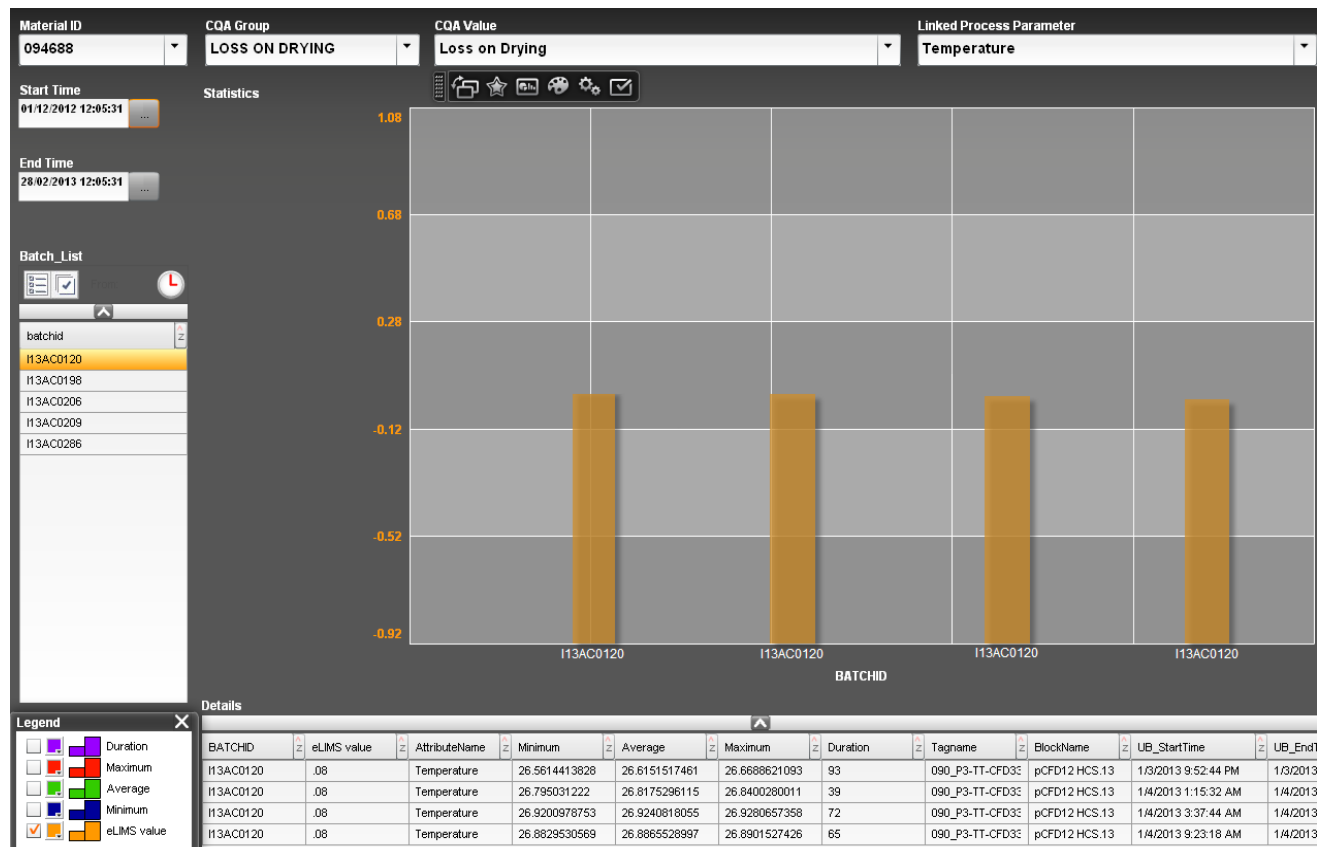
Creating Solutions – One System/ One View

VIEW PROCESS DATA

Batch Search
Batch Step Duration
Max Tag Value
Min Tag Value
Average Tag Value

VIEW PRODUCT DATA

Batch Search
Parameter List
CQA



Creating Solutions – One System/ One View

VIEW PROCESS DATA

Batch Search
Batch Step Duration
Max Tag Value
Min Tag Value
Average Tag Value

VIEW PRODUCT DATA

Batch Search
Parameter List
CQA



Creating Solutions – Data Retrieval, Review, Export

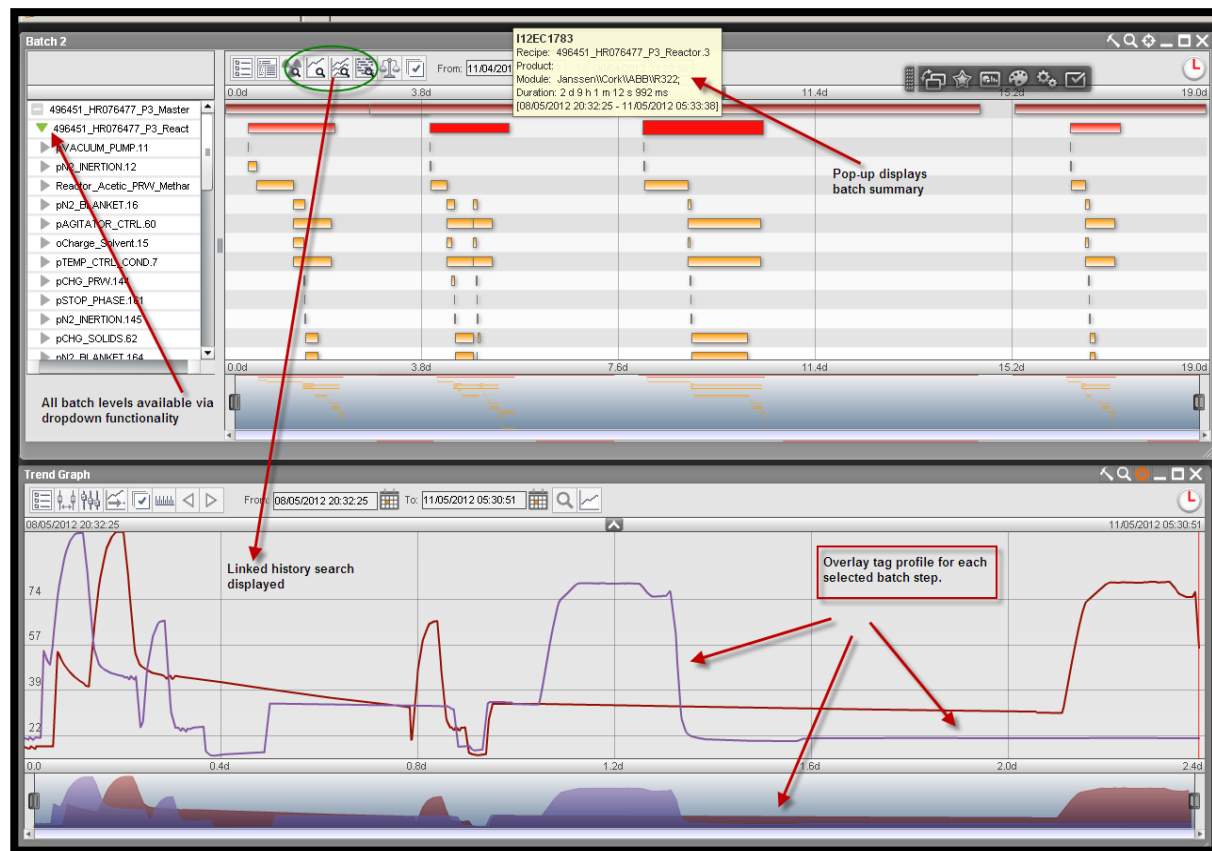
Data Selection And Retrieval

- Material ID
- ELIMS Parameters
- Linked Process Parameter
- Search Start and End Time
- Batch Search
- Batch List Populated



Creating Solutions – Linking out to Detailed Analysis

- Batch Data Analysis
 - Batch Search
 - Multiple Levels
 - Multiple Steps
 - Cycle Times
 - Export Facility
- Processing Data
 - Tag Search
 - Link to Batch Gantt
 - Multiple Batch Data
 - Overlay Analysis
 - Export Facility



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- Defining Requirements/ Creating Solutions

Supporting Elements

- Benefits and Next Steps

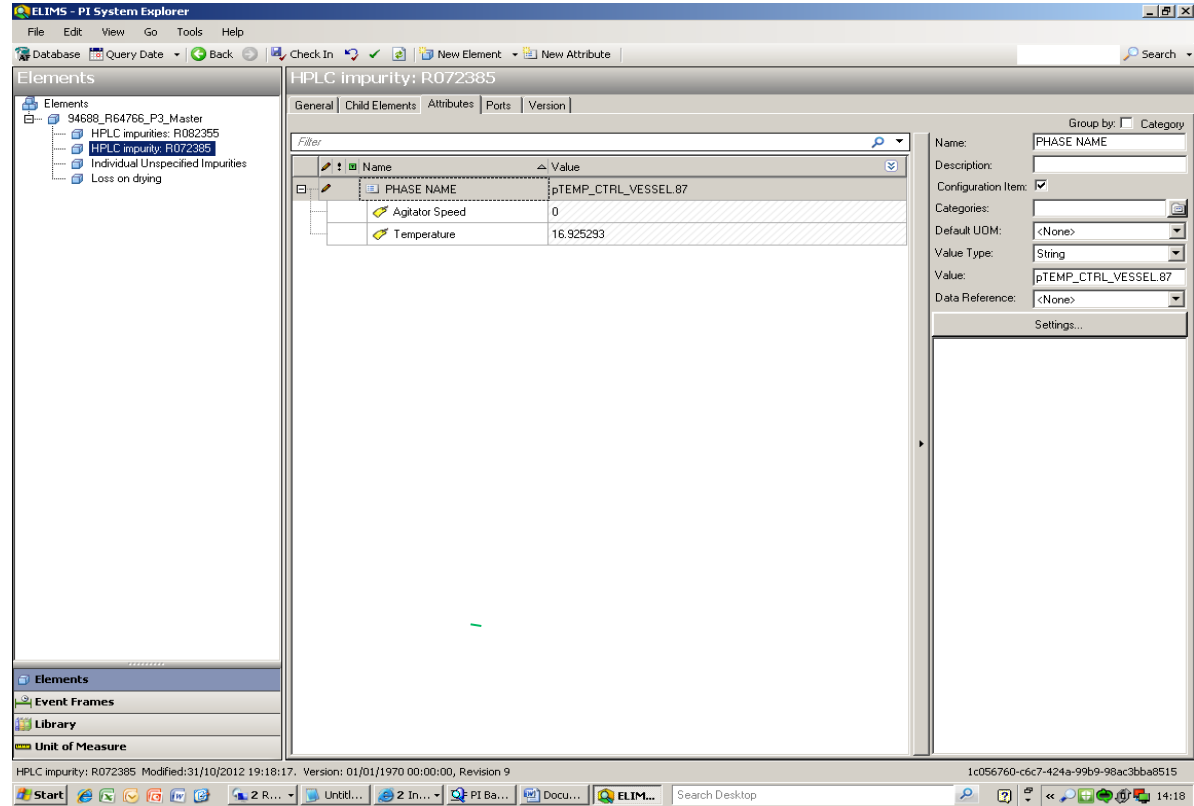
Supporting Elements - Foreword

- PI Interface Configuration Utility
- PI AF
- PI ACE
- Microsoft SQL Server 2008
- LivePoint from Mirabo Systems



Supporting Elements – PI Asset Framework

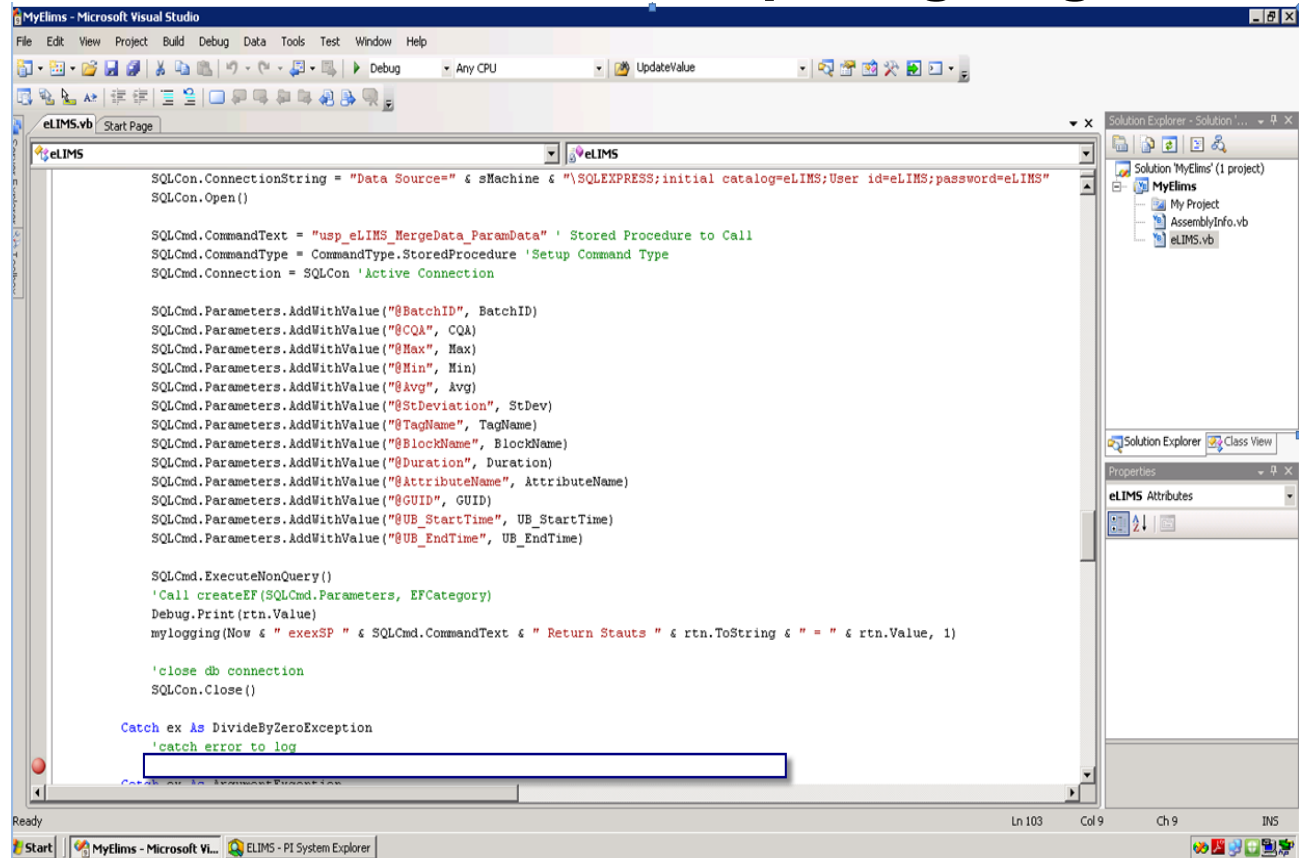
- Element Created for Process - S88 Model
- Sub element for each CQA
- Attributes represent linked process phases/ steps (S88 Procedural Model)
- Child elements represent CPPs:
PI tags –
temperature,
pressure,
etc



Supporting Elements – PI Advanced Computing Engine

- ACE Module executed
- PI AF Configuration inputs to ACE
- Code Retrieves Process Data-Batch events and tag values
- Retrieved Process Data written to SQL Database in

structured
format



Supporting Elements – SQL Server

SQL Server 2003

- Interaction with source DB too slow
- Intermediate Data Cache created

Structured

- Product Data from ELIMS Interface/ DB
- Process Data from PI ACE

Microsoft SQL Server Management Studio

Object Explorer: jaciecopis5\SQLEXPRESS (SQL Server 10.0.2531 - EU)

SQLQuery2.sql - jaciecop... (57) | SQLQuery1.sql - jacieco... (56)

```
/****** Script for SelectTopNRows command from SSMS *****/
SELECT TOP 1000 [BatchID]
, [COA_Translation]
, [Maximum]
, [Minimum]
, [Average]
, [StDeviation]
, [Tagname]
, [BlockName]
, [Duration]
, [GUID]
, [AttributeName]
, [UB_StartTime]
, [UB_EndTime]
```

BatchID	COA_Translation	Maximum	Minimum	Average	StDeviation	Tagname	BlockName	Duration	GUI	
1	I12HC2951	HPLC impurity: R072385	20.9122581482	20.8418197632	20.8817077724	NULL	090_P3-TT-R321-01.pv	pTEMP_CTRL_VESSEL.87	33.0000000000	h7c
2	I12HC2951	HPLC impurity: R072385	0.0000000000	0.0000000000	0.0000000000	NULL	090_P3-ST-R321-01.pv	pTEMP_CTRL_VESSEL.87	33.0000000000	h7c
3	I12HC2958	HPLC impurity: R072385	20.7727890015	20.6711959839	20.7433949265	NULL	090_P3-TT-R321-01.pv	pTEMP_CTRL_VESSEL.87	42.0000000000	00c
4	I12HC2958	HPLC impurity: R072385	0.0000000000	0.0000000000	0.0000000000	NULL	090_P3-ST-R321-01.pv	pTEMP_CTRL_VESSEL.87	35.0000000000	62c
5	I12GC2961	HPLC impurity: R072385	20.8577880859	20.7782669067	20.8325719912	NULL	090_P3-TT-R321-01.pv	pTEMP_CTRL_VESSEL.87	35.0000000000	62c
6	I12GC2961	HPLC impurity: R072385	0.0000000000	0.0000000000	0.0000000000	NULL	090_P3-ST-R321-01.pv	pTEMP_CTRL_VESSEL.87	35.0000000000	03c
7	I12HC2951	Individual Unspecified Impurities	21.0051422119	20.8883974311	20.9545537086	NULL	090_P3-TT-R321-01.pv	pFPR_MANIFOLD.28	81.0000000000	4f7
8	I12HC2958	Individual Unspecified Impurities	20.7927398682	20.6973495483	20.7383427758	NULL	090_P3-TT-R321-01.pv	pFPR_MANIFOLD.28	39.0000000000	4f7
9	I12GC2961	Individual Unspecified Impurities	20.8777694702	20.9638271368	20.9671355047	NULL	090_P3-TT-R321-01.pv	pFPR_MANIFOLD.28	36.0000000000	4f7

Query executed successfully. | jaciecopis5\SQLEXPRESS (10.0.2531 - EU) | admin_bhiggin2 (57) | master | 00:00:01 | 83 rows

Agenda

- Introduction
- Why MES in API
- Solution Architecture
- Supporting Elements



Benefits and Next Steps

Benefits and Next Steps - Building Solid Foundations

- **CPV Capability to Broad End User Spectrum.**

- *“Validation is an ongoing continuum of process design, process qualification and Continued Process Verification”*

- **Linking Product Data and Process Data**

- *“Recognition that more knowledge will be gained during commercial production than is present at the time of initial process qualification”*

- **Scalability**

- *S88 unified structure implemented. The system is structured so that we can add ALL materials. No limit to linked processing parameter elements in AF.*

- **Enhancing PI System**

- *“with the additional data, traditionally not available on the PI System, other useful data can be made available to the everyday user”*

Benefits and **Next Steps**

- Complete roll out to Business Units
 - Current focus on certain products. Expand the material list.
- RtReports for Annual Product Review
 - Product Data on PI. Visualization complete but what about reporting?
- Continue to Expand the PI System
 - EA , AF and ACE. A good foundation for *Event Frames* deployment.
- Bridge the Gaps
 - Connect with Process Development following Data Analysis Incentives like modelling, predictive tools.
 - Cross discipline knowledge sharing/ link with other groups.

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