OSIsoft®

USERS CONFERENCE 2016

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TRANSFORM YOUR WORLD

Migrating a Pharmaceutical Facility to Event Frames

Presented by **Myles Sumlin**
Lewis Cain

Genentech
A Member of the Roche Group

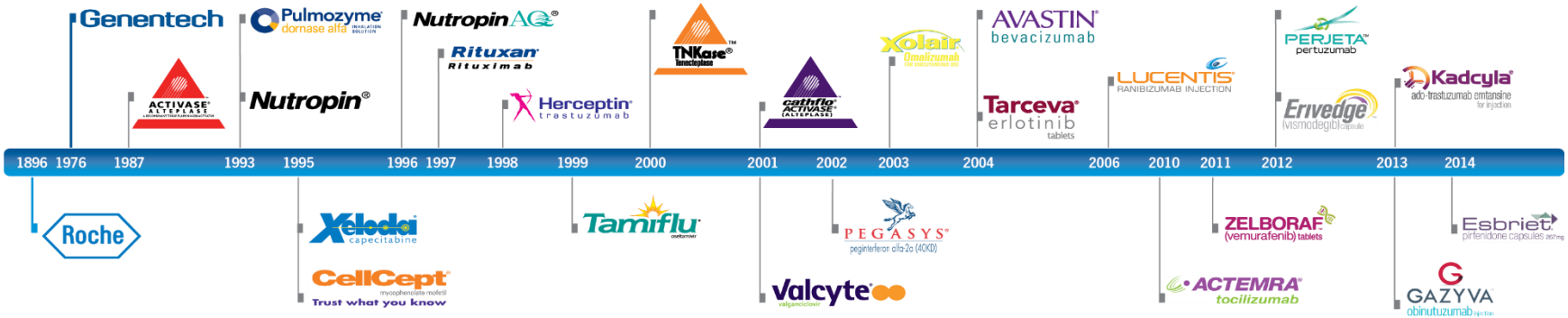
Genentech Fast Facts

- Founded in 1976
- Became a member of the Roche Group in March 2009
- Headquartered in South San Francisco, California
- Approximately 14,000 employees
- Headquarters for all Roche pharmaceutical operations in the U.S.
  - 35 medicines approved for people with various serious or life-threatening diseases
  - US Pharmaceutical 2014 sales: $17.4 billion*
  - Genentech's Research and Early Development group (gRED) has more than 30 potential new medicines in development

Roche Fast Facts

- Founded in 1896
- Headquartered in Basel, Switzerland
- Founding families still hold majority stake
- 88,500 employees worldwide
- Active in 150 countries and on every continent
- Global Roche Group 2014 sales: 47.5 billion Swiss Francs
- World’s largest biotech company
- Top five global leader in pharmaceuticals
- Number one leader in *in vitro* diagnostics

We make 35 medicines for people with serious diseases.



Doing now what patients need next

We believe it's urgent to deliver medical solutions right now – even as we develop innovations for the future. We are passionate about transforming patients' lives. We are courageous in both decision and action. And we believe that good business means a better world.

That is why we come to work each day. We commit ourselves to scientific rigor, unassailable ethics, and access to medical innovations for all. We do this today to build a better tomorrow.

We are proud of who we are, what we do, and how we do it. We are many, working as one across functions, across companies, and across the world.

We are Roche.

Control Systems Integration, Inc.

- Full service integration firm founded 1967, incorporated 2003
- Dedicated PI System Services Division w/ 16 engineers
- Headquartered in Phoenix, AZ
- PI Services include architecture/design/build, consulting, upgrades, custom modules/applications and customized training
- Control systems include MES, PLC, DCS, SCADA
- Large scale delivered PI System solutions include:
  - Pharmaceutical/Biotech with full 21-CFR compliance, IQ/OQ/PQ
  - Electrical transmission/distribution/generation with NERC/FERC/CIP compliance
  - Largest MDUS Smart Grid application in the United States (8.5m tags)
  - Lithium extraction from Geothermal Brine Water

www.control-si.com

Challenge: Addressing User Need

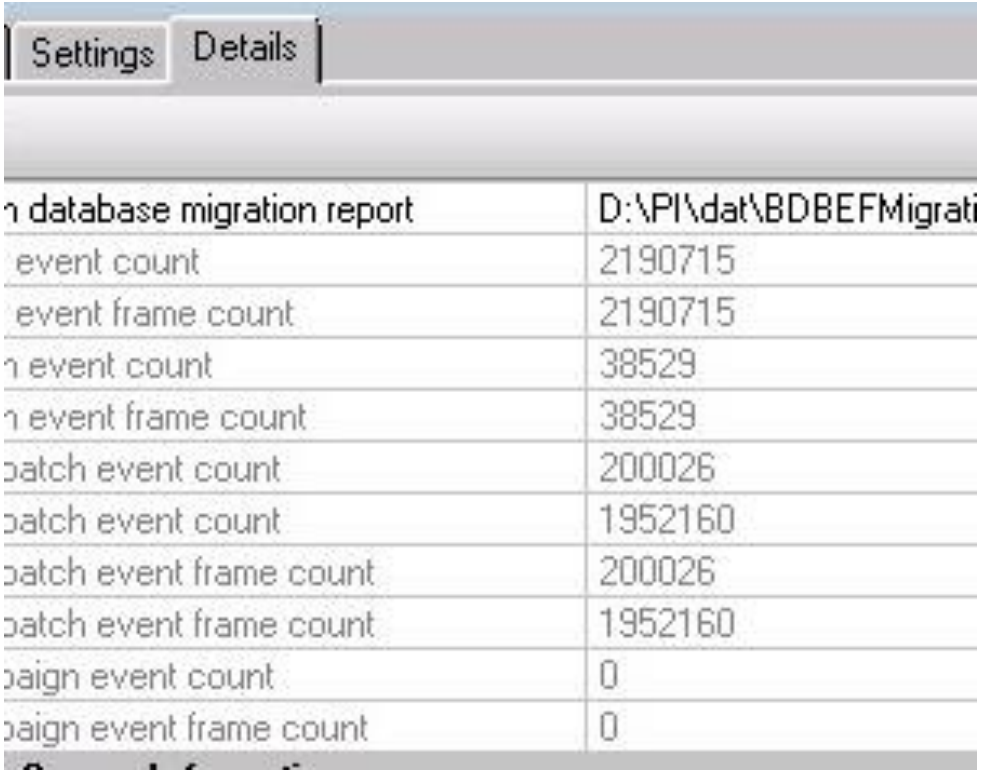
- Users spend countless hours analyzing PI System data in spreadsheets
- Many KPIs are calculated in Control System (DeltaV) and later documented in batch report
- Other KPIs are calculated manually after transferring PI System data to other tools (Excel, Matlab, etc.)
- Not all process data is directly linked to PI Batch infrastructure

Challenge: Addressing User Needs

- Event Frames???
- Change is Difficult
- System is Validated
- Migration Tool delayed
- Early Adopter reputation

Development

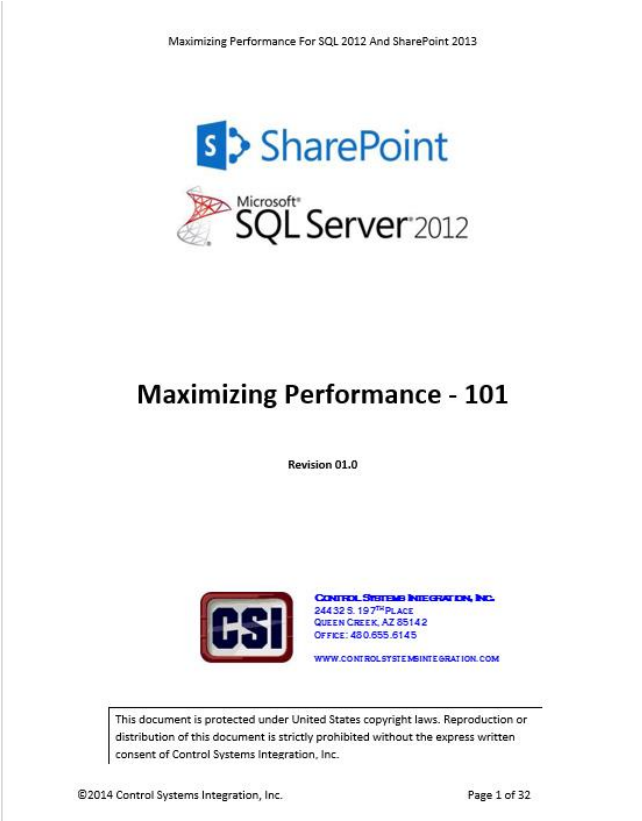
- Virtual environment for offline development
- PI Server 2015 Upgrade
- Migrated a couple of years of batches using Migration Tool
- Tested event frame generation using EMDVB Interface
- Confirm batch overlay functionality of PI BatchView is not required



Migration Preparation

- AF Server
  - 16GB minimum memory
  - Delete existing collective
  - Maximize hard drive size
- SQL Server
  - Dedicated 12GB memory
  - Configure Auto-growth
  - Remove all Replication
  - Add account for AF Link to PI for the PIFD database
  - Add the service account that will be used for the EF Gen Interface Manager

Contact CSI for a free copy of our SQL Configuration guide.


Maximizing Performance For SQL 2012 And SharePoint 2013

SharePoint

Microsoft SQL Server 2012

Maximizing Performance - 101

Revision 01.0

CSI

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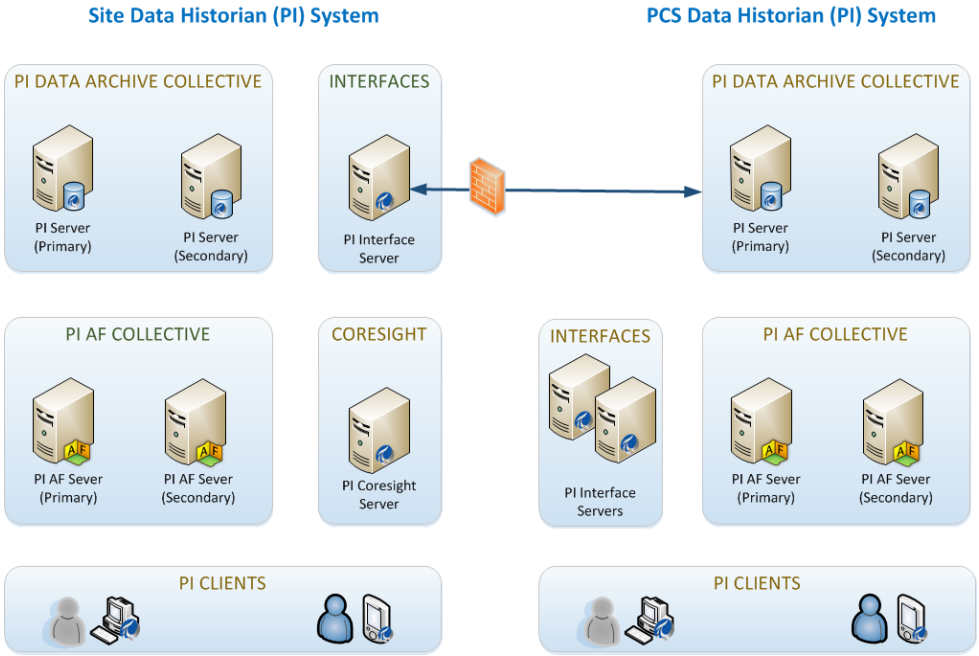
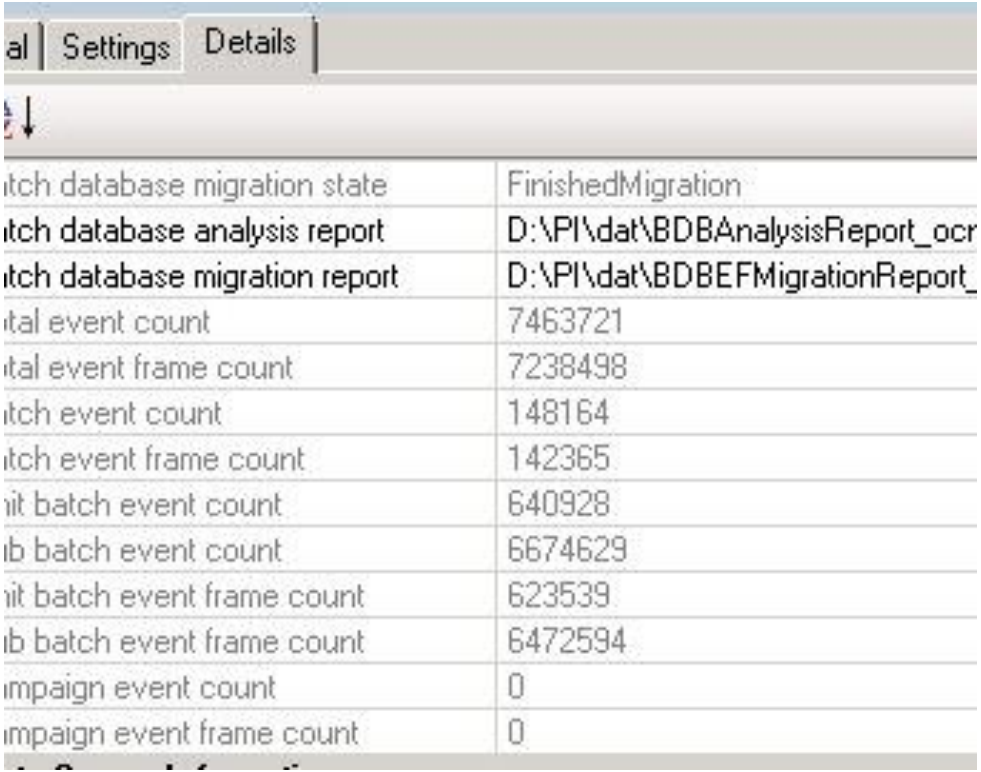
Deployment – PI Server 2015

- Upgrade completed in Fall 2015
  - PI Server 2015 R2
  - AF Server 2015 R2
  - PI Coresight 2015
  - EMDVB Interface
- PI to PI Interface connects both PI HA systems



Deployment – Batch Migration

- Batch data from April 2006
- 7.2 million events migrated
- Training
  - New client tools
- Communication to users
  - Downtime only impacts Batch Data
  - 3 days of downtime



Implementing EF Templates

- Determine user requirements

Purification Step Yield:

Step yields are calculated and compared to established ranges as part of the batch record for all purification steps. Step yield is calculated as follows for each purification step: pooled mass/processed mass x 100 (expressed as percent of theoretical). In order to ensure consistent calculation across sites, detailed calculations for step yield are shown in Equation 4 below.

Equation 4:

$$\%\ Step\ Yield^{*} = \left[\frac{Pool\ Titer\left(g/L\right) \times Pool\ Volume\ (L)}{Load\ Titer\left(g/L\right) \times Load\ Volume\ Processed\ (L)}\right] \times 100\,\%$$

* Load volume can either be: (a) load volume processed (in the case where load mass is discarded to remain within load density limits only the actual volume loaded on the column is used for calculation; in the case of multiple cycles, the loaded volumes of all cycles are added up) or (b) volume from load tank.

Equation 2: Integrated Viable Cell Count

$$iVCC = \int_{0}^{t} VCC(t)dt\,,$$

where

t = culture duration (days),
VCC = viable cell count (x10^5 cells/mL)

Equation 1: Specific Growth Rate

$$\mu = \frac{\ln \frac{N_2}{N_1}}{t_2 - t_1}$$

where

N = cell density (PCV or VCD),
t1 = culture duration associated with initial sampling/measurement operation (days)
t2 = culture duration associated with final sampling/measurement operation (days)
μ = specific growth rate

Implementing EF Templates

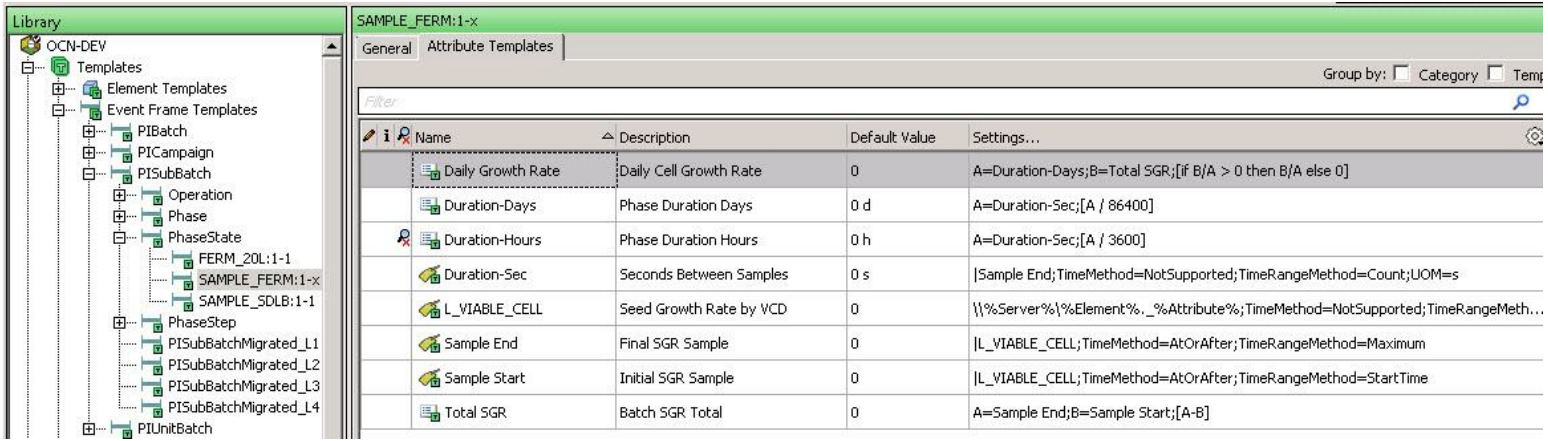
- Convert requirements to EF Templates

Equation 1: Specific Growth Rate

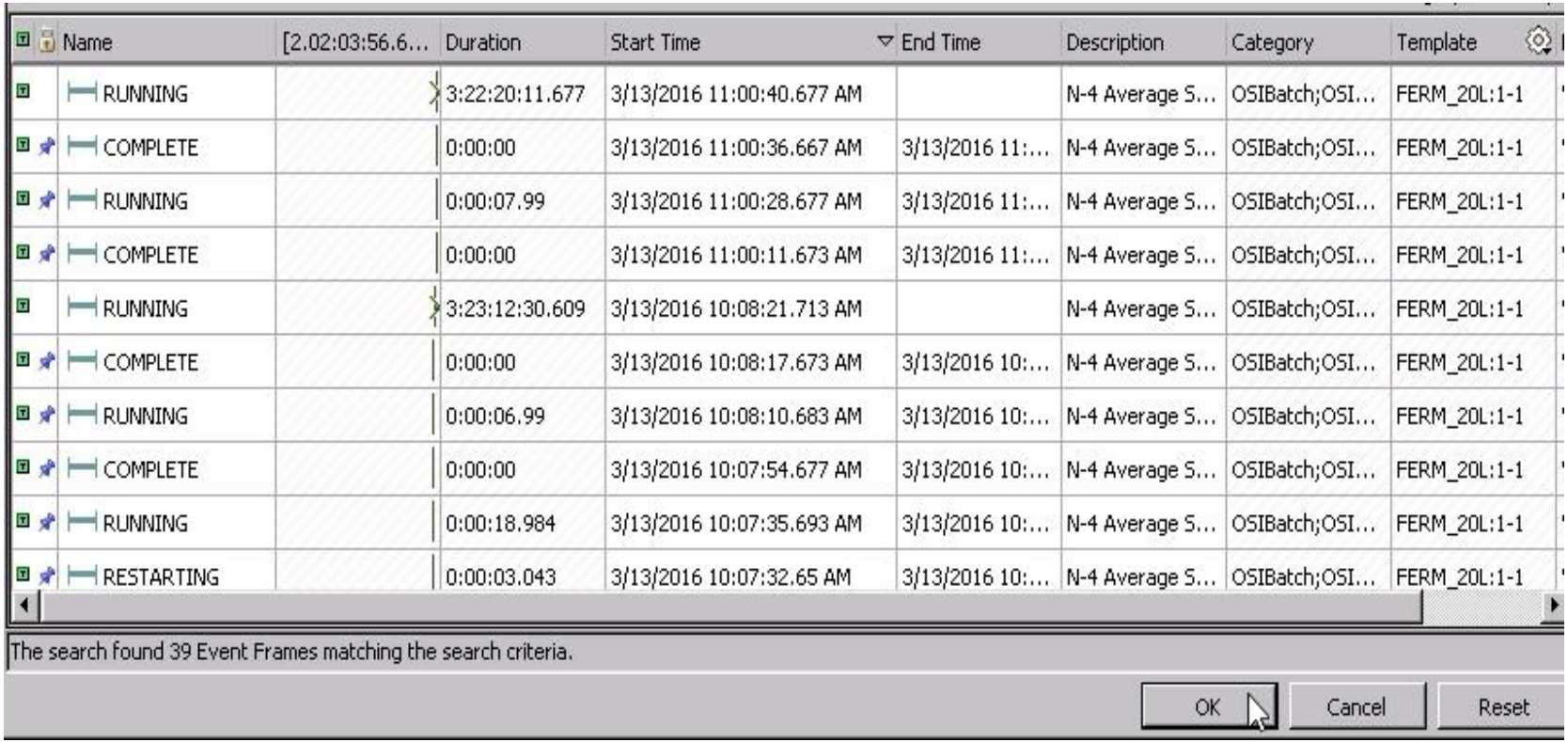
$$\mu = \frac{\ln \frac{N_2}{N_1}}{t_2 - t_1}$$

where

N = cell density (PCV or VCD),
t1 = culture duration associated with initial sampling/measurement operation (days)
t2 = culture duration associated with final sampling/measurement operation (days)
μ = specific growth rate



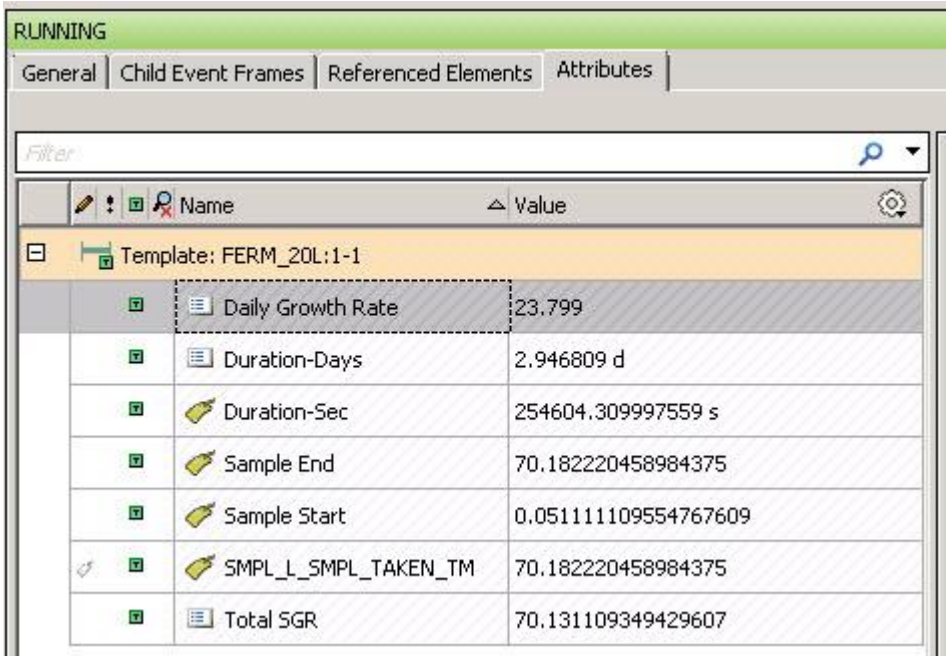
Template Generated EF's



Name	[2.02:03:56.6...	Duration	Start Time	End Time	Description	Category	Template
RUNNING		3:22:20:11.677	3/13/2016 11:00:40.677 AM		N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
COMPLETE		0:00:00	3/13/2016 11:00:36.667 AM	3/13/2016 11:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
RUNNING		0:00:07.99	3/13/2016 11:00:28.677 AM	3/13/2016 11:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
COMPLETE		0:00:00	3/13/2016 11:00:11.673 AM	3/13/2016 11:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
RUNNING		3:23:12:30.609	3/13/2016 10:08:21.713 AM		N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
COMPLETE		0:00:00	3/13/2016 10:08:17.673 AM	3/13/2016 10:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
RUNNING		0:00:06.99	3/13/2016 10:08:10.683 AM	3/13/2016 10:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
COMPLETE		0:00:00	3/13/2016 10:07:54.677 AM	3/13/2016 10:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
RUNNING		0:00:18.984	3/13/2016 10:07:35.693 AM	3/13/2016 10:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1
RESTARTING		0:00:03.043	3/13/2016 10:07:32.65 AM	3/13/2016 10:...	N-4 Average S...	OSIBatch;OSI...	FERM_20L:1-1

EF Attributes

- Allows users to view values immediately
- No need to wait on the EBR from the MES
- Attributes are used in PI DataLink upon phase completion



Lessons Learned

Being the 1st large scale pharmaceutical to utilize OSIsoft EF Migration, issues were expected!

- PI Event Frames Generator V. 4.0.21.200 had to be removed (recalled by OSIsoft) due to numerous issues, had to revert to V. 4.0.11.104.
- Security issues with PI Event Frames Generator prevented access to SQL unless you logged in as the service account.
- Found Event Frames below the second level were not created by the interface when in Realtime or Recovery mode if a reference element is defined at the second level.
- Worked diligently with OSIsoft Technical Support and the OSIsoft EF Development Team to overcome the issues encountered, their support was invaluable for our success.

Users are already benefiting from Event Frames

- Time Savings
- Confidence
- Change procedures

Next Step: Add more templates

- Many more KPIs
- Link EF templates to PI Notifications
- Build out AF Analyses templates
- Create reports with PI DataLink for users

Contact Information

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Questions

Please wait for the **microphone** before asking your questions

State your **name & company**

Please remember to…

Complete the Online Survey for this session

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감사합니다

谢谢

Danke

Gracias

Merci

Thank You

ありがとう

Спасибо

Obrigado

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