

## Coresight in Genentech PTD

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## **Agenda**

- Genentech / Roche Background
- Problem Statement
- History of Historization in PTD
- Current State
- Challenges
- Benefits of PI Coresight
- Plans

## Genentech / Roche Background

- Roche acquired Genentech in 2009
- 3 new drugs approved in 2012 and 2013, including the first antibody-drug conjugate approved by the FDA
- 31 drugs in Phase II or Phase III (Source: www.gene.com)

## Genentech / Roche Background

- PTD = Process Technical Development
- Roughly 500 users accessing data from cell culture and purification pilot plants and several cell culture labs
- 2 PI servers 60000 points & 6000 points
- Over 350 units sending data to PI

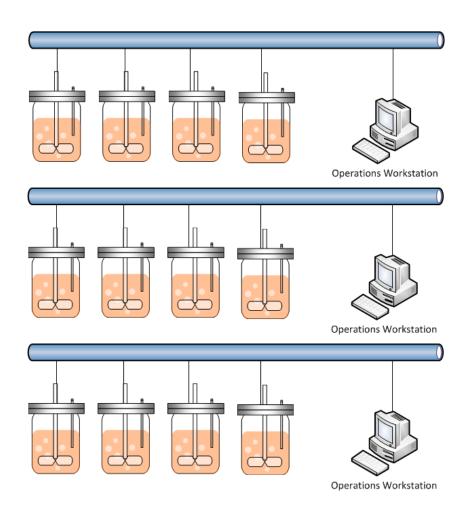
#### **Problem Statement**

All these new drugs and increased global collaboration since the Roche acquisition require better access to process development data.

## **History of Historization in PTD**

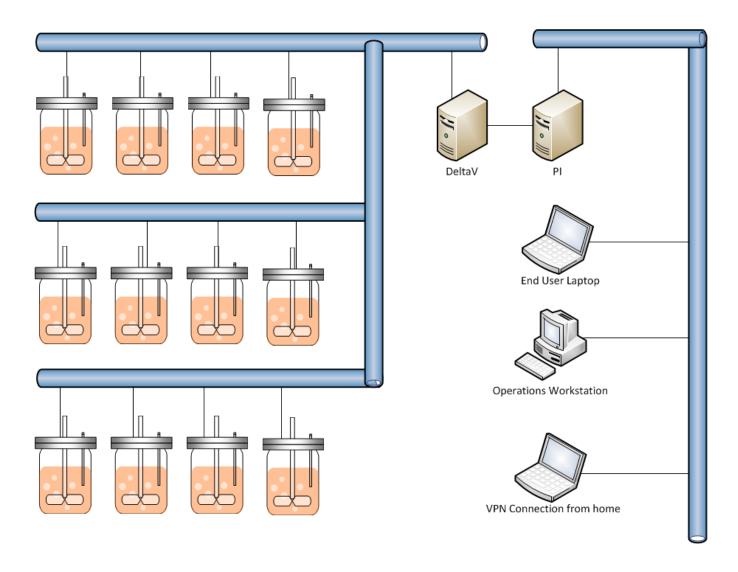
- In 2009, majority of data collection was localized on LabVIEW based systems
- 1 DeltaV system with embedded PI
- Frequent data loss and lots of support hours
- All data exported to Excel for review and analysis

### **History of Historization in PTD**



## **History of Historization in PTD**

- 2009 Cell Culture PI Server installed
- 2010 4 DeltaV systems sending data to PI
- 2010 Purification skids migrated from IP21
- 2011 Custom web client developed by GAP
- Since Additional analyzers, systems added

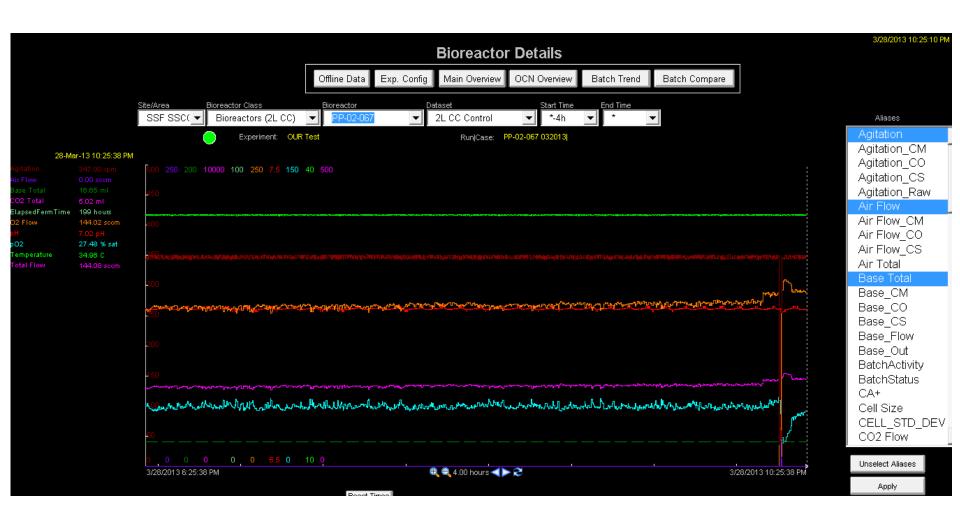


# Data Sources DeltaV Systems Rockwell PLCs Nova Analyzers GE PLCs Dasgip Bioreactors Foxboro DCS PI Clients PI ProcessBook / ActiveView Displays Data Report Tool Custom Web Client Matlab Analysis Tool PI Coresight

- PI is the primary software for trend review
- Multiple analytic tools built from one core system
- Preferred historian platform across the Roche network

- Pre-configured displays to ease navigation
- 40 ActiveView displays for on the floor of the labs and pilot plant
- 4 PI ProcessBook terminal servers
- Limited use of DataLink or local PI ProcessBook install
- Custom web based PI client

## PI ProcessBook Displays



#### **Custom Web Client**



## **Custom Web Client Challenges**

- Still difficult to share trends
- Difficult to service
- Future development expensive
- No mobile platform

## 2011 – PI Coresight on the Horizon

COTS = lower development and maintenance costs, relative to custom web client

Web based = less client install support

Very easy to share trends, not just screen shots

## PI Coresight in PTD

- Enrolled in beta test in November 2011
- Commercial release installed in January 2012
- Gathering regular feedback from a select subset of end users (PTD pilot deployment)

## Challenges to Implementing Pl Coresight

- Primary PI Server on 3.4.380 (no AF)
- Limited user experience with PI ProcessBook
- Lack of batch relativity
- Unable to specify pen colors

## **Current State of PI Coresight**

- 75 users
- 240 displays
- Still in pilot, not released to all users
- Limited application of AF element templates and categorization

## PI Coresight Benefits

- Mac compatibility
- Easy to share email a link to a trend, not just a screenshot
- Ease of use first time users don't need extensive instruction
- iPad App allows for on the go trend review

## iPad App



#### For the future

- AF structure providing asset relativity
- Event frames providing batch relativity
- Auto-generated displays from url
- Navigation improvements from Sharepoint(?)

