



OSIsoft. USERS CONFERENCE 2014

The **Power of Data** **DECISION READY IN REAL-TIME**



Reversing the Paradigm: Being Strategic About Data Management

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Process Development Operations

Summary



OSIsoft. USERS CONFERENCE 2014
The Power of Data DECISION READY IN REAL-TIME



✓ Reverse the Paradigm: Be Strategic About Data Management by Starting In Process Development

- The work product of Process Development is process knowledge in the form of data - the foundation of the technology transfer to Manufacturing.
- Manufacturing data strategies include the implementation of OSIsoft PI System to monitor data and better regulate & control the process.

But why wait until Manufacturing has begun?

We will outline the value and the rationale for implementing OSIsoft PI System first in Process Development. Topics will include:

- Why implementing in Process Development first is strategic and forward thinking
- How to assess what the tipping point is to invest in Process Development
- How tech transfer becomes more efficient and effective with OSIsoft PI System
- How OSIsoft PI System data can be strategically used in PD to make faster and more confident data analysis

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Today Shire is a Fully-Integrated Specialty Pharma Co



- Founded in UK in 1986
 - Offices in 30+ countries
 - Key sites: US, UK & Switzerland
 - Continued international expansion, including Japan, China & Brazil
-



- ~5,000 employees, including >1K engaged in Research & Development
 - Committed to a BRAVE culture and being patient focused
-



- Now sell products in more than 50 countries
- ~\$5B in sales and a market capitalization of ~\$30B*
- Historical compounded revenue growth of ~15.7% since 2003
- Listed on London Stock Exchange and NASDAQ (SHPG)

*As of March 27, 2014 (share price of 3056p; ADS \$150.89)

Shire Process Development Organization

- Process Development is Focused on Biotherapeutics for rare diseases:
- ~175 scientists/engineers
- ~15 programs in development at any given time
- >3000 pieces of equipment
- Standard unit operations
 - Bioreactors
 - Clarification
 - UFDF (Ultra-Filtration, Dia-Filtration)
 - Protein Chromatography
 - Lyophilization
- The Department develops and scales up processes for transfer to Manufacturing

Reversing the Paradigm

Shire implemented the OSIsoft PI System First in Process Development
(Manufacturing was not first!)

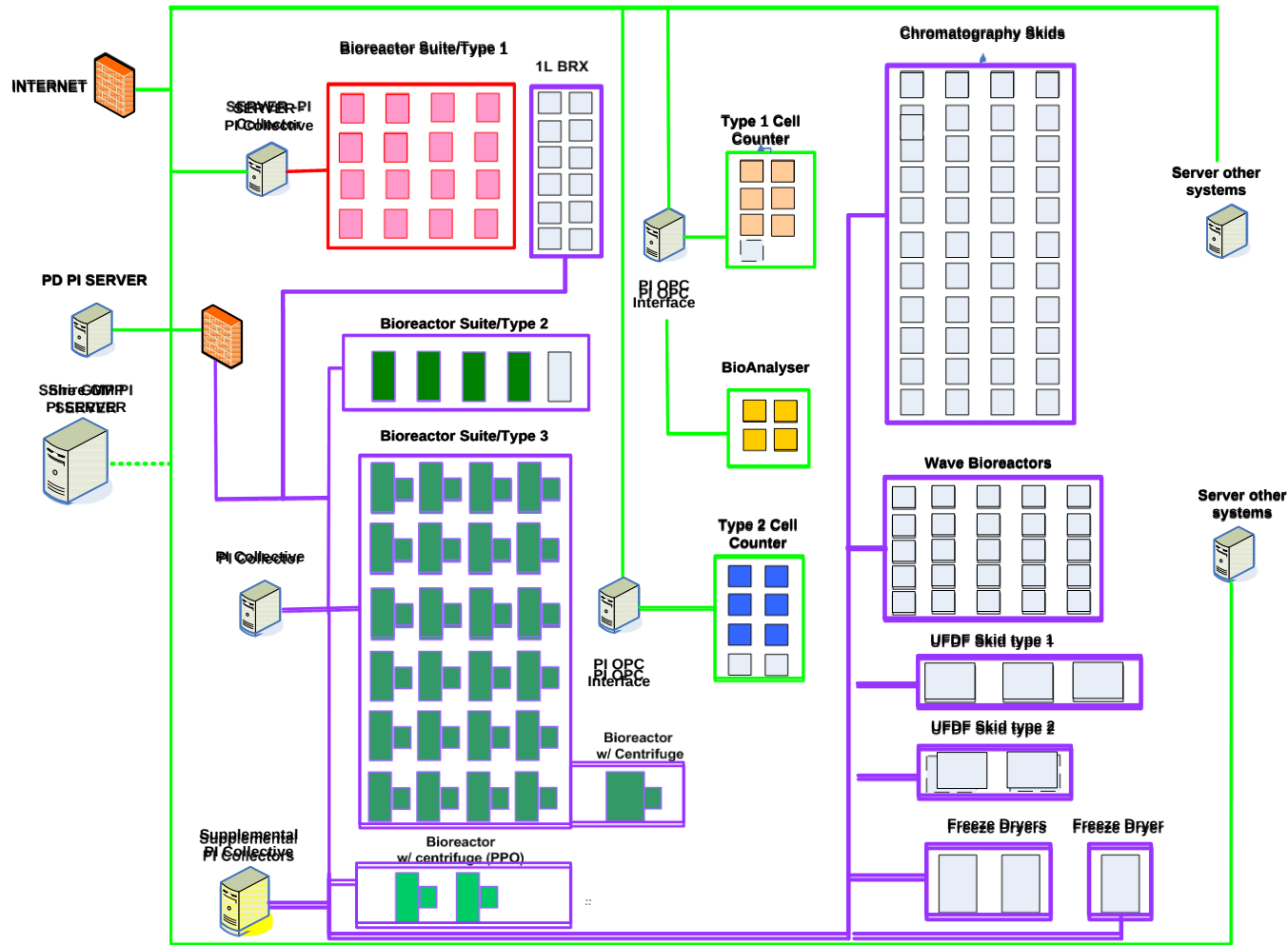


Why is this significant?

1. Process Development is recognized as a key generator of data, a place to invest in infrastructure
2. Data monitored in Manufacturing is only a subset of the data generated in Process Development
3. Efficiency in Process Development translates to efficiency and robustness for technology transfers to Manufacturing
4. Process Development is a controlled environment but not a GxP environment, so implementation can be agile, and test protocols can be vetted.

Comparison of PD and Manufacturing Infrastructure

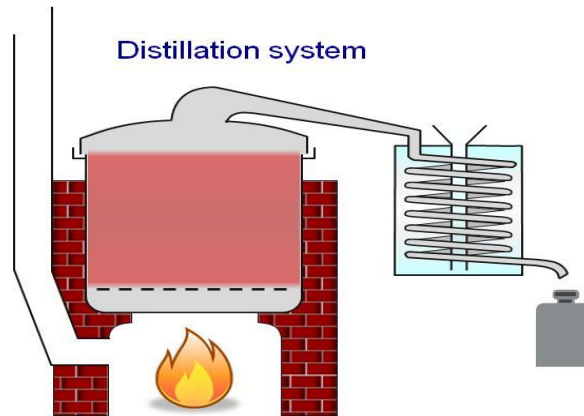
Process Development systems



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Data Management is like the Chemistry of Distillation

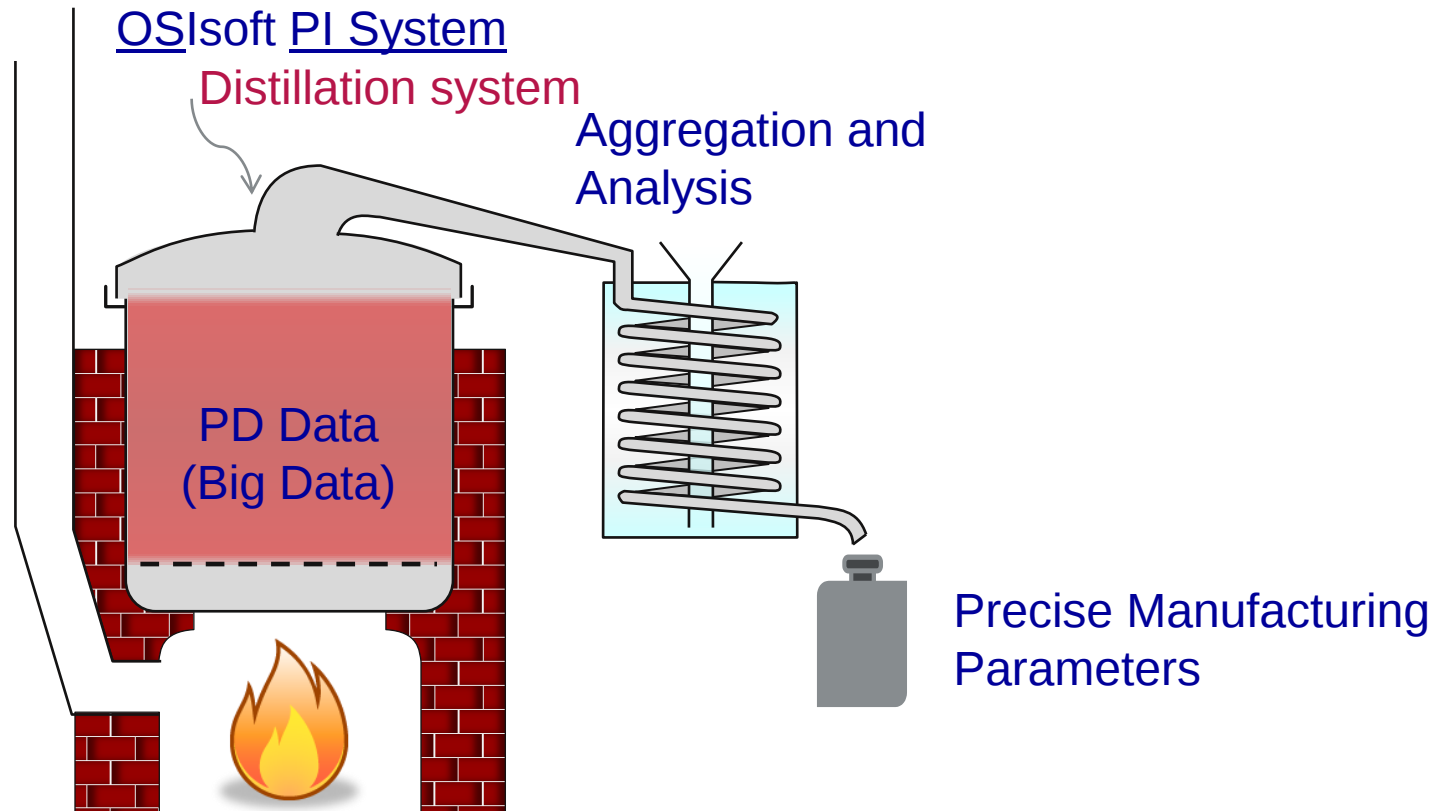


Distilling large volumes

The result of distillation of large volumes
of Malts in vats...
Produces these Fine Spirits.



Distilling Big Data

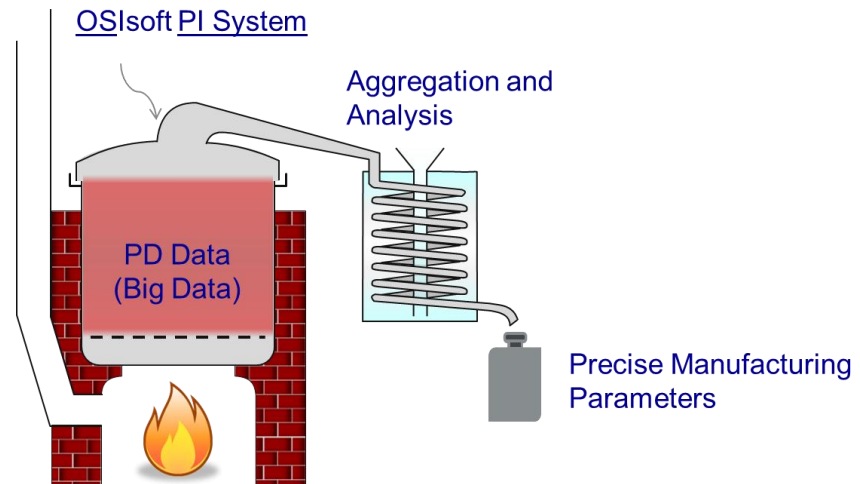


Volumes of data are generated in PD and distilled to the exact parameters to be monitored before being transferred into Manufacturing

One Platform

OSIsoft PI System Provides the Perfect Platform for:

- Managing Big Data
- Technology Transfer Data Management
- Process Development Efficiency
- Data Integrity



The OSIsoft PI System Advantage to Technology Transfer

- If you build the templates, definitions and trends in OSIsoft PI System for a process in PD, these items are ready to go for Manufacturing when its time for Technology Transfer
- Comparison between PD and MFG become simple and fast, enabling real time data analysis



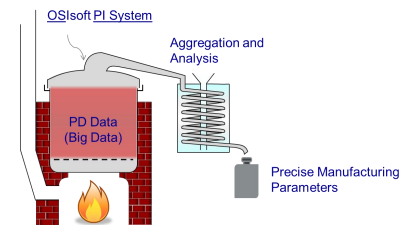
The OSIsoft PI System Advantage to Process Development Efficiencies

- The volume of systems and the number of simultaneous experiments makes Data Management in Process Development challenging



A Panacea:

OSIsoft PI System provides a platform that enables scientists to maintain their independence for their studies while providing a means to easily aggregate data for analysis (distillation)



PD Challenges for Cell Culture Bioreactor Labs

- **Integrity:** Data is not always backed up. Finite storage space means data can eventually get overwritten – resolved at Shire with OSIsoft PI System
- **Storage:** Large volumes of data from multiple platforms is not always stored centrally. Downloading & aggregating data from multiple sources for analysis is time consuming – resolved at Shire with PI System
- **Utilization:** Data is not always utilized fully. Decisions can be made from the analysis of a partial data set (offline data).
- **Tech Transfer:** Data package for technology transfer and production support is not always as robust as desired – resolved at Shire with OSIsoft PI System



Business Case for Implementing OSIsoft PI System for PD

Bioreactor Data Management Project

Date: 9 May Owner: David S., Chris A. Approval Date: Manager Approval:

PD-IT TEAM

PROMOTE PI AS THE CROSS-INDUSTRY, BARRIER-BREAKING PERFORMANCE.

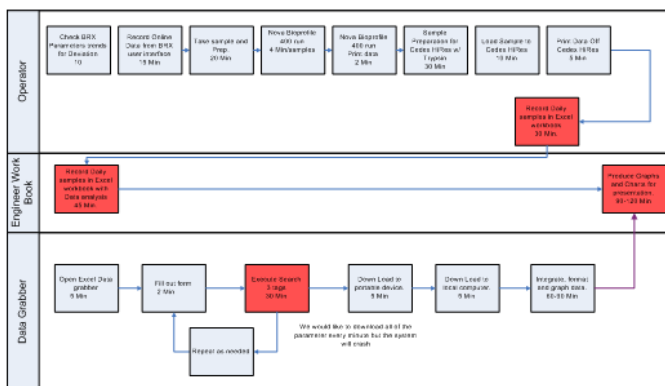


BACKGROUND

- Large Scale Development Lab (LSDL) and the Bioengineering labs currently have three independent bioreactor systems, running a total of ## bioreactors of various sizes.
- There are ## lab scale bioreactors in Bioengineering on the Finesse Delta V system, ## lab scale bioreactors in Bioengineering on the Sartorius MFCS control system and ## pilot scale bioreactors on the Finesse Delta V control system in LSDL.

CURRENT STATE

Data from the three independent bioreactor systems is not stored in a central location; it is not routinely backed up and can be overwritten due to finite storage space. An increased amount of time and effort is required to access the data since it is not stored centrally and it is necessary to utilize portable storage devices to download data from each bioreactor system and then upload it onto desktop computers. Due to this increased effort online data may not be fully analyzed, therefore process decisions are made from the analysis of a partial data set.



Bioengineering & LSDL are unable to.....	Business Impact		
	Data Integrity	Decision Making	Resource Time
Perform batch reporting – download tags by batch externally with real time and historical context		X	X
Access bioreactor data/process data remotely	X	X	X
Easily retrieve system data for analysis without significant resource commitment/time	(transcription)	X	X
Store data globally (it is not backed up) – it is only stored locally	X	X	X
Compare/trend real-time data to historical data electronically – only historical data can be downloaded		X	
Easily access data from Finesse backup files, Sartorius backup is very laborious, therefore, not done	X	X	X
Collate offline data with batch data – it's treated as a separate entity	X	X	X
Gain desktop access for real time and historical data		X	X

ANALYSIS

Bioreactor Sampling (Per Experiment of 4 hours)						
Current state	Phase 1	Phase 2	Cumulative			
Time (min)	NVA Time (min)	Time (min)	NVA Time (min)	Time (min)	NVA Time (min)	
15	15	0	0	30	15	
20	20	0	0	50	35	
10	10	10	10	60	45	
30	30	0	0	90	75	
45	45	0	0	135	120	
15	15	15	15	150	135	
Cycle time	100	100	100	100	100	100
Cycle time reduced by:	45	45	45	45	45	45
Cycle time % reduction	45%	45%	45%	45%	45%	45%

Back Up Data (per System) (Per Month)						
Current state	Phase 1	Phase 2	Cumulative			
Time (min)	NVA Time (min)	Time (min)	NVA Time (min)	Time (min)	NVA Time (min)	
20	20	0	0	20	20	
60	60	0	0	80	80	
20	20	20	20	100	100	
10	10	10	10	110	110	
20	20	20	20	130	130	
Cycle time	100	100	100	100	100	100
Cycle time reduced by:	80	80	80	80	80	80
Cycle time % reduction	80%	80%	80%	80%	80%	80%

Tag Info collection per run 12 bags (Per Month)						
Current state	Phase 1	Phase 2	Cumulative			
Time (min)	NVA Time (min)	Time (min)	NVA Time (min)	Time (min)	NVA Time (min)	
150	150	0	0	300	150	
5000	5000	0	0	5300	2700	
Cycle time	5000	5000	5000	5000	5000	5000
Cycle time reduced by:	4850	4850	4850	4850	4850	4850
Cycle time % reduction	97%	97%	97%	97%	97%	97%

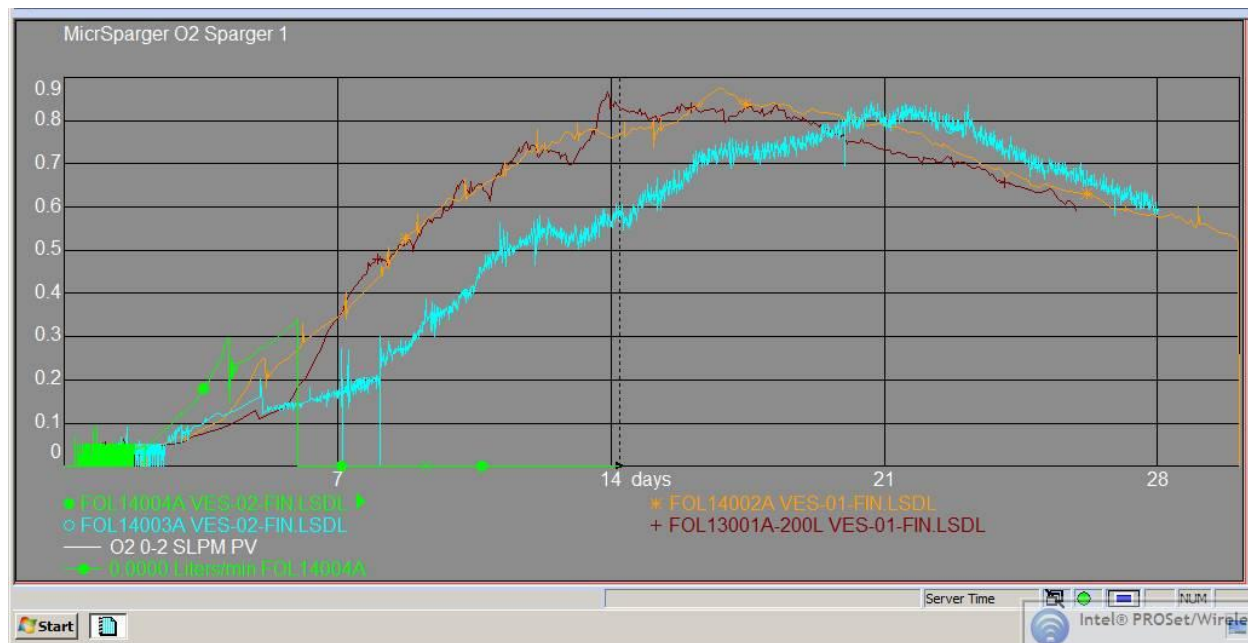
GOAL (Business Value)

This project will increase decision making integrity for bioreactor process development work by providing:

- Data Integrity:**
 - Capture – Collect data from multiple bioreactor sources and sites and associated analytical equipment in a central location
 - Result: Reduce Transcription Errors – Eliminate the current data transcription process which includes recording from bioreactor to lab notebook and then lab notebook into excel spreadsheet
 - Backup/Disaster Recovery – To have data backed up on a predefined frequency with a disaster recovery plan in place
 - Result: Be able to recover data after adverse events
- Data Accessibility:**
 - Centralized Data Storage – To have data from multiple bioreactor sources and sites and associated analytical equipment accessible in a central location
 - Local vs. Remote Access – Accessible for multiple users at multiple locations (e.g. personal workstation, offsite, SharePoint)
 - Result: Reduce time and resources required to access the data
- Data Usability:**
 - Search – Be able to search data by batch identification
 - Trending – Have data available for real time and historical trending, comparisons, data analysis by searchable batch identification
 - Analysis – Be able to perform batch analysis with continuous data instead of single point analysis as is currently done
 - Result: Reduce rework and increase decision quality
- Future Expandability:**
 - A requirement for the system is that it be based on a universal platform to enable it to communicate with other Shire systems, other Shire sites, and other enterprise systems for future growth.
 - Result: Be able to meet immediate data needs through a capital purchase that will provide a solid foundation for future growth.

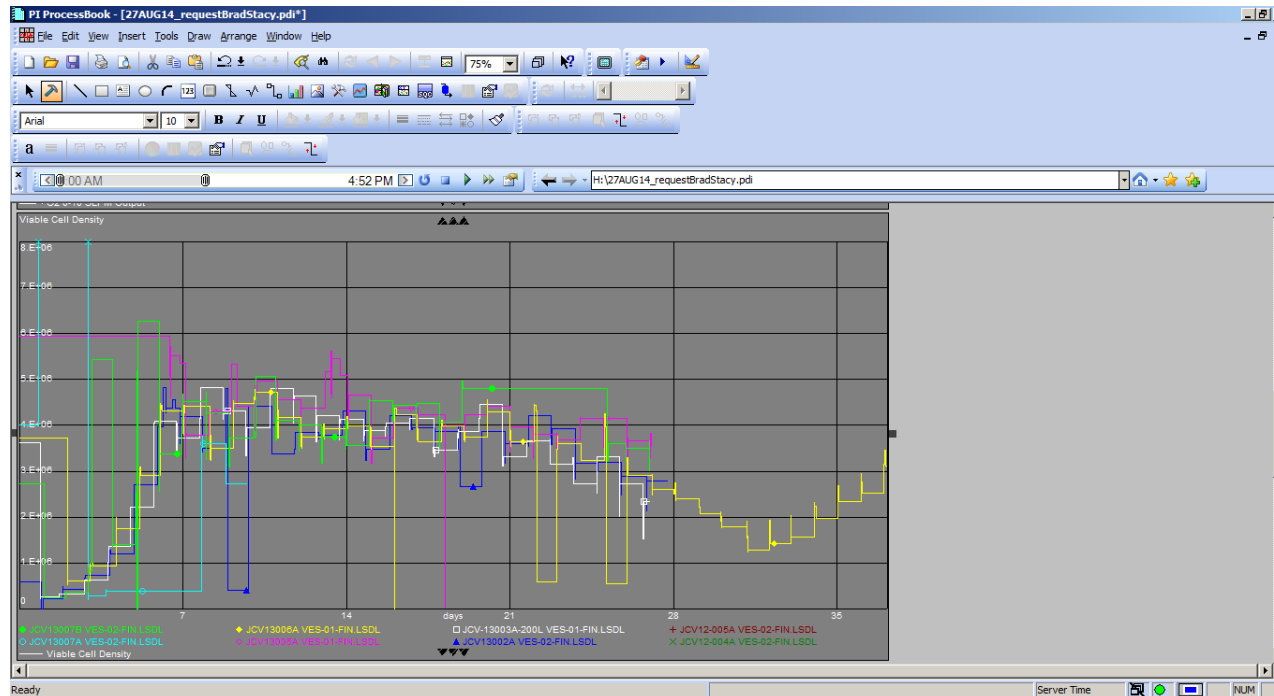
Fast and Confident Data Analysis

- With a few clicks of the mouse, batch comparison and troubleshooting is possible.
- In this example, the scientist was able to quickly draw conclusions about whether oxygen usage lag was a result of the bioreactor inoculation density



Fast and Confident Data Analysis

- Scientists spend their time analyzing data instead of aggregating data manually. They log into the system to assess how the current run compares with historical experience. No transcription or copy/paste necessary.
- Notifications are sent daily.



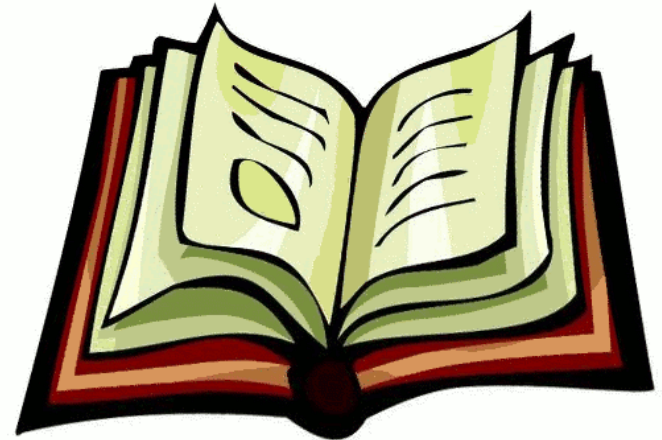
Benefit of Integrating Discrete and Streaming Data into OSIsoft PI System

Streaming bioreactor data from the control systems:

- Dissolved Oxygen
- On line pH
- Temperature

Coupled with discrete offline data

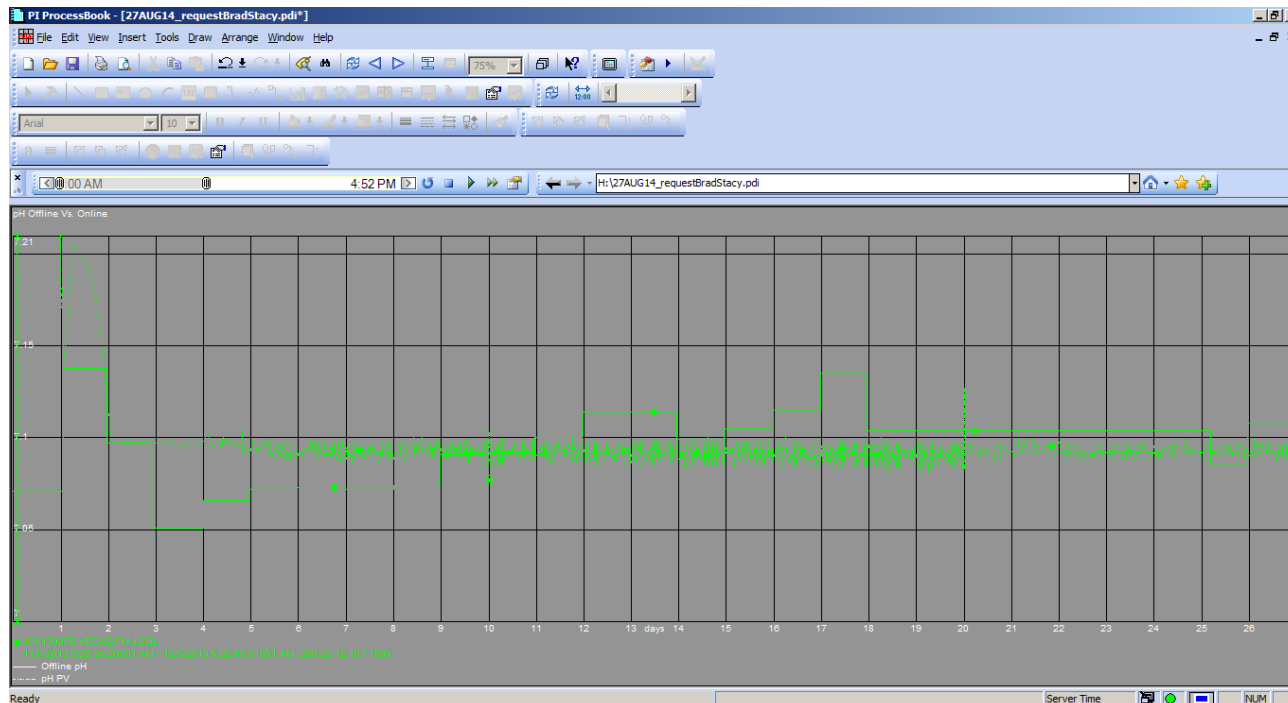
- Cell count
- Metabolites
- Off line pH



Tell the complete 'Story' of the bioreactor performance first in Process Development, later as comparison in MFG.

Benefit of Integrating Discrete Data with Streaming Data in OSIsoft PI System

- Scientists are able to look at the whole picture of the bioreactor performance by comparing streaming and discrete data on the same graph without spending time aggregating it manually.
- This graphs shows a comparison of the online pH data (streaming) with the offline pH data (discrete).



Tipping Point for Implementing OSIsoft PI System in Process Development

Factors to consider:

- Quantity of systems
- Quantity of scientists/engineers
- Data integrity – where is the data stored now? Is it accessible & useful once retrieved?
- How are data driven decisions made now? How much time does it take to aggregate and analyze the data?
- How does the current collective cost compare with implementation of a OSIsoft PI System?



Phased Approach

- PD Bioreactors provided a solid business case to justify implementation of OSIsoft PI System into the PD data and knowledge management strategy
- Phased approach included just starting with the Bioreactors with the intent to expand the use of OSIsoft PI System to other PD systems in the future
- The approach was manageable, cost effective, & an efficient use of resources
- Upcoming at Shire: expand the use of OSIsoft PI System to Protein Chromatography, Ultrafiltration, etc.

Come to Thursday presentation to understand our 'Road Map' for this phased approach!

Summary - Value of OSIsoft PI System in Process Development

- Data Integrity
 - Data Accessibility – the data is automatically there, when you need it. No manual transcription or copy/paste required
 - Provide scientists time to focus on the science - for more comprehensive data analysis
 - Timely decisions based on complete data set
- And very importantly:
- Robust Technology Transfer Package
 - Pre-configured data in Process Development yields templates for the distilled data to be transferred to Manufacturing

Summary - Value of Implementing OSIsoft PI System in Process Development

Reverse the Paradigm!

BIG Data starts in Process Development

Manufacturing monitors only a subset of the data generated in Process Development

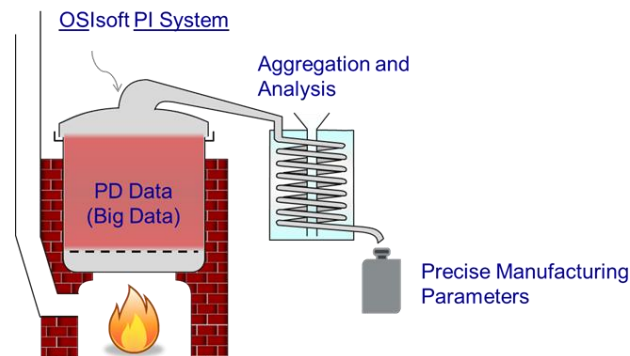
- Data is valuable: Leverage development work by utilizing OSIsoft PI System
- With OSIsoft PI System Your Technology Transfer to Manufacturing will be more robust and seamless
- Use OSIsoft PI System to distill your Process Development data in order to get your Precise Manufacturing Parameters

Thank you!

Questions?

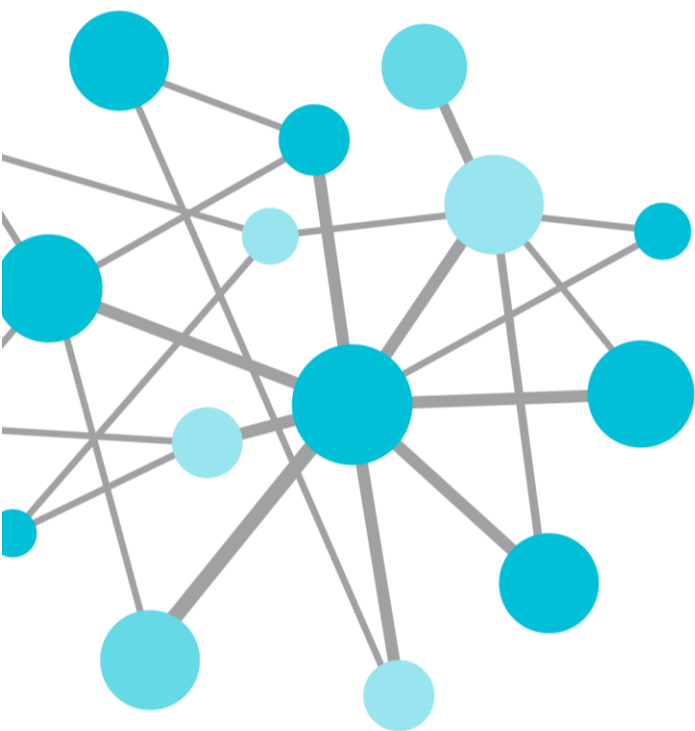
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before asking your questions

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name & company



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