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

LISBON PORTUGAL SEP 23-26

Planning for a Successful OSIsoft PI System Implementation

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Shire

Process Development Operation

Our purpose
We enable people with life-altering conditions to lead better lives.

Shire

Summary

Planning for a Successful OSIsoft PI System Implementation

OSIsoft PI System has the potential to be a large enterprise level system to support whole corporate data management needs. Just because it can handle the big data doesn't mean your program should immediately start big - ensure success with an easy incremental road map!

In this presentation you will learn the key considerations for:

- Successful OSIsoft program initiation
- Management of Stakeholders
- Development of the Business case
- Execution / Implementation approach
- Managing Change to successful completion
- Operational handoff and how to succeed incrementally

Shire - 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's Process Development Organization

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

Planning a Successful OSIsoft PI System Implementation

1. Where to start – How to Scope the effort
2. Management of Stakeholders
3. Development of the Business case
4. Execution / Implementation approach
5. Managing Change to successful completion
6. Operationalizing the Implemented system

A successful PI System implementation is like a Road Trip!

Plan your Data Road Map to start
or continue your OSIsoft PI System Journey

What's your Road Map?

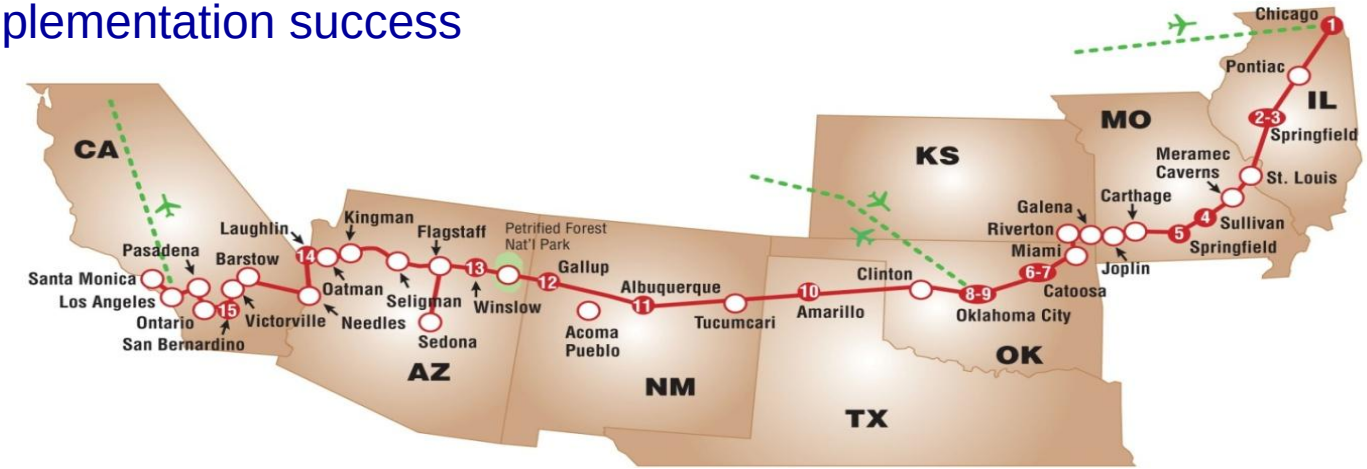
At Shire we call our Road Map Route 66

Shire's Data Road Map

Historic Route 66 goes through many States, with way-points to pass through in each state

For Shire's OSIsoft Implementation:

- Each state represents one of the Unit Operations to be integrated into to PI System (Our first Unit Op. was Bioreactors)
- There are **<u>6</u> way-points** in each state that represent a data-component within the Unit Operation
- There are **<u>6</u> repeated steps** that must be achieved at each way-point to ensure implementation success



Road Map – What states do you want to travel to?

Shire's PD Unit Operations ('States') include:

A. Bioreactors
B. Chromatography
C. Waves
D. UFDF Skids (Ultra-Filtration Dia-Filtration)
E. Lyophilizers

…And then a feasibility Study for all remaining wish list items

Bioreactors

Chromatography

Waves

6 Way-Points (checklist) for each Unit Operation

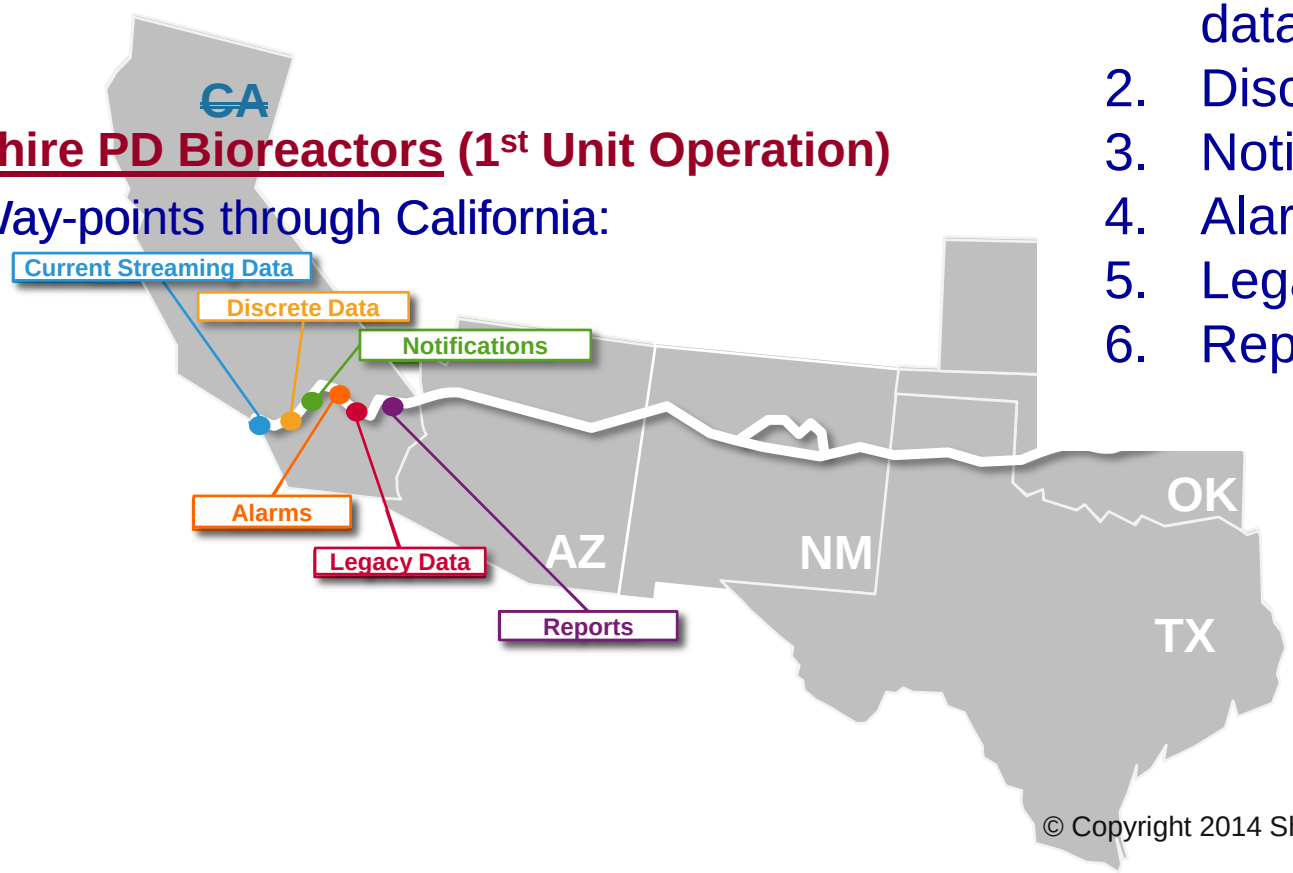
Each Unit Operation has data components, or way-points, to be integrated.

Shire PD's 6 Way-Points

1. Current streaming data
2. Discrete data
3. Notification
4. Alarms
5. Legacy data
6. Reports

Shire PD Bioreactors (1st Unit Operation)

6 Way-points through California:



6 Steps for each Way-point

Additionally, Each way-point has 6 repeated project management steps to address.

Shire's 6 Steps are:

1. Scope Management
2. Stakeholder Management
3. Business case Approval
4. Project Execution
5. Change Management
6. Operationalizing the system

We are highlighting these 6 specific steps because they have the great impact to the success of your project

For Each State in the Road Map there are 6 Way-Points and 6 Steps: Route 66!

Shire's 1st Unit Operation: Process-Development Bioreactors

1. Current Streaming Data

1. Scope
2. Stakeholder
3. Business case
4. Execution
5. Change mgmt
6. Operationalizing

2. Discrete Data

1. Scope
2. Stakeholder
3. Business case
4. Execution
5. Change mgmt
6. Operationalizing

3. Notifications

1. Scope
2. Stakeholder
3. Business case
4. Execution
5. Change mgmt
6. Operationalizing

4. Alarms

1. Scope
2. Stakeholder
3. Business case
4. Execution
5. Change mgmt
6. Operationalizing

5. Legacy Data

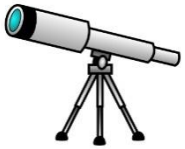
1. Scope
2. Stakeholder
3. Business case
4. Execution
5. Change mgmt
6. Operationalizing

6. Reports

1. Scope
2. Stakeholder
3. Business case
4. Execution
5. Change mgmt
6. Operationalizing

Step 1: Scope Management

1. Establish your Vision



- Describe your future state

Shire Process Development's (PD) Vision: To enable PD scientists/engineers to retrieve, compare and contrast any data within 10 minutes of conceiving the idea.

2. Describe the current state

- Process map with metrics
- Pain-point checklist and description – get clear and measurable pain-points from Stakeholders (include current and future users)

Shire PD's state: data integrity concerns, data storage shortage, data accessibility – hours to aggregate data for a simple analysis

3. Classify Needs

- Immediate, Short term, Long term

Shire PD's Needs: bioreactor data was in greatest risk of potential loss and was most labor intensive to aggregate

Step 1: Scope Management

(What "State" are you starting in?)

- Define appropriate scope
- Define priorities
  - Meeting Stakeholder priorities builds enthusiasm and adoption
- Map the plan at a high level
  - with incremental detail; one 'state' (process unit operation) at a time
- Clarify funding strategy

Step 2: Stakeholder management

Project stakeholders are those that have an interest in the outcome of the OSIsoft Implementation. Stakeholders may be inside or outside an organization

- Sponsor the OSIsoft Implementation
- Have an interest or a gain upon a successful completion of a project.
- May have a positive or negative influence in the project completion.
- Exert influence over the project's objectives and outcomes.

You must identify the stakeholders, determine their requirements and expectations, and manage their influence in relation to the requirements to ensure a successful project.

Goal:
Risk Mitigation

Step 2: Stakeholder Management

Examples of Shire OSIsoft PI System stakeholders:

- Sponsors/Primary Leadership Supporter
  - VP Process Development
- Resource/Line Managers
  - Lab Manager & department head in Pilot Plant & Development groups
- Subject Matter Experts
  - Experiment Leads in Pilot Plant & Development groups
  - System Integrator
- User Group
  - General Lab personnel in Pilot Plan & Development groups
- Groups impacted by the project as it progresses
  - IT, Engineering Technical Support
- Groups impacted by the project when it is completed
  - Manufacturing, Manufacturing Technical Support

Step 2: Stakeholder Management

For Stakeholder management:

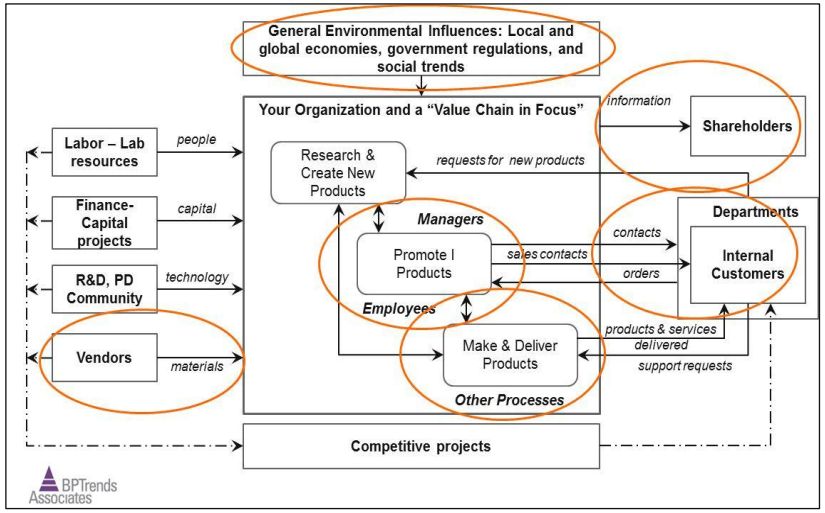
We Leveraged Business Analysis tools… (following slide)

- The outcome of analysis created clear stakeholder identification
- Identification minimized risk and uncertainty
- Tools helped in:
  1. Program approval
  2. Project Planning
  3. Support
  4. Execution through the program life cycle

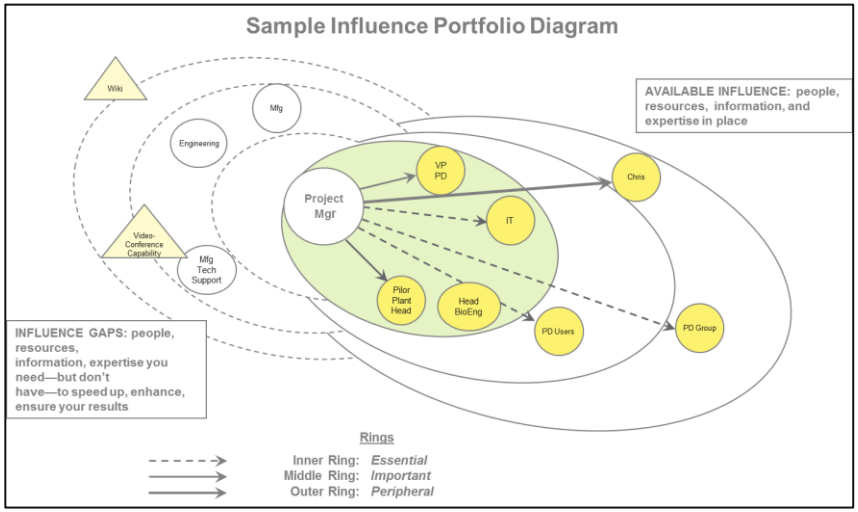
When stakeholders (along with project team) are engaged in project execution, the Stakeholders truly take ownership of the system when released!

Step 2: Stakeholder Management

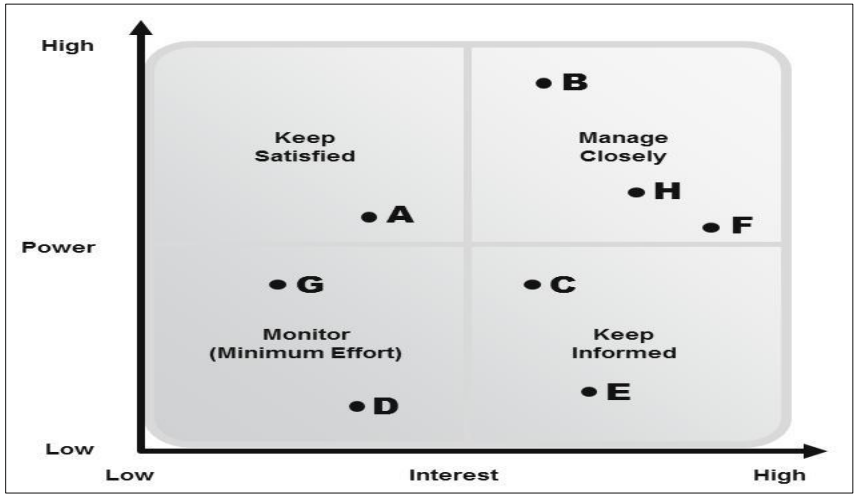
Define Your Key Stakeholders



Sample: Influence Portfolio Diagram



Example: Power/Interest Grid with Stakeholders



Step 3. Business Case development

Build your case!

- Identify Business Drivers
  - Data integrity – Measure the cost of inaccurate data
  - Data security – Estimate the cost and impact if Intellectual Property is lost
  - Data accessibility – Calculate cost of resource time (effectiveness, efficiency) when trying to retrieve the correct data
- Link Business drivers to corporate goals
  - Shire: improve the quality and speed of technology transfers, commercial investigations, and regulatory responses
- Outline high level plan
- Quantify Savings

Goal:
Approval & Buy in

Note: Circle back with Stakeholders
- to ensure continuity and success!

Step 3. Business Case development

Business Case example…

Bioreactor Data Management Project

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

PD-IT TEAM

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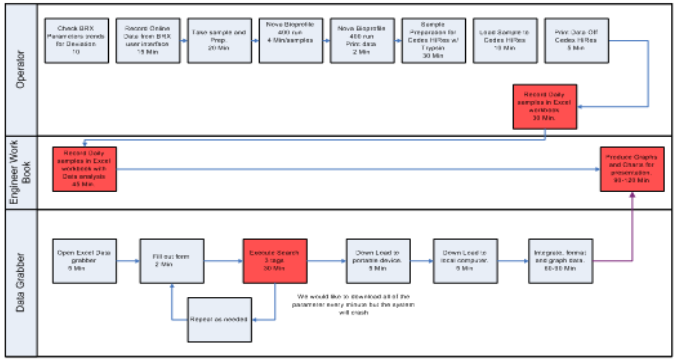
BACKGROUND

- 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 DeltaV 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	x (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 reactors)	Current state Time (min)	Current state NVA Time (min)	Phase 1 Time (min)	Phase 1 NVA Time (min)	Phase 2 Time (min)	Phase 2 NVA Time (min)	Cumulative Time (min)	Cumulative NVA Time (min)
Bioreactor Daily Data collection	15	15	0		0			
Sampling and sample Prep	30		30		30		30	
Nova and Cedex Data collection	10	10	10	10	0			
Data Transcription to excel sheet	30	30	0		0			
Data Transcription (Eng)	45	45	45	45	0			
Charts and Analysis	15		15		15		15	
Cycle time	145	100	100	55	45	0	45	0
Cycle time reduced by :			45	45	55	55	100	100
Cycle time %reduction			31%	55%	55%	100%	69%	100%

Back Up Data (per System) (Per Month)	Current state Time (min)	Current state NVA Time (min)	Phase 1 Time (min)	Phase 1 NVA Time (min)	Phase 2 Time (min)	Phase 2 NVA Time (min)	Cumulative Time (min)	Cumulative NVA Time (min)
B.Braun (Quad * 5)	20	20	0					
Finesse (Delta V)	60	60	0					
Cedex (Machine)	20	20	20	20	0			
Nova	10	10	10	10	0			
Nova Flex (Machine)	20	20	20	20	0			
Cycle time	130	130	50	50	0	0	0	0
Cycle time reduced:			80	80	50	0	130	130
Cycle time %reduction			62%	62%	100%	100%	100%	100%

Tag info collation per run 12 tags	Current state Time (min)	Current state NVA Time (min)	Phase 1 Time (min)	Phase 1 NVA Time (min)	Phase 2 Time (min)	Phase 2 NVA Time (min)	Cumulative Time (min)	Cumulative NVA Time (min)
B.Braun Quad (30 min * 5 units)	150	150	0					
Finesse (Delta V) (210 min x 28 units)	5880	5880	0					
Cycle time	6030	6030	0	0			6030	6030
Cycle time reduced:			6030	6030			6030	6030
Cycle time %reduction			100%	100%			100%	100%

GOAL (Business Value)

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

1. 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

2. 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

3. 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

4. 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.

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Step 3. Business Case development

Business Case example…Shire's is Straightforward, only 2 pages long

Bioreactor Data Management Project

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

PD-IT TEAM

Shire

PROPOSAL

- Install a Site Historian System (SHS) for the Bioengineering and LSDL Process Development Laboratories. The main function of the SHS is to provide a single, standardized interface for viewing and trending historical and real-time data from three independent bioreactor controls systems in these laboratories.
- The SHS is to enable simple and efficient retrieval of data from multiple runs and/ or multiple reactors. It will also enable researchers to quickly evaluate the status of ongoing experimental runs, compare in-progress runs with historical runs and extract historical information for use in summary reports and other evaluations of bioreactor and process performance.
- The SHS is to enable simple and efficient retrieval of data from online analytical equipment (NOVA, Cedex) and provide input forms for the manual entry of offline data. It will enable researchers to quickly compare daily online analytical data and daily manual data with real time and historical bioreactor run data and extract historical information for use in summary reports and other evaluations of bioreactor and process performance.

PLAN

Project Phases:

- Phase 1 SHS Installation and Configuration for Bioengineering and LSDL Bioreactor Data – see WBS below
  1. Historian Design and Submittal
  2. Execution, Installation and Start-Up of Historian System
  3. Development and Delivery of Baseline Trends and Reports
  4. Training on System Use & Maintenance
- Phase 2 SHS Configuration for Offline Instrumentation Supporting the Bioreactors – WBS TBD
  1. Define instrumentation data to be uploaded and define method of connectivity
  2. Execute plans to connect and configure instrumentation
  3. Develop and Delivery of Trends and Reports
  4. Training on System Use and Maintenance

Phase I WBS:

	Month				
Activity	Mo 1	Mo 2	Mo 3	Mo 4	Mo 5
Design Spec Development					
Server Purchase & Install					
LSDL App Station Install (Finesse)					
Sartorius Upgrade					
Network install and comm checks					
PI Software Installation					
Finesse Start/Stop Config					
PI Interface Config					
Baseline Trend and Report Collaborative Design					
PI Trend Config					
PI Report Config					
Site Acceptance Test Protocol Development					
Site Acceptance Test Protocol Execution					
Train Shire Personnel					
Project Post Execution Tasks (as builts, etc)					

PROJECT COST & RESOURCING (Summary):

Phase I:

Provided by Automation Vendor	
Total budgetary base price including:	$###,###
• OSI PI Software (outlined above)	
• OSI PI Configuration to meet requirements of URS	
• LSDL App Station	
• Design Specification and Site Acceptance Test Documents	
• Three (3) trends per reactor x 36 reactors	
• Two (2) Excel reports per system (PD DeltaV, PD Sartorius, LSDL)	
• Interfacing with Sartorius and Finesse bioreactor control systems	
• Eighty (80) hours of Startup and Commissioning Assistance	
• Twenty-four (24) hours of Site Acceptance Testing	
• Sixteen (16) hours of on-site training	
• Operations and Maintenance Manuals	
Required for Project - Purchased Directly from Vendor by Shire or via	
Automation Vendor	
Adder Price	
Furnishing three (s) servers, networking HW, IT installation (by Shire) By Shire	
Sartorius Upgrade	$ ###,##
Furnishing four (4) days of Finesse on-site support	$ ###,##
TOTAL PHASE I PROJECT COST (not including options or annual cost)	**$ ###,##**
Option Price	
Additional day of Vendor on-site support (e.g. training, custom reports, etc…)	$###/day
Additional 1000 tags to Server Tag License	$10,350
Additional 1000 tags to Batch Server Tag License	$932
• Additional PI Manage Pack (client) for Process Book, Datalink, BatchView	$1,294
Annual Cost	$11,000

Phase II: TBD

FOLLOW UP

- IT server purchase and installation – process is initiated, but this is on the critical path.
- B200 move coordination – depending on when this project starts and how well the critical path is managed will determine whether it can be installed at 700 Main St. before the move to B200.

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Step 4. Manage Project Execution

How to Manage Project Execution

- Build the Governance structure
- Remember the importance of Charters – and use them (Example; next slide)
- Develop a Communication plan – with buy-in from all participants
- Prepare for Change Management

Note: circle back with Stakeholders!

Goal:
A smooth
Implementation

Step 4. Manage Project Execution

Project Charter example…

OSIsoft PI System Data Aggregation Team Charter

Team Purpose	**Governance**
The purpose of this team is to implement the data Aggregation of legacy data from various systems and devices, into the Process Development instance of OSI PI	PD Senior Staff

Role	Team Members	Key Responsibilities
Project Sponsors	**Stacy Price:** Head of PD-Ops **Roland Smith:** Director IT **Gregg Santo:** Director IT	– Provide resources and budget for the project. – Provide strategic guidance and decision making. – Ensure project scope fits in with business objectives. – Endorse plans and action proposals. – Provide guidance and support for conflict resolution. – Reviews and approves the Project Charter, along with other senior managers.
Team Members	**Program Management:** Bruce Sohmer	– Coordinate business resources. – Main contact for project. – Develop and manage schedule. – Report project progress. – Issue agendas and minutes. – Facilitate working sessions and meetings.
	OSI Integration: John O'Neill & Ger O'Leary	– Support schedule development and management. – Support project progress reporting. – Lead OSI Aggregation tasks – Create and execute testing – Main OSI contact for project and support.
	User representation: Brad Ebel Rustin Shenkmen Aaron Loren	– Review schedule development. – Guide integration resources in mapping data. – Support OSI Aggregation tasks – Support and execute testing
	Lab Ops: * Paul Turvey	– Lead business administration for OSI PI. – Manage support resources upon project completion.

Team Objectives	**Expectations**
1. Aggregate data from various systems 2. Define plan to test migration effort 3. Establish and maintain the process for project execution. 4. Ensure accuracy and confidence in migrated data	1. Weekly one hour meetings. 2. Review of test approach 3. Execution of testing 4. Training of Shire Resources

NOTES: ***** Stacy will represent Lab Ops as needed

Step 5. Manage the Cultural Change

- OSIsoft PI System Implementation requires a change in daily activities for the scientists & engineers.
- Increase conversion to the new system: socialize changes & projected business value
- Address concerns & questions early to improve rate of adoption
- A robust training program should be implemented to accelerate adoption
  - Develop training curriculum relevant to future daily system use (Leverage both internal and external training)
  - Pilot the training tools (ensure effectiveness)
  - Plan for refresher classes and power-user classes

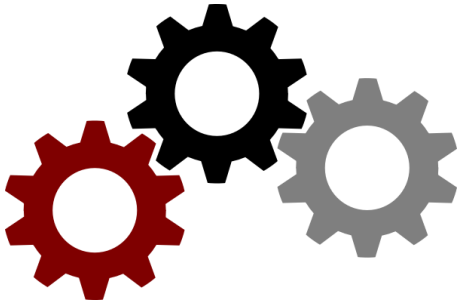
Goal:
System adoption

Circle back with Stakeholders

Step 6. Operationalize (How to keep going)

Transitioning your PI System from project to routine operations requires evaluation of:

- System ownership and role clarity
- Resource allocation - based on defined roles
- Launching of formal business processes:
  - System use SOP's
  - "Request-submission & prioritization" approach
  - Change control process (after release)
- Include Operational resources early - before the program is transitioned to routine operations.



Goal:
Ensure
System longevity

Route 66 Roadmap for OSIsoft PI Implementation Summary:

For Each 'State' (a Unit Operation) Defined:

6 Way-Points

1. **Streaming Data**
2. **Discrete data**
3. **Notification**
4. **Alarms**
5. **Legacy Data Import**
6. **Reports**

6 Steps

1. **Define Scope**
   - Outline vision and current pain points
   - Prioritize the plan & establish funding strategy
2. **Manage Stakeholder**
   - Know who to manage
3. **Build a solid Business case**
   - Determine the Technical needs
   - Outline funding
4. **Execute with a seamless program plan**
   - Leverage successful phase gates through execution
5. **Prepare People Through Change Management**
   - Prepare for change, guide through change
   - Approach one phase at a time
6. **Plan transition to Operations (Operationalizing)**
   - Train well and often
   - Establish Business Processes

Key Messages

A successful OSIsoft PI System implementation is a road trip, not a destination!

Phase your implementation to ensure quick wins.

Know your stakeholders and manage them well.

Thank you!

Questions?

Please wait for the microphone before asking your questions

State your name & company

Ask us for Route 66 Pins

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