Planning for a Successful OSIsoft PI System Implementation

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Shire
Process Development Operation
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 (Ultrafiltration, Diafiltration)
    - Protein Chromatography
    - Lyophilization
  - The Department develops and scales up processes for transfer to Manufacturing

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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

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What’s your Road Map?

At Shire we call our Road Map Route 66

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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 PI System (Our first Unit Op. was Bioreactors)
• There are 6 way-points in each state that represent a data-component within the Unit Operation
• There are 6 repeated steps that must be achieved at each way-point to ensure implementation success
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
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
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**

|---------------------------|------------------|------------------|-----------|---------------|-----------|

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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

Goal: Attaining a “Win-able” Scope
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.
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
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

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

Goal: Approval & Buy in
Step 3. Business Case development

Business Case example...

Bioreactor Data Management Project

BACKGROUND

- Large Scale Development Lab (LSDL) and Biologics lab currently have three independent bioreactor systems, running a total of 36 bioreactors of various sizes.
- There are 36 lab scale bioreactors in Biologics, running on the Phoenix Data V system, 36 lab scale bioreactors in Biologics with the Phoenix Data V system, and 36 pilot scale bioreactors on the Phoenix Data V system in LSDL.

CURRENT STATE

Data from these 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 multiple workstations to download data from each bioreactor system and then upload it into the database. The increased effort and delay may not be fully analyzed, which process decision-making is made from the analysis of a partial set.

ANALYSIS

- Redundancy/Consistency
- Data Integrity
- Data Privacy
- Data Compliance
- Data Traceability
- Data Reliability

- Data Security
- Data Recovery
- Data Quality
- Data Availability

- Data Access
- Data Usability
- Data Analytic
- Data Expansibility

GOAL (Business Values)

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

1. Data Integrity
   - Capture data from multiple bioreactor sources and sites and associate analytical equipment in a central location.
   - Result: Reduce transcription errors. Eliminate current data transcription process which includes logging from individual to lab notebooks and then data input. (We are transitioning)
   - 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 associate analytical equipment in a central location.
   - Local vs. Remote Access – Accessible for multiple users at multiple locations e.g. personal workstations, offices, Idexx lab.
   - Result: Reduce the time and resources required to access the data.

3. Data Usability
   - Search – Be able to search data by batch identification.
   - Time-efficient data available for real-time and historical trending, comparisons, data analysis by searchable batch identification.
   - Analyze – Be able to perform batch analysis with continuous data instead of single point analysis as is currently done.
   - Result: Reduce error and increase decision quality.

4. Future Expandability
   - A requirement for the system is that it will be on a platform that is compatible with external systems.
   - Result: Be able to access immediate data needs through a capital investment that will provide a solid foundation for future growth.

Shire

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Step 3. Business Case development

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

- **PROPOSAL**
  - **Main Function of the SHS**
    - To provide a single, standardized interface for viewing and trending historical and real-time data from three independent bioreactor control systems in the laboratories.
    - To enable a simple, efficient retrieval of data from multiple runs and/or multiple reactors. The SHS is also able to evaluate the status of ongoing experimental runs, complete in-progress runs with historical runs and access historical information for use in summary reports and other evaluations of bioreactor process performance.
- **PLAN**
  - **Phase 1**: SHS installation and configuration for Bioengineering and LSDP Bioreactor Data — see WBS below
    - Infrastructure and System Configuration
    - Software Integration and Testing
    - System Configuration and Final System Test
    - System Acceptance and Implementation
- **Phase 2**: SHS configuration for offline instrumentation supporting the Bioreactor – WBS TBD
  - **PROJECT COST & RESOURCING (Summary)**
    - Provided by Automation Vendor
      - Total budgetary base price including:
        - Shire PI Software (outlines above)
        - Design Specification and Site Acceptance Test Documents
        - Interface with Bioengineering control systems
        - Eighty (80) hours of Startup and Commissioning Assistance
        - Twenty-four (24) hours of Site Acceptance Testing
        - Eighteen (18) hours of online training
  - **Follow-up**
    - IT server purchase and installation — proceed is initiated, but this is an at-risk path
    - £200 move accommodation — depending on what the project starts and how well the critical path is managed

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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

<table>
<thead>
<tr>
<th>Team Purpose</th>
<th>Governance</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>PD Senior Staff</td>
</tr>
</tbody>
</table>

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

**Team Objectives**

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

**Expectations**

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

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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
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

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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

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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

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