THE INDUSTRIAL SOFTWARE REVOLUTION BEGINS NOW

invensys
Resident Engineering Services - Business Model & Success Story

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Agenda

• What is a Resident Engineer?
• Genentech Introduction
• Project Scope
• Solution Overview
• Role of Resident Engineer at Genentech
Invensys Support Offerings

- Resident Engineer
  - Dedicated On-Site Expert
  - Monitoring, Issue Triage and Resolution

- Site Monitoring (Remote)
  - Proactive Monitoring
  - Periodic Health Checks

- Customer FIRST for Solutions
  - Application Support for the lifecycle of a system

Additional Services

- Set-up support relationship
- Support and Maintenance of underlying products
- Access to support website and knowledgebase

*Required* Customer FIRST
Resident Engineer Benefits

- Maximize Accountability
- Accelerated Issue Resolution
- Increase Return On Investment
- Mitigate Risk
- Increase Productivity
- Reduced Costs
Resident Engineer Role: Technical Support & Maintenance

On-Site Technical support for ‘system’ issues
Second level support to customer maintenance personnel
Contributes technical expertise to:

• Handle corrective and preventive maintenance tasks, initiate action leading to problem resolution; consolidate and maintain current technical and commercial information and assists Customer Maintenance in developing maintenance procedures

Provides upgrade consultation, planning, and implementation support.
Product and Application testing
Reviews overall product and system health
Reviews quick fixes and maintenance releases to determine if and when they should be installed
Resident Engineer Role: Operations & Application Engineering

Provides assistance during start-up and upgrade
Reviews and implements system administration actions
Provides engineering system and design knowledge
Participates in “Design review” steps in any client process
Co-ordinates with Operations or Process Engineers to define the requirements for application changes
Manages & formally documents all changes
Serve as liaison between customer and Invensys if any problems arise
Genentech Batch & SCADA Replacement Project
Executed by
Invensys MES & Regulatory Compliance Practices
Topics

- Project Background, Summary, Objectives
- Technical Solution and Architecture
- Project Approach and Timeline
- Achievements

Project Highlights

- Replaced Siemens Unix-based DCS with Invensys Wonderware Windows-based Batch/SCADA Products
- 10 day cutover and resumption of GMP operations
- 100% virtual computing environment (VMWare)
- Met all functionality of previous system, exceeded performance, and maintained same look and feel
Background

• Technology upgrade project to replace aging and unsupported Unix based system

• Upgrade must occur with minimal downtime to avoid shortage of life saving drugs

• Aging system was functionally rich and robust and state of the art for life sciences
  – Full e-sig and EBR (21 CFR Part 11 compliant)
  – Quality release review based on exception
  – Large, robust Unix servers with full redundancy

• Legacy APACS control layer pushed to its limits
  – To be replaced in a future project

• Full GMP production operation
Project Summary

Original System Landscape

- 3 year project (May 2010 – June 2013)
- Replacing two most critical components (SCADA & Batch)
- Only 10 day cutover period (must be back to GMP production in 10 days)
- Replacing legacy Unix based system with Windows based system running on VMWare
- Meet or exceed current system performance
- Satisfy all validation requirements to return to full GMP production
- Like for like replacement to satisfy current requirements and minimize operator training
Project Objectives

1. **DCS Life Extension**
   - Improve system reliability & supportability
   - Insure continued operation through 2020

2. **Minimize Impact to Production Schedule**
   - Shortest interruption of manufacturing operations (10 days)
   - Maintain ability to make all products at 5.2 rpw (~270 batches)

3. **Minimize Overall Costs**
   - Development & Implementation Costs
   - Deployment & Commissioning Costs
   - System Lifecycle Support Costs

4. **Provide Path for Continued Incremental Upgrades**
   - Siemens APACS Control Layer
   - gPOMS MES

5. **Maintain Existing System Integrations**
   - MES/DCS Integration to gPOMS
   - DCS/LIMS Integration to LIMS
   - DCS Integration to BHDS database & OLRT applications
   - Embedded DCS process historian to Plant PI process historian
Technical Solution

Upgraded System Landscape

- Replaced Obsolete and Unsupported Siemens Products with Invensys Wonderware Products
  - Replaced Siemens Direktor batch product with Invensys InBatch
  - Replaced Siemens SCADS (APS/RTAP) with Invensys InTouch and System Platform
  - Replaced Embedded PI Historian with Invensys Wonderware Historian
- Implemented on new ‘virtualized’ computing and network infrastructure based on VMWare
- Ensured solution supports future replacement of additional legacy applications and DCS components:
  - gPOMS MES
  - Siemens APACS Controllers & I/O
Solution Architecture Overview

• Virtual computing platform (VMWare vSphere)
• Very large system
  – 948 graphic displays
  – 400,000 tag ArchestrA Galaxy
  – 20 redundant pairs of Application Object Servers
  – 8 operator terminal servers supporting up to 80 operators
• Redundancy at all levels
  – Redundant InBatch servers
  – Redundant Application Object Servers
  – Redundant Alarm providers
  – Redundant OPC interface to APACS controllers
Project Approach

• Collaborative effort between Invensys, SI, Genentech
  – Invensys development and quality oversight
  – Engineering testing leveraged to reduce validation testing

• Developed across many environments
  – 2 remote development environments in PA
  – 3 environments at Genentech (dev, val, prod)

• Robust configuration management to track objects across all 5 environments

• Leverage object templates to reduce development and testing efforts

• Full system performance test with physical and simulated APACS controllers

• 3rd Party APACS OPC Server optimized to satisfy large throughput requirements for obsolete control layer
Risk Mitigations

1. **Direktor/InBatch Batch Manager Application Compatibility**
   - Allowed automated Recipe, Equipment, and Material Database migration
   - Resulted in no impact to current DCS recipes

2. **Pilot Study for Proof of Concept**
   - Prepared design standards for HMI displays & control elements (faceplates)
   - Demonstrated successful migration of current batch databases
   - Functional prototypes of all current system interfaces
   - Developed HCCF Tank graphics for initial user acceptance
   - Established new Development and Qualification processes & deliverables

3. **Extensive Performance Testing**
   - Collected baseline metrics on current system performance
   - Proved new system meets or exceeds current metrics prior to deployment Go/No-Go decision
Project Timeline

Major Project Execution Milestones

- Pilot Study: (11/10)
- Design & Development: (12/12)
- Qualification: (2/13)
- Perf. Test: (12/12)
- Post Freeze Development: (4/13)
- Deployment: 10 days
- Co/No-Go: 3/13
- PQ: 6/13
- GMP: Go Live
Object Development and Deployment

• Object development and test (remote at dev sites)
  1. 127 Control Modules developed and tested
  2. 41 Equipment Modules developed and tested
  3. 948 Process Graphics developed and tested

• Customer site deployment
  1. Incremental deployment to validation environment
  2. Installation qualification for all deployments
  3. Deploy system to performance environment
  4. Perform complete performance test

• Cutover to new system
  1. Refresh performance environment (final production environment)
  2. Redirect control interface to production control layer
Project Numbers

- 25 FTE development resources at peak
- ~94,000 person hours

Graphics and Objects
- 948 individual graphic displays
- 510 application object templates
- 2,317 application object instances
- 24,724 application object instance attributes

Documentation
- 79 Planning Documents
- 565 Design Specifications
- 280 Commissioning & Qualification Test Procedures
- 928 Total Specs (with over 1800 updates to date)
Project Achievements

1. All Project & Technical requirements satisfied
   - Functional; System Performance; Project Execution; Qualification

2. Delivered highly compatible solution - effectively ‘Like for Like’:
   - Consistent Batch Manager, HMI Graphics, System integrations

3. Minimized Impact to Manufacturing Operations
   - Functionally equivalent HMI displays, control functionality, phase prompts, batch comments, and alarming
   - All product & equipment recipes migrated
   - Minimal impact to SOPs and associated operator re-training

4. Minimized impact to Roche/Genentech network supply chain
   - 8 Hour resumption of manufacturing operations
   - 10 day resumption of GMP manufacturing
Technical Achievements

1. Programmatic migration of Recipe & Process Model DB’s
   - No need for re-coding and re-qualification

2. Integration of Upstream & Downstream Batch Managers
   - Shared equipment arbitration
   - Hygienic status tracking (ex: “clean”, “sterile”, “batched”, “dirty”)
   - Material transfer across batch material inventories & genealogy

3. Integrated QA Lot Review
   - Batch data from 3 Batch Managers collected in BHDS
   - No impact to GMP Batch Report
   - No impact to Online Review Tools (OLRT) & BAHR applications

4. Increased system availability & reduced support costs
   - Extensive redundancy; No single point of failure
   - Virtualized system infrastructure: platforms & networks

5. Performance goal exceeded
   - Goal: 6 runs per week (270 batches)
   - Achieved: 8 runs per week (360 batches)
Genentech Batch & SCADA Replacement Project

Questions?