Eight Strategies to Ensure Successful Retrofit of Pharmaceutical Manufacturing Automation Systems

This paper presents a range of proven best practices and project strategies for performing major system retrofits in GMP manufacturing facilities, using the successful case study at the Genentech CCP1 Facility in Vacaville, CA as an example.

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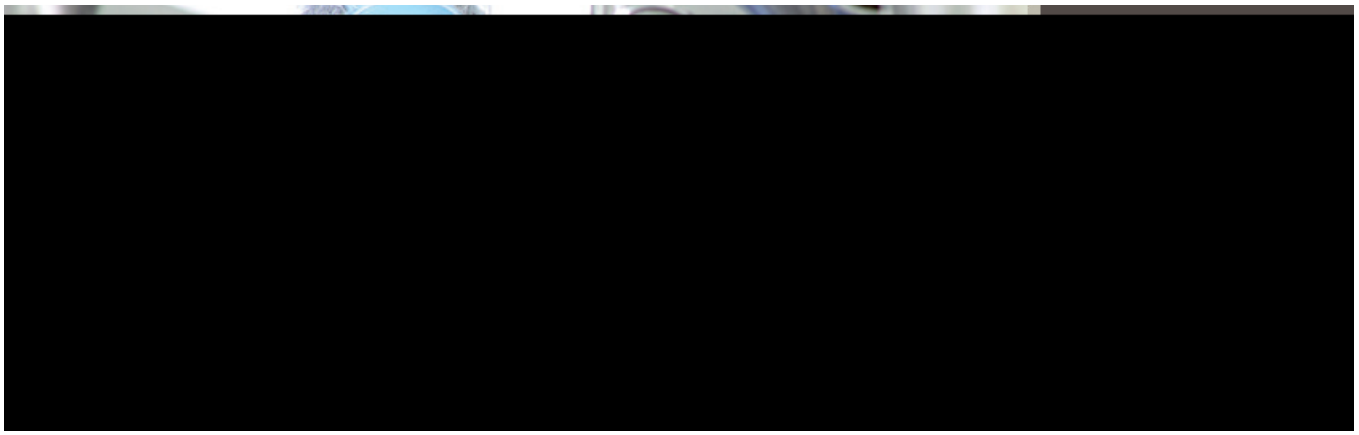


As pharmaceutical manufacturing automation systems age, mission-critical computing hardware and software components eventually fail or become obsolete for a variety of reasons. Inevitably, these systems need to be upgraded or replaced. Major system retrofits face particular challenges, risks, and constraints, and system owners must find innovative ways to limit potentially significant costs resulting from extended plant downtime. If not well planned, these projects can have an adverse impact to manufacturing operations and, in extreme cases, continued viability of the business entity. This paper presents a range of proven best practices and project strategies for performing major system retrofits in GMP manufacturing facilities, using the successful case study at the Genentech CCP1 Facility in Vacaville, CA as an example. The initial phase of the CCP1 DCS retrofit project concluded successfully in August 2013 with all business and technical objectives achieved. The facility returned to GMP operation after only 10 days of downtime, which was factored into a planned shutdown for periodic utilities maintenance.

INTRODUCTION

Since the introduction of the first digital process control systems in the 1970s, businesses and manufacturers have become increasingly dependent on highly automated and integrated computer-controlled manufacturing systems. Manufacturing facilities rely upon these technologies to consistently deliver complex manufactured goods, within acceptable levels of product quality and operator safety, all in as cost effective a manner as possible. In a pharmaceutical manufacturing facility, there is even more at risk because mistakes can lead to patient harm or even death. Inevitably, even the most advanced systems age and become potential liabilities. Proactively monitoring your systems and preparing for their eventual retrofit will help to protect both your facility and your patients from serious harm.

This paper examines the process of retrofitting the manufacturing automation systems in a pharmaceutical production facility – from knowing when to upgrade, to planning, and execution – a range of project strategies and best practices are shared. These same strategies were employed by Genentech, a member of the Roche Group, in successfully addressing the challenges associated with retrofit of an advanced Distributed Control System (DCS) in one of the most profitable and productive Good Manufacturing Practice (GMP) facilities in the Life Sciences industry. Throughout the paper, you will find examples from Genentech's experience and results.

About the Genentech CCP1 facility

Genentech's first major cell culture production facility (CCP1), located in Vacaville, California, is the premier drug substance production site in the Roche/Genentech manufacturing network. The facility plays an important role as a high-volume Active Pharmaceutical Ingredient (API) manufacturer and global supplier of urgent life-extending oncology medications.

Initial construction of the facility began in 1995 and licensure was granted by the U.S Food and Drug Administration in April 2000 to manufacture Herceptin®, the company's groundbreaking breast cancer drug. CCP1 has since been licensed for a number of other innovative and important cancer treatments including Rituxan® (non-Hodgkin's lymphoma, rheumatoid arthritis, and chronic lymphocytic leukemia), MabThera SC® (follicular and large B-cell lymphomas), Avastin® (glioblastoma, metastatic colorectal, metastatic kidney, advanced cervical, platinum-resistant ovarian, and non-small cell lung cancers), Perjeta® (HER2+ breast cancer), and Xolair® (persistent allergic asthma).

CCP1 MANUFACTURING SYSTEM ENVIRONMENT

The CCP1 facility was Genentech's first implementation of a fully integrated manufacturing system environment. Major process operations such as clean in place (CIP), steam in place (SIP), media batching and fermentation, harvest, and recovery/purification are conducted by a central Distributed Control System (DCS) with minimal operator interaction.

Since inception, continued integration of the CCP1 DCS with other business and manufacturing systems has boosted the facility's manufacturing capacity, product quality, and supply chain reliability, while also reducing operational costs and regulatory risks. While very beneficial, such integrations also introduce system inter-dependencies that increase the scope and complexity of performing system retrofits.

Figure 1 illustrates the major computer systems and software applications that make up the CCP1 manufacturing system environment employing the Purdue Reference Model for Computer Integrated Manufacturing (CIM).

Figure 1 –CCP1 Manufacturing System Environment

CCP1 Obsolescence Issues

Validated automation systems in GMP manufacturing environments must be carefully maintained to ensure they continue to function reliably and consistently. Unfortunately, even the best cared for systems eventually face obsolescence as spare parts and technical support become increasingly difficult to obtain; system vendors leave the market or are acquired by other vendors; and fundamental shifts occur in computing and automation technologies.

Following a series of acquisitions, the original CCP1 DCS vendor looked very different in 2007 than when the system was purchased just 11 years earlier. Approximately 60% of the DCS hardware and software components, including the UNIX operating system-based servers running the Supervisory Control and Data Acquisition (SCADA) and batch management software applications were no longer available for purchase, with the remaining supported components nearing obsolescence. The most critical of these, the batch management application, was declared obsolete by the vendor in 2005 and as a result technical support became increasingly difficult to obtain. While Genentech maintained a proficient engineering and technical support staff, reliance on internal expertise alone was not realistically sustainable for the expected life of the facility.

CCP1 Retrofit Objectives

In late 2007, an assessment of the CCP1 DCS was initiated with the goal of identifying and prioritizing potential system risks and mitigation strategies, determining technically viable strategies for their implementation, and estimating the associated costs and risks that each approach would incur. The primary objectives in evaluating possible retrofit options were to:

- Eliminate failure modes that would have multi-batch impact and/or result in significant plant downtime,
- Extend the support of legacy system components not subject to immediate upgrade through stockpiling of spare parts to buy time for an eventual complete upgrade,
- Ensure timely resumption of GMP operation and continued regulatory compliance,
- Minimize anticipated project and total system lifecycle costs, and
- Avoid impacting global supply chain by maintaining current production capabilities.

It's Time to Upgrade

Knowing when it's time to upgrade your systems may or may not be obvious depending on how the facility is utilized, the manufacturing automation systems already in place, and future plans for expansion or change in use. Often, pharmaceutical manufacturing facilities will need to upgrade their automation systems due to one or more of the following situations:

- The industry has shifted to new computing technologies. For example, transitioning from UNIX to Microsoft Windows or even Windows XP to more current Windows versions can necessitate total replacement of the system hardware on which the new software runs.
- The automation system vendor has gone through either a merger or acquisition with little guarantee of continued supply of key system components and technical support.
- Current system hardware or software is becoming scarce or may be nearing end-of-life or obsolescence. Basic hardware components crucial to once common system architectures, such as network interface cards, may no longer be manufactured in the form factor required by legacy computer hardware platforms.

- The manufacturing facility has lost technical personnel. Many manufacturers are dependent on the expertise and tribal knowledge gained by internal plant staff over years of operating and supporting now antiquated systems. As these employees continue to retire, finding experienced engineers and recent graduates to support 'ancient' technologies becomes increasingly problematic.

Questions to Consider

Automation engineers are increasingly tasked with finding ways to retrofit or update systems that are expected to run continuously without interrupting or degrading manufacturing operations. And delaying an upgrade project for too long can have profound consequences on business profitability and, in extreme cases, even its continued existence.

Projects to retrofit already established systems face very different challenges and risks compared to the projects responsible for their original implementation. Before embarking on a major retrofit effort, project teams need to keep the following in mind:

- What new or current technologies can provide some level of compatibility with the legacy system components? Will the updated system environment function as required to meet established performance levels and support future operations?
- What is the minimum plant downtime needed for system cutover? When can the production schedule afford such an interruption? Can production be shifted to other facilities, or inventories boosted in advance, in order to allow enough time for the deployment of replacement systems and retirement of legacy systems?
- Can the business even afford the retrofit project? In the pharmaceutical industry, it is not unusual for the cost of lost production to dwarf actual project costs by a factor of 10 or more. It's not uncommon for aging facilities to be intentionally operated until no longer practical and then sold rather than retrofitting.
- What will be the impact to system documentation and operator training programs? Large numbers of system specifications and Standard Operating Procedures (SOP) may require updating to reflect the new system implementation. Properly timed delivery of user training on the new system is critical – too early and the training fades before it can be applied, too late and the training is not effective for meeting site performance and quality requirements.
- How much of the plant will be affected during the cutover? Is the entire facility impacted at once, or can the retrofit be phased? Will unforeseen issues and extended delays in system return to service place business continuity at risk?
- In the pharmaceutical industry, will all regulatory licensing requirements continue to be satisfied? How will critical historical manufacturing data in legacy databases remain secure and accessible over entire retention periods as required by regulatory agencies?

BEST PRACTICES FOR RETROFIT PLANNING & EXECUTION

This section highlights some of project management and engineering practices employed by the Genentech project team during retrofit planning and upgrade of the CCP1 DCS SCADA and batch management application software. These same strategies can be employed by many pharmaceutical manufacturing plants to upgrade their automation systems to new technologies while maintaining compliance with regulatory standards and minimizing costly downtime.

1. Perform risk assessments to identify critical systems/components and prioritize upgrade efforts.

The first step in addressing potential issues stemming from system obsolescence and possible system failures is to have a complete and accurate understanding of the current system environment. This should include all major hardware and software components, as well as interfaces between different systems and software applications.

Once the system environment is well characterized, a risk assessment can be performed to identify, document, and quantify the conceivable hazards associated with each component. Many risk assessment methodologies employ common terms such as 'failure mode', 'cause', 'effect', and 'current controls'. Failure modes describe the major categories of failure. A typical failure mode describes the way in which a component could fail to perform its intended function. Cause is the means by which a system component becomes subject to a failure mode. Effect is the resulting impact to the manufacturing operation. Current controls are the mechanisms already in place that are expected to prevent the cause of the failure mode or the failure mode itself.

With this information, the risks attributed to individual system components can be quantified in terms of severity of impact, likelihood of occurrence, and probability of detection. Tables A, B, and C present typical values for rating severity, occurrence, and detection that can be employed in the analysis, but each business should consider and define appropriate ratings for their manufacturing environment.

Severity of Impact (S): How serious will the effect of a potential failure mode be on the manufacturing operation? What will be the size and scope of a resulting system failure or loss of production?

Table A – Severity of Impact Ratings

Severity Ratings	Description
2	No impact on product quality and/or data integrity
4	Minor issue easily resolved with no adverse effects on product quality and/or data integrity
6	Minor issue that potentially compromises product quality and/or data integrity
8	Production event and/or system failure that compromises product quality and/or data integrity for one lot/run
10	Production event and/or system failure that results in irreversible damage to product or data for multiple lots/runs

Likelihood of Occurrence (O): What is the probability that a particular cause will occur during the intended life of the component and result in the failure mode?

Table B – Likelihood of Occurrence Ratings

Occurrence Ratings	Description
2	Extremely remote: one occurrence per five+ years, or one occurrence per 500,000,000 events
4	Slight chance: one occurrence in 2 years, or one occurrence per 1,000,000 events
6	Moderate chance: one occurrence in 3 months, or one occurrence per 1000 events
8	High chance: one occurrence every month, or one occurrence per 100 events
10	Very high chance: one occurrence every few days, or one occurrence per 10 events

Probability of Detection (D): What is the likelihood that current controls or detection methods will detect the cause of the failure mode or the failure mode itself? Consider that relatively minor failures that go undetected can accumulate and compound their eventual impact and resulting consequences.

Table C – Probability of Detection Ratings

Detection Ratings	Description
2	Almost certain: detection methods will almost always detect or prevent failure
4	High: there are consistent detection methods with a high chance that failure will be detected or prevented
6	Low: there are inconsistent detection methods and chances are remote that failure will be prevented
8	Very low or remote chances that failure will be detected
10	Very remote: no established detection methods

Multiplying together the severity of impact (S), likelihood of occurrence (O) and probability of detection (D) will result in a Risk Priority Number (RPN) that can be used to quantify and prioritize the risk of possible component failure modes to the manufacturing operation.

RPN = S x O x D

Table D shows typical risk acceptance criteria values, but each organization should develop its own criteria as applicable to its business and risk tolerance.

Table D – Risk Acceptability Criteria

Risk Rating	Description
Severity ≥ 8 or RPN ≥ 125 (High Risk)	Risk must be mitigated or controlled
Severity < 8 and RPN < 125 (Moderate to Low Risk)	Further evaluation may be needed to determine level of risk mitigation or control
RPN < 64 (Low Risk)	No action required

Benefits & Considerations:

- A comprehensive risk analysis will reveal the most pressing issues and help to establish relative priorities for planning system upgrades and retrofit projects.
- The risk assessment should focus on software and equipment component failures only. Configuration and programming errors are typically not considered.
- All spare parts, even those already unavailable for purchase from the vendor, should be considered in RPN calculations.

Genentech Experience:

In late 2007, Genentech became concerned of the impact potential system failures could have on the facility's ability to deliver the quantities of medications necessary to treat current and projected patient levels. A detailed risk assessment was conducted to determine the criticality of all major CCP1 systems and probability of failure. Estimates were made of their likely impact in terms of plant downtime, the resulting effect on product inventories and availability to patients, and of course the business costs that would continue accruing until the facility's return to GMP operation.

The risk assessment clearly showed that critical components in both the CCP1 MES and DCS systems were nearing or already obsolete. Most importantly, resulting RPN values indicated that a serious DCS server hardware failure preventing execution of the SCADA graphical user interface (GUI) and batch management software would have the largest negative impact to manufacturing operations.

2. Review vendor offerings for compatibility with your legacy systems, databases, and software applications.

Evaluate your current vendors' product offerings to determine whether newer versions are available that maintain some level of compatibility with your legacy systems, databases, or applications. In some cases, new products with extended support horizons will still retain much of the functionality of the legacy system your operations personnel are already familiar with.

Benefits & Considerations:

- Vendor-supplied upgrade paths can expedite the upgrade process, minimize resulting production disruptions, and help realize savings in retrofit costs.
- The vendor may still employ resources with expertise and knowledge of your original system implementation and can assist in the retrofit planning and execution.
- The vendor may already have a migration strategy and/or software tools to simplify the deployment of the replacement system into your operating environment.

Genentech Experience:

Although the UNIX-based Direktor (sic) batch management application was obsolete and unsupported, the vendor (Wonderware by Schneider Electric) continued to offer the Microsoft Windows-based InBatch application. The underlying InBatch software was originally derived from Direktor and maintained a high degree of compatibility in terms of its user interface and application functionality.

Another significant carryover from Direktor to InBatch was the Application Program Interface (API) library of software functions for customizing batch management functionality and interfacing to external systems. Because the two APIs were functionally similar, updating the DCS integrations with other systems would not require major redesigns, risking degradation or loss of current capabilities.

3. Explore using automated migration tools to transfer data between systems.

Many technologies are available for moving configuration data between software applications and databases, such as eXtensible Markup Language (XML) utilities and Extract, Transform, Load (ETL) database functions. Coupled with native import/export capabilities found in many software applications, there is a reasonable chance that effective and reliable mechanisms exist, or can be developed, to automatically transfer legacy configuration data to the replacement system.

Benefits & Considerations:

- Automated migration procedures eliminate opportunities for manual transcription errors and omissions in the new system configuration.
- Testing and qualifying the software tool, as opposed to verification of the manually entered data, can be less expensive in the long run.
- Electronic data migration safeguards important intellectual property, such as recipe procedures, bills of material, inventory and other manufacturing data vital to the business.
- Automated migrations can be performed multiple times to snapshot configuration data at different points in the project (which helps when tracking to a moving target) and particularly just prior to system cutover.

Genentech Experience:

Given the investment Genentech made over the years in DCS batch automation, manually re-configuring over 1000 recipes and associated data parameters would put at risk being able to reliably resume production of all licensed products.

Selecting InBatch to replace the legacy Direktor application yielded additional benefit by being able to automatically transfer configuration data between old and new applications. A batch database migration program was developed (and extensively tested) that would retrieve Direktor recipe, equipment, and material information, perform the necessary syntax transformations, and load the information into InBatch. In the end, creating the batch database migration program required less time than would have manually re-entering the Direktor configuration into InBatch; and resulted in a more reliable outcome.

4. Plan to synchronize parallel system development and documentation streams.

A likely additional challenge with retrofit projects is managing development of the replacement system while design changes and software modifications continue being made to the legacy system. In typical operating facilities, automation and instrumentation changes continue long after initial deployment. New products are launched and process improvements made to boost yields, introduce new equipment and materials, reduce waste, and increase regulatory compliance and operator safety.

Large retrofit projects can take years to plan and execute. Barring changes to existing systems is generally not an option, particularly changes to address quality and safety issues. System configuration and programming will often continue to evolve, along with technical documentation and validation requirements. Essentially, the retrofit project is challenged with hitting a moving target.

Figure 2 illustrates one strategy for handling this situation. At the start of the project, a 'snapshot' is taken of the current system configuration and supporting documentation. This information will form the foundation for development of the new system. Routine modifications to the existing system can then continue independently of retrofit activities, albeit still under change control.

Genentech Experience:

Ensuring that the DCS retrofit would allow the plant to resume, or exceed its historical operating throughput was a primary objective for the project. Prior to cutover, comparable benchmark testing of the new SCADA and batch management software was repeated to demonstrate equivalent 'before' and 'after' performance.

Having an accurate characterization of DCS performance early in the project also helped to determine the optimum system configuration, number of computing platforms required, and data exchange rates between SCADA and process control layers. This allowed adjustments to be made to the underlying infrastructure before they would impact downstream development activities and the project schedule.

6. Involve users and key stakeholders early and extensively throughout the project.

Another key advantage of retrofit projects over greenfield installations is the wealth of knowledge about how a plant operates that resides with the operations staff. Knowing how best to apply new technologies is important for project success, but in many cases secondary to having a thorough understanding of how the facility's systems are employed in day to day use.

A well trained workforce with extensive experience running the plant can be a valuable asset to a retrofit project. Experienced operators can also provide valuable assistance by participating in pilot studies, performance benchmarking, functional design reviews, and drafting acceptance test plans. Including operations personnel in project planning and execution also greatly increases site/project engagement and user buy-in of the replacement systems.

Benefits & Considerations:

- Involve experienced users to help identify gaps and eliminate potential misunderstandings about system functionality early in the development process.
- Although accurate, legacy functional and technical specifications are rarely comprehensive. User experience can provide an understanding of 'why' in addition to 'how' current systems function.
- Ensure personnel from all shifts are represented on the project and included in information exchanges as some operations may purposely only be scheduled during late-shift hours.
- Establish clear roles and responsibilities for everyone participating in the project. This is critical, particularly when many different organizations are involved. Decision making can become unmanageable if there isn't a clear distinction between making recommendations and having a deciding vote. Make sure to define and enforce clear processes for escalating decision making conflicts.

Genentech Experience:

A 'user team' with representatives from various departments, including Manufacturing Operations, Quality Assurance, Facilities Support, and Manufacturing Sciences, was involved with the project from the beginning. Team members were key participants in many technical activities including an initial pilot study, performance benchmarking and testing, and design reviews of the new GUI displays and batch functionality. The user team was also responsible for disseminating important project status and information to the site. Some of the methods they used included:

- Distribution of a monthly project newsletter detailing recent accomplishments, current status, and upcoming milestones.
- Hosting frequent 'brown bag' meetings during lunch periods for open question and answer sessions.
- Preparing informational posters and staging simulated operator terminals in public areas of the plant to demonstrate the 'look and feel' of new DCS graphic displays and batch application functionality.
- Creating and maintaining a project web site on the corporate intranet to keep groups external to the site informed about the project and its progress.

Close collaboration of the project's engineering and user teams helped ensure that all site personnel were fully engaged in the DCS retrofit effort and understood the site's objectives and priorities for the project.

7. Leverage computing virtualization technologies to save space, time, and money.

Often in the case of retrofit projects, there are significant physical and environmental constraints in computer rooms already filled with equipment racks, power distribution cables, and network wiring. Finding sufficient space to stage new systems while continuing to operate existing systems can be a logistical nightmare.

Fortunately, virtualization technologies have evolved into reliable and cost effective alternatives to deploying scores of physical computers and associated peripherals. By leveraging the same computing equipment to run multiple operating systems and software applications, virtualization helps to reduce costs while increasing the efficiency and utilization of system hardware and computer room environments.

Benefits & Considerations:

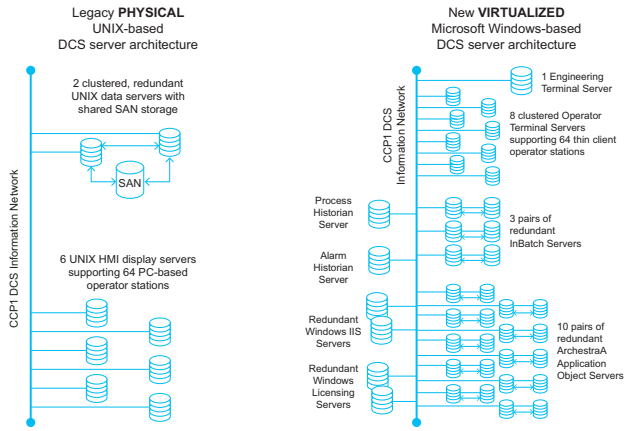
- Centralized management of operating systems, application software, security and antivirus updates greatly simplifies system administration and SOP compliance.

- Employing templates of standardized server configurations ensures consistent adherence to specifications, resulting in reduced testing and faster system deployment.
- Significant savings in computer room space, network cabling, cooling, and power consumption reduces both project installation and ongoing operating costs.
- Virtualization delivers efficient and cost effective scalability as additional systems and applications are easily hosted on virtual computing platforms.

Genentech Experience:

Switching technologies from UNIX to Microsoft Windows necessitated greatly expanding the hardware footprint of the CCP1 DCS system architecture. The retrofit project would eventually deploy over 122 computing platforms in support of separate development, validation and production DCS system environments. Figure 3 illustrates the contrast in relative size and complexity of the legacy and new CCP1 DCS server architectures.

Figure 3 – CCP1 legacy and virtualized DCS server architectures



Installing, configuring, and qualifying such a large amount of physical equipment would have been a major undertaking. Also, employing physical server platforms would have necessitated substantial increases in computer room size, environmental controls, and system administration staffing. Virtualization proved to be a significant enabler for the DCS retrofit project.

8. Develop 'fall back' contingency plans for recovering from critical post-deployment problems.

Experienced project managers are well acquainted with "Murphy's Law". They know that even the best planned projects will likely encounter unforeseen issues and delays; and that it's best to be as prepared as possible for the unexpected.

Contingency planning is the most essential aspect of a retrofit project that one hopes never to implement. As painful and disruptive as reversing a flawed retrofit deployment can be, allowing a poorly functioning system to remain in operation while major issues are addressed is rarely acceptable. This is particularly true in the Life Sciences industry where regulatory agencies can prohibit operation of non-conforming systems and suspend the manufacturing facility's right to operate.

Benefits & Considerations:

- When planning for project contingencies, be sure to consider how manufacturing data will be affected – not only during cutover to the new system, but also after reversal back to the legacy system. Will all compulsory information continue to be properly identified, securely maintained, and reliably accessible?
- Partner with Quality Assurance to determine how best to distinguish data generated by the new system to facilitate lot review and release during the startup period (e.g., employing lot flags). Reverting back to the legacy system will impact how this data needs to be handled.

Genentech Experience:

A comprehensive contingency plan was prepared jointly by the project's engineering and user teams and approved prior to cutover by the Computer System Validation and Quality Assurance groups. The plan specified detailed steps and sequencing for reversal of all system cutover activities, including additional qualification testing to verify complete restoration of the legacy system's functionality and interfaces to other systems. Although never implemented, the effort invested in creating the contingency plan still delivered benefit by providing a blue print for subsequent projects to learn from and develop their own plans.

GENENTECH RESULTS

Following the best practices outlined in this paper, the initial phase of the CCP1 DCS retrofit project concluded successfully in August 2013 with all business and technical objectives achieved. The facility returned to GMP operation after only 10 days of downtime, which was factored into a planned shutdown for periodic utilities maintenance.

The first GMP campaign following cutover was conducted at full production run rates with no system issues or product deviations. To date, the site has realized a 95% reduction in unplanned down time due to the upgraded DCS performance.

Additional projects to retrofit the remaining legacy DCS control layer and CCP1 MES are currently in the planning stages and are expected to also apply and benefit from the lessons learned on this project.

CONCLUSION

The CCP1 facility was Genentech's first implementation of a fully integrated manufacturing system environment. Not surprisingly, CCP1 was also the first to face critical system obsolescence issues. Pharmaceutical manufacturers rely upon their system automation technologies to consistently deliver quality products to improve patient care, while meeting strict regulatory requirements and ensuring business efficiency. Most, if not all of the major pharmaceutical manufacturing facilities in the Life Sciences industry will inevitably encounter similar issues as the CCP1 facility.

To summarize, the overall success of system retrofit projects largely depends on three main factors:

- Recognizing when system obsolescence issues are approaching and prioritizing remediation efforts while time remains for their implementation prior to failures occurring.
- Preparing a comprehensive assessment of system hardware and software components, their interdependencies, and potential modes of failure with resulting impacts to manufacturing operations.
- Understanding the fundamental nature of system retrofit efforts and the differences in risks, challenges, and constraints when compared to initial system implementations.

Retrofit projects that apply vital technology updates are necessary for extending the effective life spans of aging pharmaceutical manufacturing systems. If properly planned and executed, system retrofits can be accomplished without adversely impacting manufacturing operations and business profitability.

About the Author

Richard Parapar has over 30 years experience delivering advanced automation solutions for the life sciences, petrochemical refining, high purity gas production, and consumer food processing industries. Richard recently retired after over 21 years at Genentech/Roche as a Senior Principal Engineer and Technical Lead for Automation Engineering, where he was responsible for delivery of major strategic automation projects and shaping the long term direction of manufacturing execution and process automation systems for Genentech.

Schneider Electric

Boston ONE Campus
800 Federal Street
Andover, MA 01810
Phone: + 1 978 794 0800

www.schneider-electric.com

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