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The Ups and Downs of Taking the Bus

In Part 2 of this series, Wyeth's Gary Forrest illuminates the processes of commissioning and qualifying a new bioprocess facility's fieldbus-based process control system and addresses life cycle management issues.

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SYSTEM COMMISSIONING for this fieldbus-based process control system was a multi-step process beginning with factory acceptance testing that took place from September through December of 2003. During this period, there was limited coordination between the fermentation equipment manufacturer and the automation supplier, and some issues with configuration and wiring were identified. Resolution of these issues was deferred until installation and commissioning. The fermentation skids were shipped at the end of December, and placed in storage while they awaited the completion of building construction.

Site installation, start-up, and commissioning of the fermentation skids began in August of 2004. Problems identified during fermentation skid factory acceptance testing needed to be resolved on-site. Although there were a few issues with Foundation fieldbus devices, this fieldbus was found to provide a solid communications platform with sophisticated interaction between the DeltaV process control system and the field devices. Foundation fieldbus provided full digital communications and diagnostics for all devices without the need for complex configuration or interpretation of signal bits.

In contrast to our experience with Foundation fieldbus, there were problems with our specific implementation of Profibus DP instrumentation and controls. Personnel experienced with the startup and commissioning of Profibus DP fieldbus systems were not available. Eventually, the problems were traced to wiring problems, such as improper connector and wire combinations. Profibus DP wiring requirements were not well understood during system installation, and diagnostic tools for the analysis of the Profibus DP network were not readily available.

In addition, the software configuration of each Profibus DP device, through the use of a GSD configuration file provided by the instrument and controls vendor, required the complex specification of slots and signals that needed interpretation by software on a bit, byte, or word basis. The DeltaV process control system provided interaction with the Profibus DP devices in a manner that was generally limited to setpoints, process variables and digital states.

Despite specific individual difficulties with instrumentation based upon Profibus DP, Profibus DP instrumentation has provided reliable, robust communications with the DeltaV process control system upon the completion of successful commissioning.

The automation supplier, Emerson Process Management, through its local representative, Control Associates, Inc., Allendale, N.J., based the DeltaV software configuration upon a vendor functional requirement specification (FRS) supplied by Sartorius BBI. The fermenters were placed into service for R&D applications starting in the fourth quarter of 2004. Because the facility was up and operating for R&D applications, Wyeth had the luxury of entering a software development pre-qualification period for the DeltaV process control system. During this period, Wyeth created its own comprehensive functional requirement specification (FRS) for all systems not included in the Sartorius BBI vendor documentation. At the same time, these documents went through several modifications as the software was modified to conform to user requirements. The DeltaV process control system was ready for qualification in August 2005.

SYSTEM QUALIFICATION – FIELDBUS I&C

Wyeth carried out process control system validation with the help of a validation contractor that specializes in the qualification of DeltaV process control systems – Valspec, of Royerston, Pa. A validation plan was developed in accordance with GAMP 4 that established the scope, strategy, deliverables and responsibilities for system qualification. A key question addressed by Wyeth and Valspec in the validation plan was "How do we qualify fieldbus I/O?"

The strategy involved the preparation of three documents. All field instrumentation and controls were to be qualified through an enhanced commissioning loop check protocol prepared and executed by Wyeth personnel. The DeltaV process control system and the configuration software not involved with I/O configuration were to be qualified using an installation and operational qualification (IOQ) protocol developed by Valspec and executed by Valspec and Wyeth personnel. A third performance qualification (PQ) protocol document was to be prepared by Wyeth to address specific user requirements not covered in the IOQ.

Enhanced commissioning differs from normal commissioning in that it is carried out in accordance with a protocol that has been pre-approved by the company's quality organization. It is carried out using the same quality standards that are applied to the qualification of pharmaceutical manufacturing equipment. All of the instrumentation and controls installed on the DeltaV process control system were tested in accordance with this pre-approved document. The loop check protocol verified:

- I/O Model and Serial Number
- I/O Presence in the DeltaV Configuration Database
- Configuation Software Date and Audit Trail Version Number
- Correct Addressing
- Graphic Links
- Correct Functioning of the I/O Point
- Presence of the I/O in the Configuration Database

A page was provided in the loop check protocol for each I/O point. The contents of the page were customized for each type of I/O point. Conventional, Foundation fieldbus, Profibus DP, and AS-i bus input and output points were verified with information appropriate to that point type.

The IOQ protocol was developed in accordance with GAMP 4 principles to provide verification that the DeltaV process control system software and hardware met design specifications. A traceability matrix demonstrated correspondence between system design documentation and system testing. The IOQ protocol verified:

- Hardware and Software Installation
- System Graphics
- Control Loop Operation
- Phase and Procedure Operations

Additional Wyeth requirements for validated computer control systems were addressed in a PQ protocol. In accordance with GAMP 4, the PQ protocol verified and documented user requirements recorded in Wyeth policies and procedures for validated computer systems. The PQ protocol included the following documentation:

- Regulatory Analysis, Risk Analysis, and Electronic Records/ Electronic Signature Assessment
- Supplier Assessment
- Operation and Administration Procedures Assessment
- Personnel Training Assessment
- Security and Access Control Assessment
- System Performance and Capacity Assessment
- Database Backup Testing
- Disaster Recovery Plan Assessment
- Preventative Maintenance Procedures Verification

A qualification summary report for the process control system was issued and approved in November 2006.

LIFE CYCLE MANAGEMENT

Design, commissioning, and qualification are elements of the system life cycle for qualified systems in pharmaceutical manufacturing. Qualification testing establishes a qualified state, but the qualified state must be maintained. Preventative maintenance, change control, and period system reviews are practiced for the life of the system.

In summary, Wyeth, Pearl River, N.Y., has been an early adopter of fieldbus technologies. The use of fieldbus instrumentation and controls resulted in some startup and commissioning issues, but these issues were resolved after site installation. The new Bioprocess Development Facility has a fully validated process control system for the support of R&D, clinical production, and commercial manufacturing. The qualified system incorporates all of the advantages of the new digital fieldbus technologies. The functionality and reliability of the fieldbus instrumentation and controls has been outstanding.