

*Areas of Expertise*

# Automation Engineering



Photo: Boehringer Ingelheim GmbH

Boulder, CO  
North Andover, MA  
South San Francisco, CA  
San Diego, CA  
North Wales, PA  
Raleigh, NC



[www.jmhyde.com](http://www.jmhyde.com)

# Automation Engineering

JM Hyde Consulting provides complete automation solutions and control system integration services for both the pharmaceutical and biopharma industries. Services include software development, electrical control panel design, control system validation, and design document generation for manufacturing processes.

We have broad integration and programming experience in the area of GAMP, S88, and 21 CFR part 11 compliance, operator interfaces, SCADA systems, PLC-based control systems, DCS, and as-built turnover packages.

## APPROACH TO AUTOMATION

JM Hyde's approach is to work with clients closely and incorporate the GAMP4 Life Cycle Model.

The Life Cycle Model is a structured approach for developing and validating process and automated systems. This approach ensures that documented evidence is established and that the completed system will consistently operate within our client's pre-defined specifications and will have established quality attributes.

The systems we work with include the following:

- Plant-wide PLC/DCS control systems
- Standalone PLC-based control systems for CIP, cell culture, TFF, and other skids.
- Graphical human machine interfaces and SCADA systems
- Manufacturing information systems with multiple database formats

## CONTROL SYSTEM SERVICES INCLUDE:

- Control system architecture design
- Control system gap analysis/risk assessment
- Control system design document generation
- Control system software development
- Control panel design and electrical CAD drawings
- Development and execution of automation test plans
- System startup, commissioning, and optimization
- Validation protocol development and execution

In compliance with the "lifecycle" approach, we develop the following documentation for each control system integration project. This documentation can also be created retrospectively, when necessary.

- Control system architecture diagrams
- User requirement specifications (URS)
- Functional requirement specifications (FRS)
- Software detailed design (SDD) specifications
- Hardware detailed design (HDD) specifications
- Software test plans and worksheet
- Factory acceptance test (FAT) plans and worksheet
- Control system IQ/OQ protocols
- Operating instruction manuals and standard operation procedures (SOP)

## CLIENT AUDITS

The control systems development and documentation services offered by JM Hyde Consulting have been audited by the quality assurance and validation groups of Merck & Co., Bayer, SmithKline Beecham, Amgen, Vaxgen, Wyeth and Novartis.

The audits consisted of top-to-bottom review of all phases of our methodologies and practices for control system and documentation development including our own SOPs. This multidisciplinary strength has proven to be instrumental for successful completion of many turn-key automation projects both in the US and overseas.