

*Areas of Expertise*

# Validation Services



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)

# Validation Services

JM Hyde Consulting offers a wide range of validation services including strategic documentation development and support, equipment and control system IQ, OQ, and PQ documentation and testing.

## **APPROACH TO VALIDATION**

JM Hyde's approach to validation is based on the 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. In many instances we are able to refine the standardized approach into one that integrates and leverages commissioning and qualification activities to save our clients time and resources.

## **STRATEGIC VALIDATION DOCUMENTATION**

JM Hyde can help develop the strategic documentation framework that is necessary for GMP facility operation. We will identify a firmly defensible documentation structure, develop strategic documentation such as a Validation Masterplan, and identify the requisite information necessary to fully support the overall strategy.

### **Master planning**

- Corporate or Facility Validation Masterplans
- Cleaning Validation Masterplans
- Process Validation Masterplans

### **Supporting studies**

- Worst Case residue evaluations
- Surface Swab Recovery Studies
- Product and API Residue Inactivation Studies
- Residue Cleanability Studies

### **Acceptance Criteria Determination**

- Determination of scientifically sound criteria
- Integration and utilization of supporting study data

### **SOP's**

- Procedural Training Evaluation
- Analytical Methods
- Cleaning Operations (manual and automated)

### **Qualification Documentation**

- Process Validation and Envelope testing
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Computer Qualification (CQ)
- Performance Qualification (PQ)

## **QUALITY SYSTEMS**

JM Hyde Consulting has over 10 years of experience working exclusively in cGMP environments and maintains a strong internal Quality function. We pride ourselves on our ability to consistently deliver the high level of services required in the pharmaceutical industry.