

Compliance Engineering



Compliance and Validation Programs

Our goal at Hyde Engineering + Consulting is to provide our clients with high quality, cost-effective compliance and validation solutions for the manufacturing, processing, and distribution of drug products. Specific areas of expertise include:

- Risk Based Compliance Management
- Strategic Validation Documentation
- Integrated Commissioning and Qualification
- Cleaning Validation

Approach to Compliance:

At Hyde E+C, our approach to compliance integrates our entire portfolio of services. Our knowledge and experience in the Pharmaceutical and Biopharmaceutical industry, coupled with an in-depth understanding of the FDA's risk-based management approach, provides added value for our clients.

Our cGMP compliance services focus on systems that are common among pharmaceutical and biopharmaceutical manufacturers.

Key Systems include:

- Quality Systems
- Facilities and Equipment Systems
- Materials Systems
- Production Systems
- Packaging and Labeling Systems
- Laboratory Control Systems
- Aqueous Volume Reduction Strategies
- De-Bottlenecking System Analysis

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Hyde provides in-depth audits and GAP Analyses with respect to cGMP compliance, as defined by the Center for Biologics Evaluation and Research aiding our clients in preparation for any level of inspection.

Compliance Services include:

- Mock FDA GMP Inspections
- Remediation of FDA 483s & Warning Letters
- Corrective Action Programs (CAPAs)
- Contract Manufacturers and Lab Audits
- Failure Assessment Investigation
- Quality System Evaluations

Validation Services

A comprehensive approach to validation is core to our company's complete service offerings. In addition to providing traditional validation services, we also provide a fully integrated engineering and commissioning service. Our services include:

- Validation Master Plans
- Cleaning Validation
- Software Validation
- Commissioning Master Plans
- Equipment Validation
- Analytical Method Validation

We offer a full range of validation services for the manufacturing of bulk and final biopharmaceutical and pharmaceutical products.

Approach to Validation

Our approach is based on the Life Cycle Model, a structured approach for developing and validating equipment, processes, 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.

Validation Services Experience

At Hyde, our process systems expertise spans a full range of process engineering and process validation services for the manufacturing of bulk and final pharmaceutical and biopharmaceutical products. We have experience in all phases of the process validation Life Cycle including:

- Validation Master Plans
- Cleaning Validation
- Process Design
- Commissioning
- Analytical Method Validation
- Installation Qualification (IQ)
- Operation Qualification (OQ)
- Computer Qualification (CQ)
- Performance Qualification (PQ)