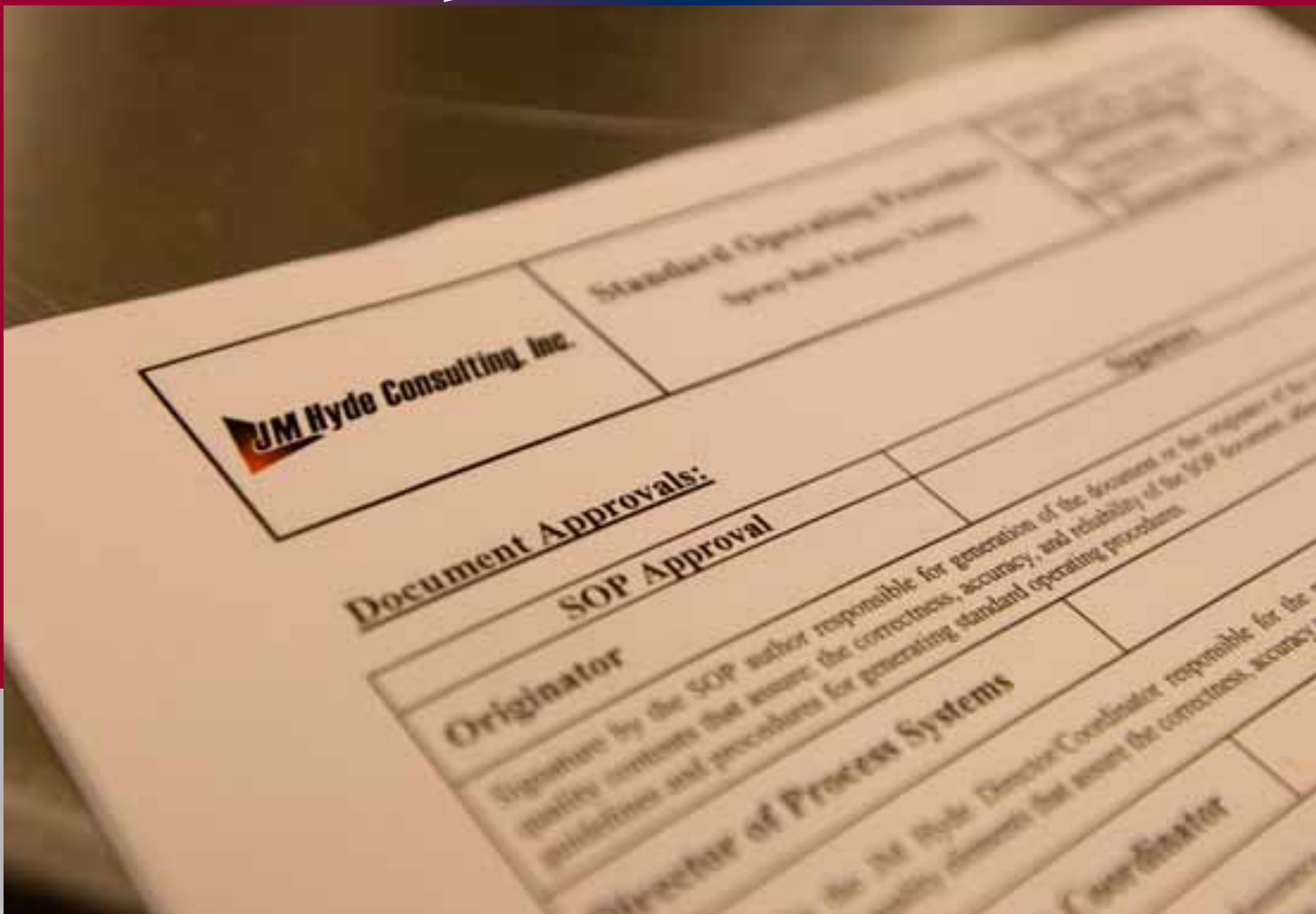


*Areas of Expertise*

# Compliance Services



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

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



# Compliance Services

JM Hyde Consulting Inc. provides a comprehensive array of compliance services involving the current Good Manufacturing Practice regulations (cGMPs), which are found in Title 21 Code of Federal Regulations (CFR) Part 211, in the relevant sections of the biologics regulations, 21 CFR Parts 600-680 and in ICH Guidance Q7A.

Our goal is to provide our clients with high quality, cost-effective compliance solutions for the manufacturing, processing, and distribution of drug products.

## **Approach to Compliance:**

JM Hyde's approach to compliance integrates our entire portfolio of services. Our knowledge and experience in the Pharmaceutical and Biopharmaceutical industry, as well as 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.

## **The 6 "Key Systems" include:**

- Quality Systems
- Facilities and Equipment Systems
- Materials Systems
- Production Systems
- Packaging and Labeling Systems
- Laboratory Control Systems

## **The 3 "Critical Elements" include:**

- Standard Operating Procedures (SOPs)
- Records & Documentation
- Training

We apply the most current scientific knowledge and "Best-Practices" regarding risk management to these common systems. By doing so, JM Hyde enables our clients to achieve cGMP compliant operating systems.

## **cGMP COMPLIANCE SERVICES INCLUDE:**

- "Mock" FDA GMP inspections
- Audits of contract manufacturers and laboratories
- Pre-Approval Inspection and Preparation
- Responses and Remediation planning for FDA 483s and warning letters
- Failure Assessment Investigation
- Corrective Action Programs (CAPs)
- Explanation and Interpretation of FDA policies, regulations, guidance documents and expectations
- Risk Analysis as related to manufacturing and FDA expectations
- Quality System Evaluations required by consent decrees

JM Hyde Consulting 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.