JIUZHOU Pharmaceutical | Raybow Pharmaceutical

Molecule to Market: Your Trusted Partner

Chemistry, Manufacturing and Control: CMC Services & Consulting

Raybow USA's Chemistry, Manufacturing, and Control (CMC) Services help you move your molecule to market efficiently and safely.

Whether you need full project management or selected CMC services, our vertically and horizontally integrated team of professional chemists supports you with all stages and scales of the drug development process, from process development, though analytical validation, and into facility selection, tech transfer and production.

Raybow USA is your source for quality, multi-scale local and global options.

Analytical Development & Quality Control

- **Method Development and Validation:** Establish and validate reliable analytical methods for the identification, quantification, and purity assessment of drug substances.
- **Impurity and Degradation Profiling:** Characterize and quantify process- and degradation-related impurities to ensure compliance with global standards.
- **Method and Process Validation:** Confirm analytical and manufacturing reproducibility through structured validation studies in accordance with regulatory expectations.
- **Quality Control Testing:** Perform raw material, release, and in-process testing to verify compliance with defined specifications and support ongoing quality assurance.

Process Development & Scale-Up

- **Process Design and Optimization:** Develop efficient, scalable, and reproducible manufacturing processes for APIs, excipients, and intermediates.
- **Scale-Up and Technology Transfer:** Execute smooth transitions from laboratory to kilo-scale production while maintaining yield, quality, and reproducibility.
- **Process Characterization and Validation:** Define critical process parameters and validate consistency across multiple production campaigns.

Drug Substance Characterization & Stability

- **Drug Substance Characterization:** Perform comprehensive assessments of key physicochemical properties such as solubility, stability, polymorphism, and hygroscopicity to support early formulation design.
- **Stability Programs:** Design and execute ICH- and custom-condition stability studies to establish shelf life, guide formulation decisions, and ensure product robustness.

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CTD Module 3 Supporting Studies

- **Manufacturing Process Outlines:** Deliver detailed process descriptions, including synthesis flow diagrams, isolation and purification methods, and associated process controls.
- **Control of Materials:** Provide recommendations and justifications for raw materials and intermediates, ensuring traceability and compliance with quality standards.
- **Drug Substance Characterization:** Compile data supporting elucidation of structure and impurity characterization in accordance with regulatory expectations.
- **Fate and Tolerance of Impurities:** Study impurity formation and clearance through manufacturing and purification stages to confirm robustness of impurity control strategies.
- **Control of Drug Substance:** Generate analytical data packages covering identity, purity, and impurity profiles to support control strategy sections of CTD Module 3.
- **Regulatory Starting Material (RSM):** Identify and justify appropriate regulatory starting materials (RSMs) to ensure process control and GMP compliance ahead of Phase III development.

Quality & Compliance Support

- **Deviation and Change Control:** Prepare, review, and manage documentation supporting deviations, investigations, and process or method changes.
- **Troubleshooting and CAPA:** Conduct root cause investigations and implement corrective and preventive actions (CAPA) for technical and compliance-related issues.
- **Risk Assessment:** Evaluate and mitigate process and analytical risks across all phases of development to ensure product and regulatory integrity.

Project Management

- **Integrated Program Oversight:** Provide project management and cross-functional coordination to ensure clear communication, defined milestones, and efficient execution across CMC workstreams.

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