MP Biomedicals

Custom and Contract Manufacturing Services

With 50 years' experience in contract manufacturing for the life sciences, we've established a track record of reliability and exceptional services. We are the company other chemical suppliers and biopharmaceutical companies come to for uncompromised quality, customized solutions, and global reach to save time and increase efficiency.

Accelerate your path to market by leveraging our expertise, wide-ranging capabilities and extensive services. MP Bio can serve as your single source for custom and contract manufacturing, creating a seamless supply chain, technology transfer, and go-to-market strategy. We can support our clients from pilot studies and early research through commercial production.

SERVICES

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CONTRACT DEVELOPMENT

- Life science reagents
- Formulation, filling, testing, labeling, packaging and kitting
- Molecular diagnostic tests
- Rapid diagnostic tests
- ELISA and Chemiluminescence assay kits

STRATEGIC SOURCING AND SUPPLY CHAIN MANAGEMENT

- Sustainability, transparency, stability
- Supplier qualification
- CDAs
- Regulatory documentation support
- Timely delivery

ENGINEERING AND SCALE-UP

- Design, development and optimization
- Process development and validation
- Controlled environments
- Dedicated ISO cleanrooms and certified IVD manufacturing environment

QUALITY SYSTEMS AND CONTROL

- Supplier-certified quality systems
- Change control
- Specification testing
- Certificate of origin, BSE/TSE, GMO, melamine, shelf-life statements
- Dedicated equipment train for animal and non-animal origin materials
- ISO certified and GMP compliant

REGULATORY SUPPORT

- Consultation
- Technical dossier compilation
- IVD product registration
- Enhanced regulatory documentation

PRODUCT COMMERCIALIZATION SUPPORT

- Worry-free product launching
- B2C and B2B networks
- Global logistics

QUALITY

MP Bio's multiple global production sites utilize robust Quality Management Systems to maintain tightly regulated manufacturing standards. Our facilities are ISO 9001:2015 certified at a minimum and audited to cGMP principles. Our ISO 13485 certified and FDA registered facilities in the U.S. and Singapore provide customers with a stringent quality management system for medical devices and ensures product specifications are consistently being met. At MP Bio, we have an experienced regulatory team to help deliver customer support on manufacturing documentation under our quality management system guidelines.

ISO 9001:2015

ISO 13485:2016

US FDA cGMP for IVD (21. CFR Part 820)

APPLICATION AREAS AND PRODUCTS

- In vitro diagnostic (IVD) manufacturing
- Organic synthesis
- Custom adsorbents for chromatography
- Healthcare products including intermediates and APIs
- Animal-derived proteins
- Non-animal origin recombinant protein expression
- Bioprocessing reagents
- Biopharmaceutical raw materials
- Biological buffers
- Active Pharmaceutical Ingredients (APIs) distribution
- Fine and specialty chemicals
- Lithium battery additives and stabilizers
- High performance LCD and OLED components
- Specialty environmental protection products

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ISO 9001:2015 CERTIFIED COMPANY

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Connect With Us: