



MP Biomedicals IVD Custom Manufacturing Services

IVD DEVELOPMENT, MANUFACTURING, REGULATORY & COMMERCIALIZATION

From production and assembly, QC, technical support and regulatory, to the final commercialization of your product, MP Bio is your trusted partner for IVD development and manufacturing. Together with our own subsidiaries in strategic locations, we have built a solid network of trusted distributors around the world to reach global markets. At MP Bio, we can help manage all aspects of your development, manufacturing and commercialization needs and every step in between. Contact us today to explore the endless possibilities.

SERVICES



CONTRACT MANUFACTURING

- Rapid diagnostic tests (RDT)
- ELISA
- Molecular diagnostic tests
- Life science reagents
- Formulation, filling, packaging



RECOMBINANT PROTEIN DESIGN AND PRODUCTION

- Expression vector design
- Protein expression and purification
- Industrial-scale production



CONTRACT DEVELOPMENT

- Design and development of Rapid Diagnostic Tests
- Prototype verification, process validation, scale-up



PRODUCT COMMERCIALIZATION

- Worry-free product launching
- B2C and B2B networks
- Global logistic solutions



REGULATORY SUPPORT

- Consultation
- Technical dossier compilation
- IVD product registration

▶ Learn more at www.mpbio.com

▶ QUALITY



Our ISO 13485 certified and FDA approved facilities in Singapore and the U.S. 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 13485

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

OUR IVD FACILITIES

MP Bio has been developing and producing IVD products since 1984 and currently manufactures IVD products in four platforms: Immunoblot, ELISA, Rapid Test, and Real-Time PCR. Our products are used for the detection of antibodies, antigens, analytes and biomarkers associated with diseases and medical conditions. We also develop and produce antigens (recombinant & native proteins) for IVD and research use. Our products are manufactured under the strictest international regulatory standards at both our U.S. and Singapore facilities to meet your requirements.

OUR CAPABILITIES

With more than 35 years of experience in the IVD business, we work with our business partners to develop and produce IVD products from prototype development to finished product. We also provide regulatory advice and services for product registration to the various authorities through the compilation of technical dossier required for registration. Need help with product commercialization? Through various collaborations, we can help our partners distribute products globally through our worldwide subsidiaries and distribution network.



MP BIOMEDICALS

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Learn more at www.mpbio.com

