Medical Device & In Vitro Diagnostic Consulting and CRO Services

Your Trusted Service Partner for the U.S., Europe, Japan and Asia

CMIC

Change ourselves. Change the future.

One-Stop solutions for the world's largest markets

As the largest CRO in Japan, CMIC group provides end-to-end solutions for medical devices and in vitro diagnostics in the U.S., Europe, Japan and most of Asia. We can tailor our services in accordance with your needs.

Example of Japanese Market Entry Services

QMS Organization Setup

- Setup of Quality Management System (QMS) in compliance with local regulations (e.g. QMS ordinance & Good Vigilance Practice (GVP) regulations in Japan)
- Design/setup of Standard Operating Procedures (SOP)
- Marketing Authorization Holder in Japan

Design & Development

- Regulatory strategy development
- Practical device design in accordance with regulations
- Risk management system setup

Non-Clinical & Clinical Studies

- Gap analysis for non-clinical studies
- Study and protocol design for non-clinical and clinical studies
- Regulatory dossier preparation, submission and correspondence
- Regulatory authority meetings/consultation
- Medical writing for non-clinical and clinical studies
- Full non-clinical and clinical study services including ICCC (local country agent), monitoring, data management, statistics, laboratory etc.

Approval / Certification

- Applications/notification preparation & submissions
- Regulatory inspection support & interpreter services
- Response to regulatory authority inquiries
- Manufacturing business license registration

Reimbursement

- Reimbursement applications
- Negotiations with regulatory authorities

Post Marketing Surveillance

- Medical writing for Post Marketing Surveillance (PMS) studies
- Full PMS services including monitoring, data management, etc.

Experienced in over 200 consultations including…

Medical Devices

- Absorbability hemostatic material
- Artificial ears
- Artificial joints
- Cerebrovascular stents
- Combination products
- Coronary stents
- CT/MRIs
- Deglutition monitoring systems
- Dental implants
- Dental unit/dental material
- Drug-eluting stents
- ECG monitors
- EEG monitor/ PSGs
- Electroencephalographs
- Enteral nutrition tubes
- Flexible laryngoscopes
- Others (Biologics, adhesive for bio-tissue, kits…etc.)
- Glucose monitors
- Infusion set for contrast agents
- Insulin injectors
- Intraocular lens
- Medical device programs
- Medicine Injectors
- Neuromuscular electrical stimulation devices
- Orthopedic implants
- PET
- Programmable implantable pumps
- Pulse oximeters
- Pump-oxygenators
- Stent-grafts
- Surgical navigation systems
- Thrombus suction catheters
- Wound dressing

In Vitro Diagnostics

- Biomarker business consulting
- CNS biomarkers
- Companion diagnostics (CoDX) products for oncology
- DNA chip products
- Immunohistochemistry products
- MEMS products
- Next Generation Sequencing (NGS) products
- PCR products
- Project management for NGS/CoDX products
- STD biomarker products

Vast regulatory expertise and experience in the U.S., Europe, Japan and Asia

Our consultants are experienced with regulatory requirements in the U.S., Europe, Japan and Asia.
Let us guide you to wherever your next destination.

U.S.	● FDA (PMA or 510(k)) consultation & applications
Europe	● CE Marking acquisition consultation & applications
Japan	● ICCC service ● Designated Marketing Authorization Holder (dMAH) service (Type 1 license; License number: 13B1X10146)
Asia	● Services in 10+ countries
Global	● ISO 13485 certification & registration consultation

CMIC
Pharmaceutical Value Creator

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