

Medical Device & In Vitro Diagnostic Consulting and CRO Services

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





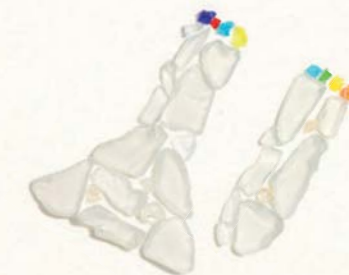
One-Stop solutions for the world's largest markets

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



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

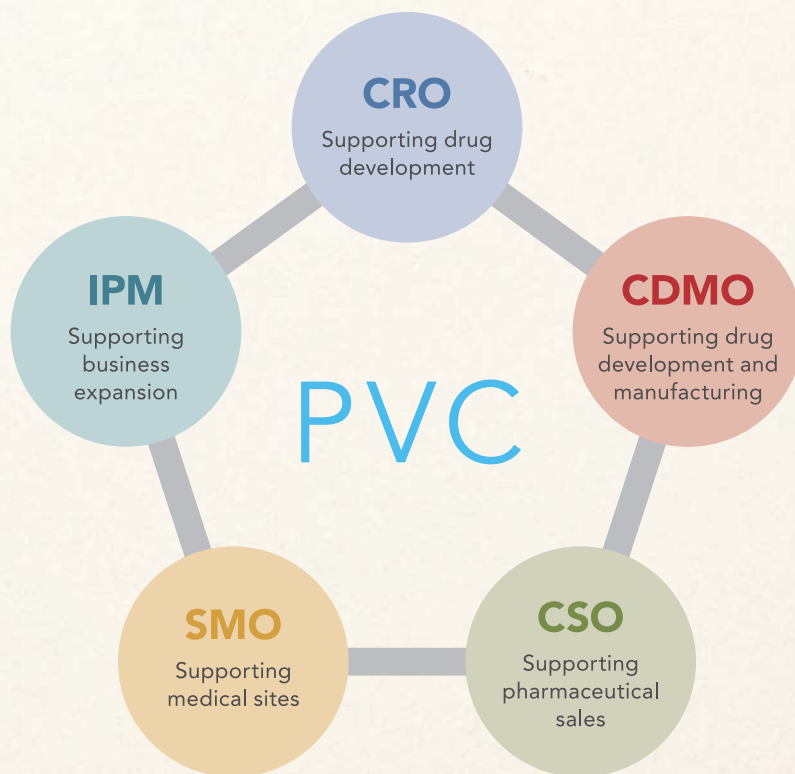
- Biomarker business consulting
- CNS biomarkers
- Companion diagnostics (CoDX) products for oncology
- DNA chip products
- Immunohistochemistry products
- MEMS products
- Next Generation Sequencing (NGS) products
- PCR products
- Project management for NGS/CoDX products
- STD biomarker products

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 Group

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