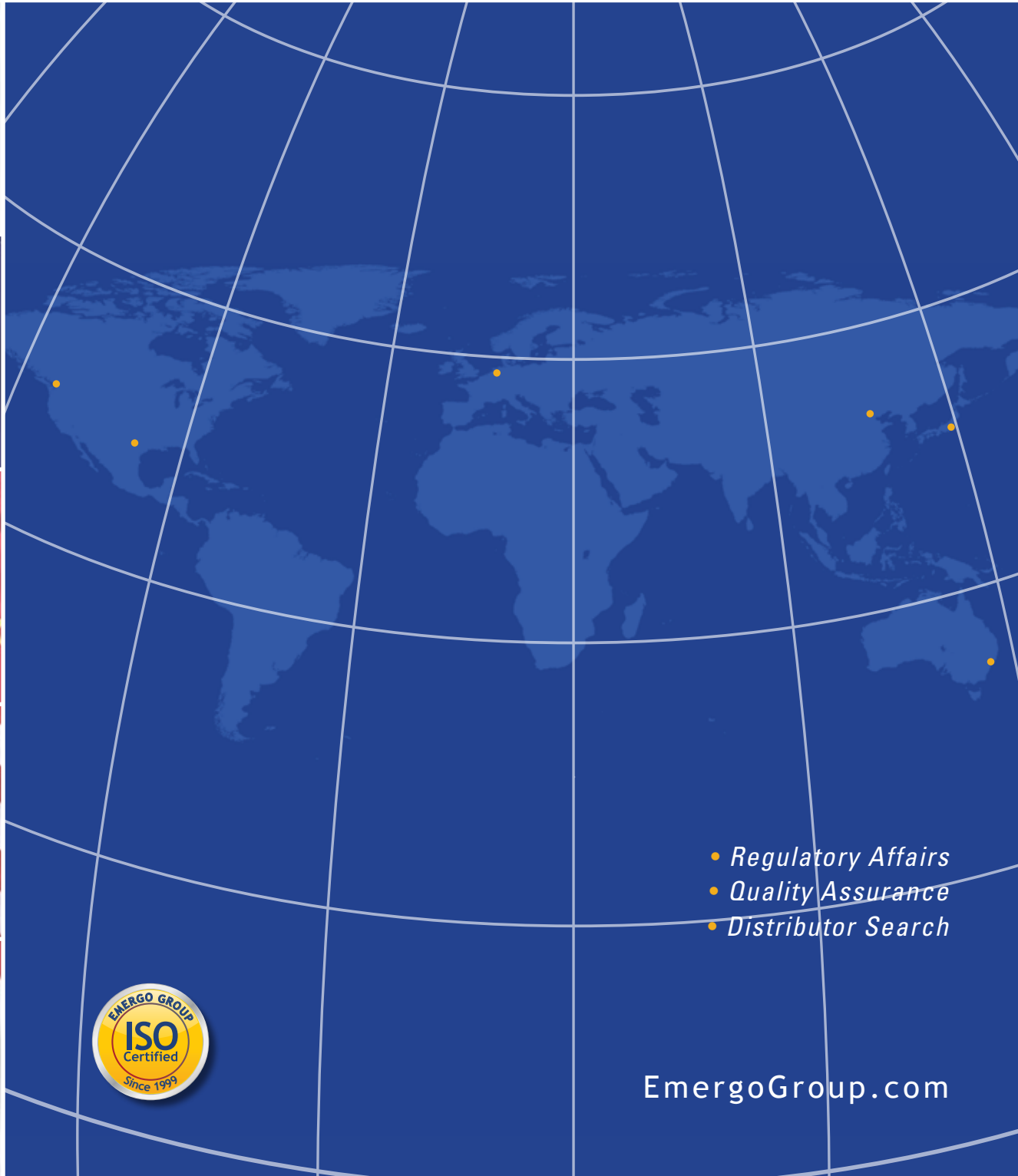
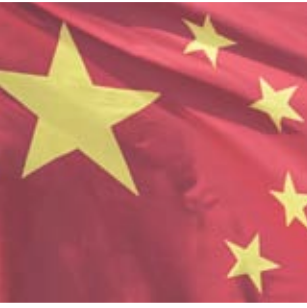


Medical Device Consulting



- *Regulatory Affairs*
- *Quality Assurance*
- *Distributor Search*



Your Partner in International Expansion

Since 1997, Emergo Group has specialized in regulatory compliance, quality assurance and distribution management consulting for medical device and IVD companies.

We assist clients to:

- Obtain regulatory approval to sell devices in specific countries / markets
- Maintain compliance with national regulations
- Maximize sales potential through identifying and managing distributors

Emergo Group's competitive advantages make us your best partner for medical device and IVD consulting:

A single consulting resource for the largest international markets

We offer a wide array of consulting services for North America, Europe, Asia and Australia. With offices in each region, Emergo is a one-stop solution for obtaining regulatory approvals, maintaining compliance and establishing distribution in countries that account for over 85% of the current medical device market.

Collective industry expertise

Every member of our consulting team has experience in the medical device industry. They understand the regulations and know how to apply them to your products.

Specialization to complete projects faster

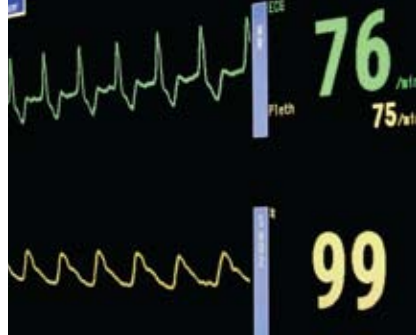
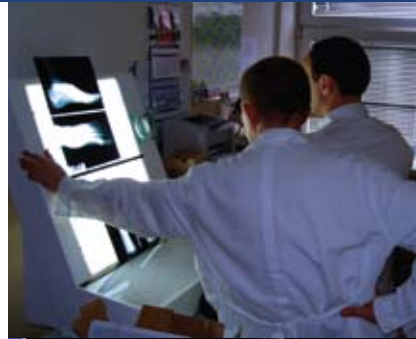
Emergo focuses solely on medical devices and IVDs. Our in-depth knowledge and experience working with over 1,000 device companies enable us to complete projects faster than firms that do not specialize in the device industry.

"Your guidance at the beginning of this process was critical to our success, and we are grateful for the advice and information you generously offered us. We are very pleased with the outcome and glad to have you as advisors."

— Gianluca De Luca,
Manager, Product Development

"Thank you very much for your support in helping us pursue our ISO 13485:2003 certification. All your dedication is really appreciated."

— Maritza Maysonet Ruiz,
Quality Assurance Manager
Ortho-Tain, Inc.





UNITED STATES

The US is the world's largest medical device market, but competition is intense and the FDA clearance and compliance process can be confusing. Our team can assist with many aspects of quality assurance, regulatory compliance and distribution management as shown below.

- 510(k) Submissions
- GMP Quality System Implementation
- Quality Management System Audits
- US Agent Representation
- Form 483 or Warning Letter Response
- ISO 14971 Risk Management & Analysis
- Validation for Processes/Equipment/Software
- Medical Distributor Search and Qualification



EUROPE

The European Union is the second largest medical device market in the world behind the US. We offer a wide variety of services to help companies take full advantage of this large market.

- European Authorized Representative (EC REP)
- CE Marking Consulting
- Technical File / Design Dossier Preparation
- ISO 13485:2003 Implementation & Audits
- ISO 14971 Risk Management Consulting
- Own Brand Labeling Consulting
- Packaging Waste Directive & Green Dot Compliance Consulting
- Medical Distributor Search and Qualification



JAPAN

Japan has a complex regulatory system which is compounded by language challenges. Through our Tokyo office, we offer full service assistance for regulatory approvals, distributor search and ongoing compliance with the Pharmaceutical Affairs Law (PAL).

- Quality System Consulting to Meet MHLW Ordinance #169
- Designated Marketing Authorization Holder (D-MAH) Representation
- Seihin Hyojun Sho Compilation
- Japan Medical Device Nomenclature
- Clinical Trial Management
- Medical Distributor Search and Qualification
- Medical Device Reimbursement Consulting



CANADA

Canada is an excellent (and often overlooked) market for US and European device companies. Obtaining approval from Health Canada is comparable to obtaining European approval. Emergo can assist in all aspects of Canadian compliance.

- Medical Device License (MDL) Applications
- Medical Device Establishment License
- ISO 13485:2003 Quality System Consulting
- Canadian Medical Device Regulations (CMDR) Consulting
- Auditing for ISO 13485:2003 and CMDR
- Medical Distributor Search and Qualification



AUSTRALIA

Australia has largely mirrored European device regulations. Thus, companies that already have CE Marking for their devices find this English speaking market very appealing. Let us help you obtain approval from the Australian Therapeutic Goods Administration (TGA).

- TGA Sponsor Representation
- Medical Device and IVD Registration
- Summary Technical Document (STED) Preparation
- Clinical Trial Management
- Medical Distributor Search and Qualification



CHINA

Many companies are intimidated by the Chinese market. However, manufacturers of high quality devices do well there. Through our Beijing office we can help you obtain regulatory approval from the State Food & Drug Administration (SFDA).

- SFDA Medical Device Approvals
- Legal Agent and After Sales Agent Representation
- CCC Mark Certification
- Clinical Trial Management
- Medical Distributor Search and Management

In-Country Representation

Emergo Group maintains offices in the largest medical device markets around the world. The regulations in most countries require foreign manufacturers to appoint an in-country representative to act as the point of contact for inspection authorities and assist in device registrations and vigilance/adverse event reporting. The responsibilities of the in-country representative vary by country.

Many companies prefer to appoint Emergo as their in-country regulatory representative to help manage their device approvals, registrations and regulatory responsibilities, including vigilance. Having a single company act as your representative in several markets gives you more control over device approvals and coordinated adverse event reporting, including recalls. We ensure that all your regulatory responsibilities and interests are handled professionally. Emergo represents more than 500 companies worldwide as an in-country representative in the following markets:

AUSTRALIA: TGA Sponsor

CHINA: Legal Agent or After Sales Agent

EUROPE: Authorized Representative (EC REP)

JAPAN: Designated Marketing Authorization Holder (D-MAH)

UNITED STATES: FDA US Agent

Distribution Management Services

If you are looking for new medical device distributors in Europe, Japan, Canada, China, Australia or the United States, our EDM Services division can assist you. EDM (Emergo Distribution Management) helps medical device manufacturers find, evaluate, select and manage distributors to ensure a successful long term relationship.

Our approach to finding distribution partners goes far beyond simply doing searches online. We utilize a detailed, multi-step process to ensure that potential distributors are objectively evaluated based on your needs. The ultimate goal is the selection of distributors who are eager and committed to selling your products and have the existing customer base in place to ensure your success. You can learn more about these services at www.Medical-Distributors.com

Contact us for more information

UNITED STATES (Austin): +1.512.327.9997

EUROPE (The Hague): +31.70.345.8570

JAPAN (Tokyo): +81.3.3513.6641

CHINA (Beijing): +86.10.8260.9650

CANADA (Vancouver): +1.800.956.6588

AUSTRALIA (Sydney): +61.2.9006.1662



Six brochures clearly explain the regulatory process in the US, Europe, Japan, China, Canada and Australia. Request your free copies online: www.emergogroup.com/literature