Global Medical Device Market Access
Regulatory | QMS Compliance | Registration | Representation | Distributor Search
EmergoGroup.com
Emergo as your partner.
Medical device and IVD manufacturers—from start-ups to multinationals—choose Emergo as their partner to achieve and maintain compliance with global regulations. Founded in 1997, we have grown to become the leading medical device consultancy with clients in 55 countries worldwide.

Local expertise gives you access to markets worldwide.
Emergo maintains offices on five continents, and all of those offices are staffed by local teams with expertise in the unique regulatory requirements of their countries. That is especially important in markets where having a local presence is imperative due to the complexity of the regulatory environment.

Expanding internationally? We are ready to assist.
Understanding how to efficiently achieve compliance with overlapping international regulations is critically important. When you work with Emergo, you are tapping into the collective expertise of a global consulting team versed in many areas of regulatory compliance. If you are interested in realizing the rewards of a global marketplace, we have the knowledge to get you there.

A full suite of services to help you succeed globally.
Emergo can help medical device and IVD manufacturers evaluate a market, comply with its regulations and establish distribution throughout North and South America, Europe, Middle East and the Asia Pacific region. There is no need to hire multiple consulting firms, or firms with loose affiliations in other countries, to address specific market entry or regulatory issues. Our global offices can handle all of your needs.

Our mission is to facilitate quality medical care worldwide by helping medical device manufacturers introduce products to global markets efficiently without compromising on compliance and safety for patients and users.
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| **Asia Pacific**        |                                                                 |
| AUSTRALIA              | • Medical Device Registration • TGA Sponsor Representation • Clinical Trial Management • Distribution Consulting |
| CHINA                  | • CFDA Device Registration • In-Country Representation • Clinical Trial Management • Distribution Consulting |
| HONG KONG              | • MDCO Device Registration • Local Responsible Person • Regulatory Research • Distributor Qualification |
| JAPAN                  | • Medical Device Registration • PAL Ordinance 169 Compliance • D-MAH Representation • Reimbursement Consulting • Distribution Consulting |
| MALAYSIA               | • Malaysia Authorized Representation • MDA Device Registration • Regulatory Research |
| NEW ZEALAND            | • MedSafe Registration • MedSafe Sponsor Representation • Distributor Qualification • Regulatory Overviews |
| SINGAPORE              | • Device Registration • In-Country Registrant • Distribution Consulting • Importer of Record |
| SOUTH KOREA            | • MFDS Device Registration • KGMP Compliance • Korea License Holder • Reimbursement Consulting • Distribution Consulting |
| TAIWAN                 | • TFDA Device Registration • QSD Letter Holder • Product License Holder • Distribution Consulting |
Medical device and IVD Regulatory compliance is our core specialty, and no other consultancy can help you obtain approval in more markets worldwide. Regardless of your geographic focus, our goal is to help you achieve compliance in your chosen market(s) quickly and cost effectively.

**We understand complex international regulations.**
Emergo maintains local offices in more than 25 countries worldwide. Our offices are staffed by in-house consultants who are experts in their national medical device regulations. We understand the differences between national regulations and apply this knowledge for your benefit in a way that could not be achieved by working with separate consultancies or affiliates.

**Specialized regulatory expertise allows us to complete your projects quickly.**
We have diverse experience with a wide range of devices and disciplines. If you hire us to compile a US FDA 510(k) submission or CE Technical File, you can be assured that our breadth and depth of institutional knowledge, field experience and peer review process will result in a better outcome for you. Smaller consulting firms typically cannot offer this level of specialization, because they do not serve the variety of medical device manufacturers that Emergo does.

**Making sure your needs are addressed.**
If we are assisting you with a regulatory submission for another country, our regional project management team may assist with communication and project coordination. Our global consulting teams can access and share project related documents using our fully secured electronic data platform—regardless of where you are in the world. This is one way we use technology to complete client projects more efficiently.

“Many of our clients are small medical device and IVD manufacturers. It’s our mission to help companies develop their global regulatory and compliance strategies. Smaller companies often choose to work with us because they know we are ready to grow with them over the long term, both domestically and internationally.”

* Rene van de Zande  
* President and CEO
Regulatory compliance consulting
Shown below are a few of the many regulatory compliance services we offer.

Regulatory requirement overviews
If the regulatory pathway for your device is unclear, we recommend making a small investment to determine the device classification, specific regulatory requirements, cost and timeline for approval before deciding to enter a specific market. We can provide customized Regulatory Strategy Roadmaps for your countries of interest.

Device submissions and registrations
We prepare applications and technical dossiers for the US FDA, European Notified Bodies, Japan PMDA, Mexico COFEPRIS, Brazil ANVISA, Australia TGA, Health Canada and many other regulatory agencies worldwide. We often prepare regional submissions (example: Spanish speaking Latin American countries) and submissions in global formats including STED and CSDT.

Postmarket surveillance and vigilance
Emergo Group is fully prepared to assist you with medical device/ incident reports and global vigilance in most markets including the US, Europe, Japan, Mexico, Canada, and Australia.

Risk management
Risk management is essential for manufacturers of medical devices. We can assist with risk assessments and implementation of ISO 14971.

Clinical evaluation reports
There is increasing pressure to provide clinical data to support safety and effectiveness in device submissions, even for low-risk devices. We can assist you in preparing clinical evaluation reports as needed.

Regulatory strategy
Making the right decisions about how to group devices for registration, or how to properly classify products, can have profound implications on costs and time-to-market. We utilize years of hands-on experience to ensure that our clients get their products to market as efficiently as legally possible.

Markets where we can assist with regulatory compliance and consulting.
Thanks largely to the internet, it is easier than ever to do business across borders and time zones. National medical device regulations, once a mystery, are now available online, often in English. Yet, the availability of information has created a new problem – information overload. Emergo can help you make sense of it all. Our job is to help you successfully navigate a maze of national regulations so you can access new markets and start generating sales as quickly as possible.

**One company. Access to 65+ countries worldwide.**
Emergo can help you gain access to markets in Asia, Europe, Middle East and the Americas. There is no need to work with multiple consulting firms or distributors in far off places. Emergo can compile, submit and manage all of your device registrations worldwide.

**Local offices staffed by Emergo employees.**
Some consulting firms may promise to assist you with registrations in many countries, but simply refer you to another consulting firm with whom they maintain a loose partnership. That will not happen when you work with Emergo. Nearly all of our offices are staffed by Emergo employees. Our registration specialists know their market and the nuances of national regulations governing devices in their country. They also have established contacts at their Ministry of Health. Having a local presence can be critical, especially in Asian, Middle Eastern and Latin markets where personal meetings are preferred and often result in better outcomes.

**Ongoing project management and updates.**
We work with clients worldwide so we understand the benefit of working with someone in your own time zone. Our multilingual Project Management teams work closely with our device registration specialists in 25+ countries. In most cases, North American clients work with our US project management team and EU clients work with our European team. As we work on your device registrations, our project management team will be your point of contact, keeping you updated on the status of your registration and working with you to address issues that may arise. Also, all clients have access to their documents 24x7 using our secure, cloud-based document management system.

**Diverse device expertise**
We support clients making a wide range of medical devices and IVDs. This experience allows us to complete projects with speed and precision, saving you time and money. We have proven expertise in:

- Anesthesiology
- Cardiovascular
- Combination Devices
- Dental
- Ear, Nose and Throat
- Gastroenterology/Urology
- General Hospital
- Hospital Hardware
- IVD
- Obstetrics/Gynecology
- Ophthalmic
- Orthopedic
- Radiology
- Surgical Devices
- Wound Care
We can register your device in these markets globally

**NORTH/SOUTH AMERICA**
- Argentina
- Brazil
- Canada
- Colombia
- Costa Rica
- Mexico
- Peru
- United States

**EUROPE/MIDDLE EAST/AFRICA**
- Egypt
- Europe
- Israel
- Russia
- Saudi Arabia
- South Africa
- Turkey

**ASIA PACIFIC**
- Australia
- China
- Hong Kong
- India
- Japan
- Malaysia
- New Zealand
- Singapore
- South Korea
- Taiwan

Markets where we can obtain regulatory approval for your medical device(s).
Medical device regulations in many countries require foreign manufacturers to appoint an in-country representative to act as the point of contact for regulatory authorities and assist in device registrations and vigilance/adverse event reporting. Emergo Group offices fulfill this important role for hundreds of medical device and IVD companies worldwide. Most of our clients are small to medium-sized companies that prefer to have a professional firm rather than a distributor representing their regulatory interests.

**More control over your device registrations.**
Many companies select Emergo as their in-country regulatory representative in order to maintain control over their device approvals, registrations and regulatory responsibilities. The in-country representative often requires full access to your technical documentation and most companies prefer not to put confidential design information in the hands of their distributors. Labeling, manuals and other information often include your selected in-country representative’s name and address. If you elect to use a distributor as the in-country representative and then decide to switch distributors, certain countries will require you to start the registration process over again.

**Coordinated regulatory support.**
In-country representatives are liaisons with national regulatory agencies, and therefore the company representing you should be qualified to handle regulatory issues. As your selected in-country representative, Emergo is available to coordinate inquiries about, analysis of, and responses to, reportable events disclosed by users, distributors or agencies. You will have access to our personnel who are experienced with the national regulatory requirements that apply to your devices in overseas markets. We ensure that all your regulatory responsibilities are handled professionally.

**One company, global representation.**
Having one company act as your representative in numerous international markets gives you more control over medical device approvals and coordinated adverse event reporting, including recalls. Having Emergo as your regulatory representative means all of your technical documentation and device registrations will be with a single company that understands your product(s) and will represent your interests to regulatory authorities in multiple markets where you may be selling your devices.

Emergo can act as your regulatory representative in 20+ markets worldwide.
Markets where we can act as your local regulatory representative.

All representation services are provided by the companies of Emergo Global Representation, LLC.
We develop, implement and maintain integrated quality management systems that comply with the US FDA Quality System Regulation (21 CFR Part 820), ISO 13485, the European Medical Devices Directives (93/42/EEC, 98/79/EC and 90/385/EEC), Japan Ordinance #169, Canadian Medical Device Regulations, Brazil GMP and other national quality system requirements.

**Full service consulting tailored to your needs.**

We focus on the medical device industry and know how to implement a quality management system (QMS) that will not only comply with regulations, but will also improve product quality, raise customer satisfaction and increase overall efficiency. The return on investment (ROI) of an effectively implemented quality system exceeds the cost. Our consultants guide you through every step of the process, writing custom procedures, conducting and monitoring the implementation and training your employees.

**Many markets, one single integrated QMS solution.**

Emergo Group develops and implements a QMS that meets the requirements of the United States, Europe and Canada at no additional cost. Where requested, we can advise you on how to make your QMS compliant with other quality system requirements such as Japan Ordinance #169 and Brazil GMP.

**Hands-on QA management expertise.**

Our consultants have worked for many years in medical device companies and know the specific needs of the industry very well. They know exactly what the regulations require and ensure that your QMS meets the expectations of the US FDA, European Notified Bodies and other regulatory agencies, as needed. Our team’s experience, combined with a strong ability to foster collaboration within companies for whom we consult, makes Emergo your best choice for assistance in developing and implementing quality management systems.

Emergo is ISO 13485 and ISO 9001 certified.
Quality management consulting
From startups to multinationals, we provide a variety of QMS consulting services, including system development, implementation and/or integration. We also assist with gap analyses, due diligence, internal, supplier and pre-assessment audits.

These services are geared towards the following standards and regulations:
• ISO 13485
• European Medical Devices Directives
• US FDA Quality System Regulation (21 CFR Part 820)
• Canadian MDR/CMDCAS
• Japanese Ordinance #169
• Brazil GMP
• South Korea GMP

Ongoing QMS Maintenance
• US FDA Form 483/Warning Letter Response
• Corrective And Preventive Action (CAPA)
• Procedure Development
• QMS Maintenance Outsourcing
• Global Internal, Subsidiary and Supplier Audits

On-Site Group Training
• Internal Auditor
• QSR or ISO 13485
• ISO 14971 Risk Management

Our track record
Since 1997, we have assisted more than 500 clients globally with their quality system compliance efforts.

Markets with specific QMS compliance requirements in which we can assist.
Proper qualification of distributors goes well beyond chance meetings at trade shows or online searches. Foreign languages, different cultures and vastly different time zones all present obstacles to conducting business effectively. There are also time consuming challenges in the distributor selection process such as identifying and contacting distributors that match your requirements, thoroughly screening and qualifying these distributors, and conducting proper follow up. We offer a convenient outsourcing solution for identifying and selecting qualified distributors in major medical device markets.

**Medical distributor search in specific countries or regions.**
There are obvious challenges to entering a new market and finding qualified distributors. Our mission is to assist companies in making well-informed decisions when selecting distribution partners in medical device markets worldwide. Ultimately, we want to match you with distributors who are committed to selling your products and have an existing customer base in place. We achieve this by first helping you define your ideal distribution partner profile. We then use a systematic approach to identify, analyze and screen distributors in specific markets.

**Medical device distributor qualification.**
We know from experience that objective evaluation based on a well documented profile leads to mutually beneficial, long-term relationships. During this process we contact the distributors, introduce your company and provide product information, pricing and samples. Interested distributors will be interviewed, asked to provide details on how they intend to launch your products, and we will check their references. This process narrows the list substantially, leaving two or three distributors per selected market that have expressed a sincere interest in selling your products and meet all of the requirements set forth in your distributor profile.

**Market entry strategy and analysis.**
Before entering a new market, it is vital to know the sales potential for your product and create a market entry strategy. A well-executed market scan can yield valuable information on competing products already in the market, competitor pricing, market opportunities, sales channel strategy, reimbursement levels and more. Emergo can perform market analyses on your behalf, gathering high quality information from local end-users, distributors and industry/product specialists.

*Emergo*
Distributor qualification

Whether you are looking to expand your existing network of distributors, or are entering a new market for the first time, properly evaluating new distributors is vital.

All too often, companies rush into a new market after obtaining regulatory approval only to discover later that they wished they had done more due diligence before selecting distributors.

Choosing the wrong distributor can lead to significant loss in potential sales and a poor relationship with end-users, damaging your brand name and potential for future success.

Worldwide distributor search consulting

Emergo’s local offices can assist you in finding distributors in most major and emerging markets worldwide. Please ask us if you are interested in a country not highlighted on the map below.
Understanding the intricacies of medical device reimbursement from market to market is vital for manufacturers seeking steady revenue sources among public and private insurance providers. Emergo Group can identify key reimbursement issues related to your device in your target markets, as well as the best path to meeting reimbursement requirements specific to your device.

We offer two categories of services. Our Reimbursement Roadmap is designed for clients with little to no familiarity with the reimbursement systems in the countries they plan to enter. Our Reimbursement Assessment is ideal for clients who are familiar with their markets’ reimbursement systems but want support to develop an appropriate reimbursement strategy.

**Reimbursement Roadmap**
- General overview of pertinent reimbursement systems
- Recent or upcoming changes to those systems
- Required steps for reimbursement based on your product
- Recommendations for next steps

**Reimbursement Assessment**
- Mapping a market’s current reimbursement for a specific procedure or treatment, including clinical pathway and guidelines
- Identifying existing codes and corresponding funding
- Mapping processes, barriers and (temporary) alternatives to national and/or regional reimbursement
- Identifying key groups that influence the reimbursement process for this specific procedure
- Investigating data, evidence and other requirements in order to obtain reimbursement
- Investigating specific challenges and opportunities
- Recommendations for short- and long-term market access

Our Reimbursement Roadmap and Reimbursement Assessment services are available for single- or multi-market scenarios.
Clinical Strategy

As user safety and cost containment issues come to the forefront, manufacturers are increasingly being asked to demonstrate the safety and efficacy of their devices. Such “proof” often must be based on clinical data.

We have a broad understanding of the complete spectrum of international compliance issues, from design control and validation to clinical investigation, all the way through to regulatory submission and post-market surveillance. Our knowledge of device regulations in numerous markets means we understand how to leverage your clinical research investment to support your product claims in markets you plan to enter in the future, as well as those in which you are already approved for sale.

Varying levels of clinical support
The extent of our involvement in your clinical research project depends on the availability of in-house resources at your disposal. Emergo can be involved in up-front market analysis and clinical trial strategy/design. We also support all stages of pre-investigational activities, project management and monitoring, and post-market surveillance of clinical studies, which often may be required to show longer-term safety or effectiveness.

In cooperation with our partners at Theorem, we can help you formulate a comprehensive strategy for collecting clinical data needed to support regulatory or reimbursement submissions.

Emergo and/or Theorem offer clinical expertise in the following areas.

- Cardiovascular
- Combination products
- CNS
- Dental
- Dermatology
- Diagnostics
- Endocrinology
- Gastroenterology
- Immunology
- Musculoskeletal
- Nephrology
- Oncology
- Ophthalmology
- Pulmonary
- Surgery

Markets where we can assist with clinical trials.