# 2 Day Workshop Product Registration and Navigating the Approval Process with Regulatory Authorities in Asia Pacific, Europe, Middle East and The Americas

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**Organizer :** conference Manager

**Venue :**

**Location :** WCS Consulting Inc.3190 Stirling Rd, Unit K4, Hollywood, FL 33021,
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**Ticket Price: Seminar One Registration - $1,295.00 Special Group Discount Register for Four attendees - $ 3885**

Course “Product Registrations and Approvals “has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

Although **China’s** medical regulatory bodies are becoming more harmonized with international standards, the Chinese registration process still poses significant difficulties for Western medical device and pharmaceutical firms. Learn how prepare the necessary documents and register your product with the Chinese regulatory authorities. As a special administrative region of China,

**Hong Kong** has its own medical device regulations, separate from the mainland. While Hong Kong had little legislative control over the import of medical devices in the past, recent changes to Hong Kong’s medical device registration system have led to stricter requirements.

The **Indian** medical regulatory system has become more complicated in recent years. In the past, medical devices did not need to be approved at all, but that is not the case today. In India, there are about 30 device “families” that outline which specific medical devices need to be registered.

Registration of medical devices in

**Japan** is complicated, costly, and will generally take between 1-3 years depending on the device classification. In some cases, Japanese regulators require clinical trials in Japan to be conducted, and the costs of these trials can be very high. Product registration in Japan needs to be pursued carefully and only after determining that there is a strong market demand for your product.

**South Korea's** medical regulatory system can be complicated for Western medical device manufacturers due to its increasingly strict requirements and Korea's unique business culture. Learn the process and determine the necessary documents and submitting your application to the **Singaporean** medical device regulatory authorities. The complexity level of **Taiwan's** medical device registration process is comparable to that of Japan's and China's registration processes, though somewhat simpler. In certain cases, U.S. or EU approvals can be substituted for local requirements. In addition, Taiwan's government has recently been overhauling the approval system to improve its efficiency. Before any medical device can be supplied in **Australia**, the device must be included in the Australian Register of Therapeutic Goods (ARTG) which is regulated by the Australian Therapeutic Goods Administration (TGA).

**Canada**

The Canadian Medical Device License (MDL) is required for companies selling Class II, III, or IV medical devices in Canada. The MDL is a product approval, while a MDEL is a permit for the company/distributor/importer itself. Canada's Medical Devices License (MDL) is comparable to the US FDA 510(k) process.

**United States**

One of the first steps towards selling a Class II medical device or IVD in the United States is to file a Premarket Notification with the FDA, also known as an FDA 510(k) submission. Technically, the FDA does not "approve" medical devices or IVDs for sale under the 510(k) process; the agency gives "clearance" for them to be sold in the U.S. We use the term "FDA approval" for simplicity. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

**Mexico**

Mexico is the second largest medical device market in Latin America behind Brazil, and can prove to be a profitable target for medical device and IVD manufacturers. However, registering a device or IVD in Mexico can be challenging. COFEPRIS, the division of the Mexican Ministry of Health (Secretaría de Salud) is responsible for medical device and IVD oversight.

**South America**

Medical devices in **Brazil** are regulated by the Agência Nacional de Vigilância Sanitária (ANVISA). Brazil's base regulations and medical device classification schemes are similar to those found in the European MDD 93/42/EEC. Commercializing your medical device for sale

in **Peru** requires registration with DIGEMID (Dirección General de Medicamentos, Insumos y Drogas), the country's medical device regulator. DIGEMID currently does not have a formal classification system in place, so a device's classification in its country of origin is usually accepted by Peruvian regulators. A four-tier classification system is currently under consideration by the Peruvian government.

**Europe**

In order to sell medical devices and IVDs in the European Union, you must first CE Mark your product. The CE Mark is not a quality mark, nor is it intended for consumers. CE marking indicates to EU regulators that your device meets all applicable requirements of the appropriate EU Directive, such as the Medical Devices Directive (MDD), In Vitro Diagnostic Device Directive (IVDD) or Active Implantable Medical Device Directive (AIMD), as they apply to your product.

**Israel**

Gaining access to the Israeli medical device market—one of the largest in the Middle East—requires registering your device with AMAR, the Israeli Ministry of Health's medical device regulation unit. Medical device registration in Israel is based having prior approval in one of the five founding Global Harmonization Task Force (GHTF) countries: Australia, Canada, Europe, Japan, or the United States. Manufacturers that have already obtained approval for their devices in those markets can leverage those registrations to satisfy most of Israel's medical device regulatory approval requirements.

**Turkey**

All medical devices imported into Turkey are required to have European CE marking. The classification of medical devices is the same used in the EU. Medical devices in Turkey are governed by the General Directorate of Pharmaceuticals and Pharmacy Department of Medical Device Services. The regulation covering medical devices is the Turkish Medical Devices Directive, which uses the framework of the EU Medical Devices Directive (MDD) 93/42/EEC.

## Areas Covered

- Get assistance with medical device registration and medical device approval
- Learn how to access new markets and obtain medical device approval in all the countries listed
- Complete your registration in order to obtain medical device approval as efficiently as possible while realizing that some markets/countries will be more challenging
- Navigate the regulatory system, achieve product registration, and access the medical market
- In a group setting, review and discuss pain points, challenges and workable regulatory and compliance solutions

## Who will Benefit

This seminar will provide an overview and in-depth snapshot of the product registration and approval process for Asia Pacific, Europe, Middle East, United States, Canada, Mexico and South America. Employees who will benefit include all levels of management and departmental representatives from key functional areas and those who desire a better understanding or a "refresh" overview of the registration and approval process in select countries, including:

- Regulatory Affairs Management
- Regulatory Affairs Specialist
- Auditors
- Compliance Officer
- Compliance Specialist
- Clinical Affairs
- Quality Assurance Management
- Marketing & Sales
- Distributors/Authorized Representatives
- Legal Counsel
- Engineering/Technical Services
- Operations/Manufacturing
- Consultants

## Learning Objectives

David R. Dills, is an independent Global Regulatory Affairs & Compliance Consultant and has an accomplished record with more than 26 years of experience in regulatory affairs, compliance and quality consultative services for early-stage/established Class I/II/III medical devices, IVD's, and bio/pharmaceutical manufacturers on the global landscape.

**Event Categories :**