BOSTON EVENTS LIST

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 : NYMT

Venue :

Location : Hilton Garden Inn Boston Logan Airport100 Boardman StreetBoston, MA 02128United States,
Boston, MA, US, ZIP: 02128

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

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.

AGENDA

Course Outline:

09:00 AM - 06:00 PM

Day 1:

Breakfast/Registration: 8-9 am
Start Time: 9 am
Break: 10:15-10:30 am/3:00-3:15 pm
Lunch: Noon (1 hour)
Adjourn/Wrap-Up: 6 pm
Topics: China, Japan, Australia, South Korea, Singapore, Hong Kong, Taiwan

- Which regulatory bodies in the Chinese government are responsible for medical device registration in China?
- In China, are medical devices required to be registered before they can be sold?
- What are the different regulatory classifications for medical devices?
- What does the registration pathway look like for each regulatory classification?
- What are the document requirements for registration for each regulatory classification?
- Is local testing (type testing/sample testing) required for registration?
- When are clinical studies required for registration?
- Is approval in the Country of Origin required for registration?
- In Hong Kong, are medical devices required to be registered before they can be sold?
- What are the advantages of registering for voluntary listing?
- What are the different regulatory classifications for medical devices?
- What does the registration pathway look like for each regulatory classification?
- What are the document requirements for registration?
- Is local testing (type testing/sample testing) required for registration?
- Are clinical studies required for registration?
- Is approval in the Country of Origin required for registration?
- In India, are medical devices required to be registered before they can be sold?
- What are the different regulatory classifications for medical devices?
- What does the registration pathway look like for regulated medical devices?
- Is local testing (type testing/sample testing) required for registration?
- Are clinical studies required for registration?
- Is approval in the Country of Origin required for registration?
- Which regulatory bodies in the Japanese government are responsible for medical device registration in Japan?
- In Japan, are medical devices required to be registered before they can be sold?
- What are the different regulatory classifications for medical devices?
- What are the different application categories for medical device registration?
- What does the registration pathway look like for each regulatory classification?
- What are the document requirements for notification for Class I medical devices?
- What are the document requirements for registration for Class II medical devices?
- What are the document requirements for registration for Class III and IV medical devices? What are other requirements that are necessary for approval in addition to the device application?

- Is local testing (type testing/sample testing) required for registration?
- When are clinical studies required for registration?
- Is approval in the Country of Origin required for registration?
- Which regulatory bodies in the Korean government are responsible for medical device registration in Korea?
- In Korea, are medical devices required to be registered before they can be sold?
- What are the different regulatory classifications for medical devices?
- What does the registration pathway look like for each regulatory classification?
- What are the document requirements for registration for each regulatory classification?
- Is local testing (type testing/sample testing) required for registration?
- When are clinical studies required for registration?
- Is approval in the Country of Origin required for registration?
- Which regulatory bodies in the Singaporean government are responsible for medical device registration in Singapore?
- Which regulatory organizations are considered independent reference agencies by the HSA?
- In Singapore, are medical devices required to be registered before they can be sold?
- What are the different regulatory classifications for medical devices?
- What does the registration pathway look like for Class A medical devices?
- What does the registration pathway look like for Class B-D medical devices?
- What are the document requirements for registration for each regulatory classification?
- Assess the Australian TGA registration requirements for your device(s).
- Research the proper GMDN codes for your medical device(s) in Australia.
- Conduct a Technical File review to ensure completeness, review of clinical summary (a TGA requirement) and file documentation with the TGA.
- Determine the classification of your medical device according to Schedule 1 of the Canadian Medical Devices Regulations (CMDR) and knowing that devices fall into Class I, Class II, Class III or Class IV.
- Prepare 510(k) premarket notification and PMA (Premarket Approval) submissions for US FDA.
- Classify your device, choose the correct Premarket Submission and prepare the appropriate information for your Premarket Submission to the FDA.
- Determine the proper regulatory pathway for your devices andthe documentation required within the applicable registration route for Mexico.
- Determine classification of your medical device or IVD and determine a grouping strategy for your registration in Mexico and prepare and submit registration application documents to COFEPRIS.
- Determine the proper regulatory pathway for your devices and the documentation required within the applicable registration route with ANVISA in Brazil.
- Certain devices require INMETRO Certification in Brazil.
- For all classes, ANVISA reviews registration application and upon approval, ANVISA will publish registration number in the Diario Oficial da Uniao (DOU).
- Prepare a CE Marking Technical File or a Design Dossier (for a Class III device) that includes data demonstrating compliance with the applicable directives (MDD, IVDD, AIMD) in Europe.

- Medical device and IVD CE Marking Technical File or Design Dossier compilation and review.
- Verification of Essential Requirements and Europe.
- Implementation, modification and maintenance of a quality system (usually ISO 13485) that will meet European and other international requirements for Europe.
- Appoint an authorized representative in Israel to interact with AMAR on your behalf and manage your application process.
- Additional Requirements for Obtaining Medical Device Approval in Israel.

09:00 AM - 04:30 PM

Day 2:

Breakfast/Registration: 8-9 am
Start Time: 9 am
Break: 10:15-10:30 am/3:00-3:15 pm
Lunch: Noon (1 hour)
Adjourn/Wrap-Up: 4 : 30 pm
Topics: US, Canada, Mexico, Europe, Israel, Brazil

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- In Japan, are medical devices required to be registered before they can be sold?
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- What are the document requirements for notification for Class I medical devices?
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appropriate information for your Premarket Submission to the FDA.

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- Additional Requirements for Obtaining Medical Device Approval in Israel.

SPEAKER

David R Dills*Regulatory Affairs & Compliance Consultant*

David R. Dills,Global Regulatory Affairs & Compliance Consultant currently provides regulatory affairs and compliance consultative services for early-stage and established Class I/II/III device, IVD, biopharmaceutical, cosmetics and nutraceutical manufacturers on the global landscape, and has an accomplished record with more than 27 years of experience in the areas of Regulatory Affairs, Compliance and Quality Systems. He has been previously employed, with increasing responsibilities by device manufacturers and consultancies, including a globally recognized CRO and has worked directly with manufacturers engaged in compliance remediation activities involving consent decrees, CIA's, warning letters, and customer generated compliance events, conducts QS, regulatory, compliance assessments/audits and FDA Mock Inspections for State of Readiness.

He has been directly involved with constructing, reviewing, and remediating regulatory submissions, U.S. Agent for OUS companies, works closely with the key stakeholders and Agency/Center Reviewers regarding submission meetings and negotiations; clinical affairs/CTM and provides regulatory submissions and post-market project leadership and guidance covering multiple therapeutic and medical specialties based on classification. He has a strong background in the interpretation and applicability of FDA and international regulations, leads activities for the registration and approval process and working with the Agencies in Asia Pacific, EMEA and The Americas, including FDA, European Medicines Agency–EMA, MHRH, ANVISA, PMDA, MOH, CFDA, TGA, and Health Canada and works with management on regulatory strategies and plans supporting a company's commercialization strategy. He directs and leads efforts for PM support involving all phases of the premarketing to postmarketing; establishes Medical Device Single Audit (MDSAP), UDI, and Digital Marketing/Promotion/Advertising compliance strategies; lead efforts regarding AE/Incident Reporting, all aspects of Postmarketing Surveillance and Vigilance Reporting; establish QMS and documentation systems for GxP compliance; ISO 13485 registration and CE Mark, Technical File, Design Dossier and CER consultation; and facilitates multi-country product registrations and licensing.

He recommends action to senior leadership to ensure effective resolution for manufacturers to achieve sustainable and proven compliant systems. Background encompasses broad capabilities in quality systems; documentation development and remediation; regulatory oversight and governance; design controls; CAPA investigations; GxP training; software embedded medical devices/all aspects of SW/SDLC and process validation with compliance oversight; supplier management; and demonstrates credible experience to optimize business performance through proactive strategies to mitigate compliance exposure. Mr. Dills has served on the Faculty Advisory Board for the Pharmaceutical Training Institute, Editorial Advisory Boards for Software Quality Professional and the Institute of Validation Technology (IVT), publisher of the Journal of GXP Compliance and Journal of Validation Technology and on the Readers' Board for Medical Device & Diagnostic Industry and Medical Product Manufacturing News and was nominated and accepted for inclusion into the 2005-2006 Strathmore's Who's Who of Professionals.

Mr. Dills has authored and published validation, regulatory and compliance-related articles, commentaries and technical guides, and is an accomplished global industry presenter. Mr. Dills' academic degrees include Environmental Science and Biology. He is a former Chair and Co-Chair of ASQ's Section 1506 and affiliated with the Biomedical Division, RAPS, AdvaMed, PDA, ISPE, and other industry working group.

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