

Medical Devices & IVDs: A Practical Approach to the Japanese Market

Webcast of live RAPS conference sponsored locally by RMRAS

**Thursday, October 15 and Friday, October 16, 2009
6:30 am – 3:00 pm each day**

This must-attend program for regulatory professionals planning to introduce a medical device or IVD product onto the Japanese market will feature first-hand information from experienced regulatory professionals. Speakers will address the key challenges and provide useful advice for overcoming hurdles throughout the regulatory introduction and clearance process in Japan.

Introducing your product onto a new market can raise many challenges. Whether your product receives regulatory clearance depends heavily on your ability to learn and adhere to different sets of procedures and regulations. In this program, experienced regulatory and related professionals with personal knowledge of Japanese submissions requirements will provide a roadmap of related knowledge and real-life examples of what is required for regulatory clearance in Japan to equip you with up-to-date and relevant information to successfully introduce your product onto the Japanese market

Who should attend:

Mid-level regulatory professionals from small, mid-size and large companies working in the following medical device and IVD regulatory areas that are currently introducing or anticipate introducing a medical device or IVD product onto the Japanese market.

Thursday, October 15 – Medical Devices

Presentations will cover:

- Identify key medical device regulations in Japan
- Identify recent changes to the Pharmaceutical Affairs Law (PAL) legislation
- Recall key notifications of overseas clinical data use to support product application
- Identify strategies to prepare for a Good Clinical Practice (GCP) audit
- Identify steps a company should take to apply for existing or new reimbursement categories
- Develop a strong business strategy that includes reimbursement

Speakers

Program Chair: **Rica Morris**, RAC, senior regulatory affairs specialist, American Medical Systems

Carole Carey, director, international staff, US Food and Drug Administration's Center for Devices and Radiological Health
Alan Gardiner, regulatory affairs specialist, Medtronic
Michael Halper, Small World Medical
Stephen Hull, Hull Associates
Rica Morris, RAC, senior regulatory affairs specialist, American Medical Systems
Keith Roth, director, US Department of Commerce's Office of Japan

Friday, October 16 - IVDs & Overarching Topics

Presentations will cover:

- Identify useful tips for working effectively with Japanese partners and subsidiaries
- Identify techniques and critical areas of consistency for English and Japanese submissions
- Identify best practices for developing an effective relationship with Japanese colleagues
- Identify ways to prepare local submission dossiers
- Understand Foreign Manufacturer Accreditation (FMA) and Quality Management Systems (QMS) requirements and how to incorporate these requirements into existing Quality Systems

Speakers:

Program Chair: **Rica Morris**, RAC, senior regulatory affairs specialist, American Medical Systems

Jason Heaton, ForeignExchange Translations

Kimberly McCoy, RAC, senior quality assurance/regulatory affairs consultant, Emergo Group Inc.

Location

Doubletree Hotel Denver Tech
7801 East Orchard Road
Greenwood Village, CO 80111

We must have at least 15 register in order to host this web conference. The cost for RMRAS members is \$125 for a single day or \$200 if you sign up for both days. To register, please go to www.regonline.com/japan. Your credit card will not be charged until we reach the required number of attendees. To participate, you must go to the Doubletree Hotel.

**For questions or additional information, please contact Nan Matthews,
Error! Hyperlink reference not valid. or 303-843-6414.**