Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Japan - Regulatory Filing Requirements and Compliance Processes for Medical Devices

Singapore

October 16th & 17th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,695.00**

(Seminar for One Delegate)

Register now and save $200. (Early Bird)

Register for 5 attendees

Price: **$5,085.00** You Save: $3,390.0 (40%)*

~~$8,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

David R. Dills

Global 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.

Overview :

- Japan's classification system differs from that of the United States or European Union
- Medical devices are classified to Class I, II, III, or IV depending on their risk level
- Medical devices must also comply with Japanese Industrial Standards and these standards define industry-wide safety and performance requirements
- Strict new package insert requirements

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2-day In-person Seminar:

Japan - Regulatory Filing Requirements and Compliance Processes for Medical Devices

Agenda:

Day One

Lecture 1: Medical Device Registration and Approval Process

- Introductions and Background
- What is the classification scheme for medical devices?
- What are the registration procedures?
- How are devices classified?
- How do regulatory requirements differ for domestic vs. foreign manufacturers?
- How long does it take to register devices?
- New Registration Pathways for Manufacturers
- Revised medical device registration and approval requirements in Japan
- Some Class III medical devices can undergo third party certification
- Medical software programs are independently regulated
- Manufacturers are required to be registered rather than be licensed
- Quality management systems (QMS) are streamlined
- QMS inspection is conducted on the Marketing Authorization Holder and is conducted per product family, not on individual products
- Changes to Marketing Authorization Holder System
- Key Guidelines and Resources
- Will our clinical studies and testing conducted outside Japan be accepted?

Lecture 2: Exercise and Recap of Day 1

- Interactive Discussions
- Review of Regulatory Documents

Day Two

Lecture 1: Medical Device Registration and Approval Process

- Medical Device Registration and Approval Process and Recap from Day 1
- Documentation required for review and approval
- Registration and JMDN Codes
- In-Country Representative/DMAH
- QMS and other requirements
- Documentation and Additional Materials for Registration and Approval
- Consultation sessions with Regulatory Authority, how to maximize foreign clinical data, and how to expedite product registration
- Trends and lessons learned with recent and current registrations
- New medical device regulations and approval requirements are released on a regular basis sometimes and companies must keep track and current
- Regulatory inspection process

Lecture 2: Exercise and Recap of Day 2

- Interactive Discussions
- Review of Regulatory Documents

Lecture 3: Debrief/Adjourn

- Recap of topics and key discussion points and take away message
- FAQs and latest trends

Why should you attend:

- Understand the entire Registration and Approval Process in Japan
- Identify and understand the Major Changes to Medical Device Registration Process in Japan
- Streamline the medical device registration process so that you can obtain approval for your product in the most cost-effective and timely manner
- Participants will discuss their own device registration and approval process relative to their work-related responsibilities and handling submissions

Who Will Benefit:

- Clinical Research Associates
- Clinical Project Managers
- Regulatory Affairs Professionals
- Clinical Investigators and Clinical Research
- Regulatory Affairs Management
- Regulatory Affairs Specialists
- Regulatory Project Leads/SME's
- Auditors
- Compliance Specialists

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
3. PO: Please drop an email to support@globalcompliancepanel.com or call the our toll free +1-800-447-9407 for the invoice and you may fax the PO to 302 288 6884
4. Wire Transfer: Please drop an email to support@globalcompliancepanel.com or call our toll free +1-800-447-9407 for the wire transfer information

What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
9. Networking with industry's top notch professionals

European Regulatory Procedures - Comprehensive Overview of EMA and National Requirements and other Agencies

Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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