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EVENTS LIST

Japan Regulatory Compliance Requirements for Life Science Products

Date : Jun 07, 2018 - 09:00 AM - Jun 08, 06:00 PM

Event URL : http://www.sfbayeventslist.com/events/japan-regulatory-compliance-requirements-for-life-science-products-jun-2018

Organizer : GlobalCompliancePanel

Venue :

Location : 16038, West Vly
Highway Tukwila, WA, USA, ZIP: 98188

This 2-Day seminar covers the details of the Regulatory Requirements for a wide-range of Life Science products in Japan: Pharmaceuticals, Biologics, Medical Devices and Combination Products. The syllabus also covers the change in Japan caused by the re-write of the Pharmaceutical Affairs Law [PAL] into the Pharmaceuticals & Medical Device Law [PMDL] and the country's latest update to GMP requirements.

The information presented will help you gain a comprehensive understanding of the Regulatory Structure, Product Classification, Clinical Trial Requirements, Marketing Authorization Procedures, Variations Processing, License Renewals, GMP requirements and cultural working aspects within the Regulatory Environment in Japan. It will prepare you for regulatory approval processes, Agency meetings, the complexities of running clinical studies, the importance of partner selection and also add the cultural knowledge needed for success in-country. The recent changes made by PMDA to be more sponsor and applicant-friendly, along with the impact this has had on dossier review times, will be shared. Real world experiences on actual interactions with the Agency, since these changes have been implemented, will also be discussed.

Course Objective:

Attendees will leave this Course clearly understanding the Regulatory Procedures necessary to be successful in getting your products to market in a timely fashion. This Course has been updated to provide participants with competitive insight into:

- The impact of the PAL to PMDL Law change to applicants
- Who can legally register Life Science products in Japan
- If you want to be the legal License holder, what will you need: establishment office & personnel type
- When will additional clinical trials be needed on products and on which ones
- Will Japan accept global, clinically-developed data
- How does a Japanese CTD submission differ from ICH requirements
- What is required to register a Medical Device in Japan
- Japan's Medical Device classification procedures and regulatory pathways
- Can you expect a GMP inspection of your facility by PMDA staff; updates to GMP Regulation & Guidelines
- What are your post-marketing responsibilities as a License Holder
- How best to work with the Authorities from a Business and Cultural Aspect

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Who will benefit:

This seminar will benefit Project Team Members, whose specific functional discipline comes from:

- Clinical Operations Staff
- Quality Assurance
- Monitors / CRAs
- Regulatory Affairs Personnel
- Pharmacovigilance Reporting personnel
- Global Supply Chain personnel
- Manufacturing personnel
- Global Business Development personnel
- Commercial Management
- Country Managers
- CRO's, Consultants

Day 1 Schedule

Part I: Japan Regulatory Compliance

Lecture 1:

Japan's Regulatory Structure for the Life Science Product Industries

- Country Healthcare System
- Regulatory Framework: Key Agencies Involved / Reporting Structure
    - MHLW (Ministry of Health, Labor and Welfare)
    - PMDA (Pharmaceutical and Medical Device Agency)
    - Agency Consulting Committees

- Patent System
- Pharmaceutical Affairs Law (PAL) → Pharmaceuticals & Medical Device Law (PMDL)

Lecture 2:

Beginning Your Company Involvement in Japan

- Local Office and Personnel Requirements
- Language Requirements & Translations
- License Types
- Options for Importers / Overseas Manufacturers

Lecture 3:

Objectives of the Rules Governing Medicinal Procedures

Life Science Regulations and the Regulatory Processes in Japan

- Conducting Clinical Trials
- New Product Registrations
- Handling of Risk Management
- Post-Marketing Requirements: Variations / amendments, Safety Reporting, Renewals

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Lecture 4:

Japan's Use of ICH Standards / Principles

- GCP
- GMP
- CTD / e-CTD Submissions

Lecture 5:

Starting-Up and Conducting Clinical Trials

- Who can conduct Clinical Trials?
- When are they needed?
- Start-up Process & Timelines

Day 2 Schedule

Part II:

Lecture 1:

Marketing Authorization Processes - Product Registrations / Licensing

- Drugs
- Medical Devices
- Biologics
- Combination Products
- Drug / Device Master File (DMF) Use in Japan
- Labeling Requirements
- Packaging Information Leaflets

Lecture 2:

Variations: Changes to Marketed Products

- Types of Variations & Dossier Maintenance Expectations

Lecture 3:

License Renewals

- Process and timing for Renewing Licenses

Lecture 4:

Comparing and Contrasting Japan's Procedures vs. U.S. FDA

- Comparison of Processes
- Expected Timelines

Lecture 5:

How and When to Influence the Regulatory Process

- The Do's and Don'ts of Regulatory Involvement in Japan
- Utilizing Local Regulatory Resources

Robert Russell

President / CEO , RJR Consulting, Inc.

Robert J. Russell (Bob) is President / CEO of RJR Consulting, Inc. which specializes in helping clients navigate through Global Regulatory Compliance requirements for Pharmaceuticals, Medical Devices, Biologics, Combination Products and Dietary Supplement / OTC products. Prior to founding the company 17 years ago, Bob had more than 27 years of experience in CMC, Global Business development and Regulatory Affairs for two Fortune 200 firms developing innovative Pharmaceuticals and Medical Devices.

Bob has specific expertise helping companies expand into new regions globally and meet establishment and licensing requirements, clinical trial data expectations, marketing authorization / registration preparation, meet variations / amendment filing responsibilities and license renewal filings. He has practical experience counseling Pharmaceutical and Device manufacturers through GMP, GCP, GLP requirements, CE marking / ISO certifications, Drug / Device Master File preparation, mock pre-audits and issues management with Global Healthcare Authorities. Bob is a past member of the International GMP Working Group on Standards for Industry harmonization with several colleagues from Europe. He holds a B.S. And M.S. in Chemistry.

Please contact Marilyn Turner: Phone: +1 929 900 1853 Email: marilyn.turner [a] nyeventslist.com for registrations

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