2-day In-person Seminar:
Latin America: Regulatory Compliance Requirements for Life Science Products (Focus: Brazil, Mexico, Argentina)

By: Robert J. Russell, President of RJR Consulting, Inc

**Location**: August 25-26, 2016 | Philadelphia, PA

**SPEAKER**

Robert J. Russell, President of RJR Consulting, Inc

Robert J. Russell, (Bob) is the President of RJR Consulting, Inc., a Global Regulatory Consulting company, specializing in understanding regulatory issues for the pharmaceutical, medical device and combination products industry. Bob has more than 30 years of experience working with FDA, EMA, Healthcare Authorities and Agencies across Latin America, Middle East and Asia / Pacific supporting clients projects in these regions. Licensing, registrations, GMP, DMFs and borderline products are core competencies of the Course Director.

Prior to entering the consulting field, Mr. Russell was the Global Director of Regulatory Affairs for two Fortune 100 manufacturers of Drugs and Medical Devices. RJR's offices are located in every major region with in-country experts on staff handling local regulatory needs. Bob has a BS and MS in Chemistry.

**WHY YOU SHOULD ATTEND**

This course specifically focuses on the overall regulatory compliance requirements and procedures for Pharmaceuticals, Medical Devices, Biologics and Combination Products in Latin America. The primary countries covered will include: Argentina, Brazil and Mexico. Other countries such as Chile, Costa Rica, Dominican Republic, Panama, Peru and Venezuela will be discussed. The course will cover topics relating to pre-clinical and clinical requirements, as well as, addressing the structure of the regulatory agencies in Latin America. Content will include descriptions of the methods by which regulators in the corresponding agencies process filings and registrations and what is expected in the authorization and dossier maintenance of the wide array of licensed products.

The current regulatory climate in Latin America is discussed in detail and several examples will be provided to illustrate effective compliance procedures and techniques. Common issues that have caused difficulties for Life Sciences firms in the region are outlined. Course content will explain how Latin America interacts with and utilizes ICH standards and how they relate with other National Healthcare Authorities. Additionally, participants will learn how personnel can best address the conflicts, which arise and the best course for resolution.

Course "Latin America: Regulatory Compliance Requirements for Life Science Products (Focus: Brazil, Mexico, Argentina)" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.
This two-day comprehensive Course on Latin America Regulatory compliance requirements will cover topics ranging from pre-clinical and clinical requirements through product registration, amendments and renewals across Pharmaceuticals, Biologics, Medical Devices and Combination Products. The Course will address the structure of the regulatory agencies in Latin America and discuss local cultural nuances to help you be successful in working with the regulators.

COURSE DESCRIPTION

WHO WILL BENEFIT

- Regulatory personnel whose responsibilities require knowledge of Latin America’s regulatory environment
- Administrative staff responsible for ensuring compliance with regulatory filings and overall regulatory compliance requirements will also find this training highly relevant.
- QA / QC Personnel
- Global Supply Chain personnel
- Clinical / Pharma & Device personnel
- Manufacturing personnel
- Global Business Development personnel
- Any sales or general management employee requiring an understanding of how regulations and compliance issues impact the organization

AGENDA

Day One: 8.30AM – 4.30PM

Registration Process: 8:30 AM – 9:00 AM
Session Start Time: 9:00 AM

- LA Overview
- LA markets
- Harmonization efforts
- Understanding the Regulatory Process
- Regulatory Overview (gov't offices, organization, contact info)
  - Brazil - ANVISA
  - Mexico – COFEPRIS
  - Argentina – ANMAT
- Country Establishment
- Clinical Trials
  - Clinical Trial Start-up
  - Clinical Trial Application
  - IND’s
  - Reporting
  - GCP
- Scientific advice
- Stability studies
- Pharmaceuticals
  - Marketing Authorizations/Registrations
  - Registration requirements
  - Registration documentation/CTD
  - Summary of Product Characteristics
  - Package insert
  - Labeling
  - Pharmacovigilance/Post-marketing
  - Amendments/Variations/Changes/Renewals
  - Fees
- Submission Process
- Paper filings
- Electronic filings

Day Two: 8.30AM – 4.30PM

- Generics & Bioequivalence
- Biologics
- Compassionate use
- Orphan drugs
- Medical Device
  - Device Classification
  - Testing Standards
  - Registrations
  - Amendments/Variations/Renewals
  - Cost build-up model
  - Fees
  - Post-marketing
- Combination products
- Patents/Copyrights/Trademarks
- Import/Export procedures
- Tax exemptions
- Advertising/Promotion
- Comparing & Contrasting LA and US
- Challenges in Latin America
- Influencing the Regulatory Process
- Conclusions & summary

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2650 E. Bayshore Road Palo Alto, CA 94303 | Ph: +1-888-717-2436 Fax: 650-963-2556
Bob was a great instructor, very helpful. Thanks to ComplianceOnline.com for conducting this seminar. Medical Device companies always need to be compliant so guidance/updates are always needed. I would recommend ComplianceOnline.com to others. Thanks!

- Manager, Clinical Operations, Clovis Oncology

This seminar had great overview and introduction to Japan & S. Korea regulatory and clinical environment. Medical Device related material was most valuable for me as it is most aligned with my work. The amount of interaction between the participants and presenter was ideal. I would like to attend future seminar on "Regulatory and Clinical for Latin American countries".

- Director of Global Product Safety, Kimberly-Clark Corporation

Understanding the regulatory structure in the countries and how they interact, was the most valuable topic for me. Overall it was a good seminar - I learned a lot. Enjoyed the informal nature and being able to ask questions as went along. I would like to give thanks to ComplianceOnline for good customer service on the phone.

- Clinical Project Manager, Global Clinical Affairs, Kimberly-Clark Corporation

Instructor was very knowledgeable on topic. Length of the program was appropriate. I like the session of overall submission process. I would like to attend future seminars on China & Asia, and BRIC.

- Regulatory Affairs Specialist, I-Flow, LLC

Overall it was a good course for Japan/S. Korea familiarity. More content on device, more discussion using application of data in real life scenarios, and less straight reading slides. I would like to attend future conferences on "Medical Device Tech Files" and "Medical Device Directives & Essential Requirements."

- Regulatory Affairs Specialist, I-Flow, LLC

ComplianceOnline website was helpful and informative for the conference. I like the areas covered on "Identification of regional differences, and regulations & processes". subject was well chosen and overall it was good experience.

- Sr. Director, Gilead

This course was offered by ComplianceOnline and it was excellent. Bob is very knowledgeable and have answered all my questions. I like the knowledge delivered on Clinical, however, got a lot more on other topics as well. Good Summary. I would like to attend future seminars on China and Latin America.

- Sr. Director of Regulatory Affairs, STAAR Surgical
**Registration Form**

**Terms & Conditions**
Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ +1-888-717-2436 or email us @ editor@complianceonline.com

**Cancellations and Substitutions**
Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($200) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after the event. ComplianceOnline cancels the seminar, if in case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, we will issue a credit for the amount paid minus administration fees ($200). Conference material will be given on the spot if it is available after the event. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after the event. In the event ComplianceOnline cancels the seminar, we will issue a credit for the amount paid minus administration fees ($200). Conference material will be given on the spot if it is available after the event. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after the event.

**Seminars Topic:** Latin America: Regulatory Compliance Requirements for Life Science Products (Focus: Brazil, Mexico, Argentina)

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Email address (so you can receive order acknowledgements, updated news, product information and special offers)

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(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 650-963-2556.