IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmaceutical Regulatory Affairs in Latin America

22 October 2024
+ 25 February 2025

This programme offers a detailed examination of the regulatory landscape, emphasizing both challenges and opportunities for the pharmaceutical industry across key Latin American markets, including Argentina, Brazil, Chile, Colombia, Mexico, and Peru.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Overview

Explore and gain insights into the regulatory framework of the main authorities in key Latin America countries (Brazil, Mexico, Colombia, Chile, Argentina and Peru).

Pharmaceutical products undergo evaluation based on the regulatory requirements outlined by each country for their sanitary registration. The Latin American region faces significant regulatory challenges due to the absence of a unified and standardized procedure among authorities. Each regulatory body has its own set of regulations, making it daunting to navigate through the diverse legal frameworks. In this course, participants will gain insights into the specific regulations of each country, delve into various approaches to obtaining marketing authorization, and analyse commonalities and differences among the most advanced regulatory authorities in Latin America.

Throughout the training, participants will engage in in-depth case studies to explore options and strategies for fulfilling crucial regulatory activities. This interactive learning experience will provide opportunities to discuss and exchange experiences with our expert trainer and fellow delegates.

Benefits of attending

- **Explore** Latin America's regulatory landscape, registration processes, and recognition mechanisms.
- **Understand** varied pathways and strategies dictated by legislation based on the Certificate of Pharmaceutical Product and its compliance criteria.
- **Gain** insight into legislation regarding products demonstrating Therapeutic Equivalence, strategy design based on experience, and regulatory intelligence.
- **Compare** registration dossier structures covering legal, chemical/pharmaceutical, and clinical aspects.
- **Utilise** practical examples to formulate strategies with regulatory authorities.

Key topics to be addressed:

- Pharmaceutical regulations in Latin America covering the following countries: Brazil, Mexico, Colombia, Argentina and Peru
- Regulatory strategies to grant the registrations and access to Latin America markets.
- Good interactions practices with Health Authorities of Latin America region
- Registrations procedures, renewals, and variations in all mentioned countries
- GMP inspections and stability studies

Who should attend?

- Regulatory Affairs Professionals
- Research and Development
- Project Management
- Business Planning
- Business Management
- Manufacturers
- Quality Assurance/Quality Control
- Labeling and Artwork
- Pharmacovigilance

This seminar will be of particular interest to all those who need to learn about successful marketing authorisation applications and in-market regulatory compliance in this region. You will find this seminar useful both as an introductory or refresher course.

Programme

Latin America regulatory environment: Legal Basis

Key Regulations, Directives and Guidelines

Impact and influence of the Main Regulatory Authorities in Latin America

- Argentina
- Brazil
- Chile
- Cuba
- Colombia
- Mexico

Harmonisation initiatives within Latin America

Adoption of the Common Technical Document

Drug Development: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Regulatory Authorities
- Regulations and regulatory considerations

Marketing Authorisation: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Regulations, requirements and regulatory intelligence-based strategy
- Registration and certification/legalisation samples

Compilation of Dossiers: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Contents and formats
- Tips for success/failure
- Country-specific requirements

Compilation of Dossiers: Argentina, Brazil, Chile, Cuba, Colombia & Mexico (continued)

- Regulatory authority/agency assessment
- Process
- Deadlines

Regulatory Submission Strategy: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- How to determine an appropriate submission strategy
- A practical approach - case studies

Commercial Structure: Argentina, Brazil, Chile, Cuba, Colombia & Mexico

- Registration of companies and products
- Regulation and guidelines

Presenter

Belkys Ruiz

Pharmaceutical Chemist graduated from Universidad Central de Venezuela, with more than 15 years of experience in the Pharmaceutical Industry and solid knowledge in the life cycle of medicines. Proficient in the different categories and types of products (new, innovative, generic and specific), medical devices, cosmetics including research, development, authorization and commercialization. I have a postgraduate degree in Drug Health Surveillance, and I play a strategic role in the area of regulatory affairs, leading teams and building links with the health authority in national and international companies in different countries (both Latin American and European region).

Course dates

22 October 2024	**Live online** 09:00-17:30 **UK (London)** (UTC+01) *Course code 15178*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 17 Sep**
25 February 2025	**Live online** 09:00-17:30 **UK (London)** (UTC+00) *Course code 15179*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 21 Jan**

How to book

Online:
ipi.academy/2731

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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