Seminar

FORUM

Marketing Authorisation in Latin America

Focus on: Brazil, Mexico, Argentina, Colombia, Peru & Chile

Topics

- LATAM - regulatory environment and harmonisation trends
- National procedures in Brazil, Mexico, Argentina, Colombia, Peru & Chile
- Dossier requirements for NCEs and generics
- Maintenance: variations and renewal

Including hands-on practical activity - discuss real regulatory affairs cases for each country

Your speakers

Esther Gil López
PAREXEL Consulting,
Madrid, ESPAÑA

Anita Patel
PAREXEL Consulting,
São Paulo, BRAZIL

23 — 24 September 2019 in Frankfurt—Raunheim

Marketing Authorisation in Latin America

Aims and objectives

What are the key success factors in introducing your products in the LATAM region? What do you have to keep in mind when applying for a marketing authorisation in these countries?

This workshop will enable you to answer these questions and will provide deep insights into the regulatory environments of the various markets.

Two LATAM experts will share valuable information regarding:

- dossier requirements,
- marketing authorisation procedures and
- maintenance duties.

In interactive sessions, you will learn about key challenges for each market and will also be given the chance to discuss your own cases. Thus, you will gain better understanding of the regulatory affairs business in the LATAM region.

Who should attend?

This seminar will be of benefit to all those working in the pharmaceutical industry, particularly in regulatory affairs and business development, who are interested in marketing pharmaceuticals in Latin America.

The seminar will focus on human medicinal products (chemicals and biologics; herbals will not be addressed).

Your speakers

Esther Gil López

PAREXEL Consulting, Madrid, ESPAÑA

Regulatory affairs Director South Europe and Latin America

Esther Gil López has 20 years' experience working in Regulatory Affairs, from early phase to late phase clinical trials across all regions, as well as in the provision of scientific and technical support on matters related to product development and marketing approval of drug products. Currently, she manages large international teams of regulatory professionals in Southern Europe and Latin America.

Anita Patel

PAREXEL Consulting, São Paulo, BRAZIL

Pharmacist
Associate Director

Anita Patel has 12 years' of experience in the
field of regulatory affairs, having previously worked at pharmaceutical companies in Brazil. She is experienced in the evaluation and preparation of marketing authorisation applications for medicinal products (new synthetic drugs, biological products, orphan drugs, generics, branded generics). She, furthermore, has participated in meetings with Brazilian health authorities.

Fokus: Brazil, Mexico, Argentinia, Colombia, Peru, Chile

Day one: 09:00 - 17:00

The pharmaceutical market and marketing authorisation in Latin America

Esther Gil López

- LATAM - key figures and regulatory environment
- The local pharmaceutical market - success strategies
- Registration for emerging markets
- Harmonisation trends in the LATAM region

Marketing authorisation and maintenance in Brazil

Anita Patel

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal
- Practical activity: discuss real cases/challenges for marketing authorisation in Brazil*

Marketing authorisation and maintenance in Mexico

Esther Gil López

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal
- Practical activity: discuss real cases/challenges for marketing authorisation in Mexico*

Day two: 09:00 - 17:00

Marketing authorisation and maintenance in Argentina

Anita Patel

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal
- Practical activity: discuss real cases/challenges for marketing authorisation in Argentina*

Marketing authorisation and maintenance in Colombia

Esther Gil López

- National procedure
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal
- Practical activity: discuss real cases/challenges for marketing authorisation in Colombia*

Marketing authorisation and maintenance in Peru & Chile

Anita Patel

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal
- Practical activity: discuss real cases/challenges for marketing authorisation in Peru & Chile*

*Own cases can also be discussed. Please email the case details to h.wolf-klein@forum-institut.de so that the speakers can prepare themselves prior to the meeting.

Registration under
service@forum-institut.com or
Fax +49 6221 500-555

Registration Form

Yes, I will attend the seminar
☐ Marketing Authorisation in Latin America

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no.

E-mail

Contact person at office

Date, signature

FI8417/0/0/0/0/0

How to register

Registration: +49 6221 500-500
Conference no.: 19 09 234

Website:
www.forum-institut.com

Date and venue
23 – 24 September 2019 in Frankfurt–Raunheim
09:00 - 17:00 seminar (08:30 registration day one)
NH Frankfurt Airport West
Kelsterbacher Str. 19-21 · 65479 Frankfurt-Raunheim
Tel. +49 6142 990-0 · Fax +49 6142 990-100

Fee
€ 1890.00 (+ German VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Any Further Questions?

Please feel free to contact me if you have any questions.

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Cancellation Policy

Our general terms and conditions apply (as of 1 January 2016) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.com/t&c