Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES

FORUM

Marketing Authorisation for Human Medicines in Latin America

Topics

- LATAM - regulatory environment and harmonisation trends
- Brazil - current role of ANVISA
- Mexico - dossier requirements for NCEs and generics
- Colombia and Argentina - national procedures and maintenance duties

Focus on:
- **Brazil**
- **Mexico**
- **Colombia**
- **Argentina**

Your speakers

Ana Amélia Padua
Latin America
Regulatory Affairs Expert,
São Paulo, BRAZIL

Esther Gil López
PAREXEL Consulting,
Madrid, ESPAÑA

21 November 2017 in Frankfurt

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 Brazil, Mexico, Colombia and Argentina?

This seminar 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.

They will also inform you on the harmonisation trends in the LATAM region. You are invited to join this seminar for a first-hand update.

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).

Limited number of attendees

This seminar is restricted to 20 participants. This limitation will give participants the opportunity for a thorough discussion.

Your speakers

Ana Amélia Padua

São Paulo,
BRAZIL

Latin America Regulatory Affairs Expert

Ana Amélia Padua has been working in the pharmaceutical industry for 17 years (Medley, Novartis, Parexel, Roche) starting with analytical development in her first year and then moving on to regulatory affairs. Most recently, she has been leading the regulatory policy activities on chemical and bio-therapeutic products for the LATAM region at Roche, driving science-based regulations via local and regional industry associations.

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.

Your programme 09.00 - 17.00

> 9.00

The pharmaceutical market and marketing authorisation in Latin America

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

> 10.15 Coffee break

> 10.30

Marketing authorisation and maintenance in Brazil

- ANVISA - current tasks for the authority
- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal

> 12.15 Lunch

> 13.30

Marketing authorisation and maintenance in Mexico

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal

> 15.00 Coffee break

> 15.30

Marketing authorisation and maintenance in other Latin American countries, such as Colombia and Argentina

- National procedures
- Dossier requirements for NCEs and generics
- Maintenance: variation and renewal

> 17.00 End of the seminar

Marketing Authorisation in Latin America

Registration recommended 30 days in advance

Registration under
formacion@qualitecfarma.com or
Telf.: +34 91 372 83 99

Registration Form

Yes, I will attend the seminar

☐ Marketing Authorisation for Human Medicines in Latin America

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to Register

Registration: +34 91 372 83 99

Conference No. 17 1 232

Internet:
www.qualitecfarma.com

Date / Venue:
Tuesday, 21 November 2017 in Frankfurt
08.30 registration; 9.00 - 17.00 seminar
NH Frankfurt Niederrad
Lyoner Str. 5 · 60528 Frankfurt
Tel. +49 69 666080 · Fax +49 69 66608100

Fee:
€ 1090.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as mid-session refreshments, lunch and certificate. Invoice and confirmation will be forwarded to you.

Hotel accommodations:
A limited number of rooms have been reserved at the hotel and are subject to availability. Please book at least six weeks prior to the seminar to obtain a hotel room at the discounted rate. All bookings should be made directly with the hotel quoting FORUM Institut and the Course No.

Any Further Questions?

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

Pablo García
Conference Manager
Tel. +34 91 372 83 99
formacion@qualitecfarma.com

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