Book before 21 December 2018 and SAVE £100 / €140

Medical Device Regulations in Latin America

To book online go to: **management-forum.co.uk/1644** W

Dates and venue

11 February 2019 **Ref: 10489**

The Cavendish Hotel
81 Jermyn Street, London SW1 6JF
Tel: +44 (0)20 7930 2111
(Note: Entrance via Duke Street)

Programme schedule

Registration and refreshments: 09.00

Start 09.30
Close 17.00

Accommodation

When available we have arranged a preferential rate for accommodation at the venue. To take advantage of this price please mention that you are attending the Management Forum seminar when booking your accommodation.

Email: enquiry.cavendish@the-ascott.com
Web: www.thecavendish-london.co.uk

For information on alternative accommodation please visit our website: **management-forum.co.uk/accommodation**

Three ways to book

management-forum.co.uk | **info@management-forum.co.uk** | **+44 (0)20 7749 4730**

Fees and payment

EARLY BOOKING DISCOUNT **Book BEFORE 21 December 2018**
£599.00 + VAT = £718.80 • €839.00 + VAT = €1006.80

FULL PRICE **Book AFTER 21 December 2018**
£699.00 + VAT = £838.80 • €979.00 + VAT = €1174.80

Multiple booking discount for 2nd or subsequent delegates - 15%
£594.15 + VAT = £712.98 • €832.15 + VAT = €998.58

Payment options

1. Invoice which can be paid by bank transfer or credit/ debit card
2. Online through our secure website when registering

In-house TRAINING

Management Forum in-house training

Coming to Management Forum 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.

To get a **FREE** consultation and to find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***

To find out more please visit: ***management-forum.co.uk***

FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.

PLEASE NOTE: Management Forum Ltd 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 Management Forum will refund the registration fee and disclaim any further liability.

For event cancellation policy and T&Cs see our website

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New event

MANAGEMENT forum

Medical Device Regulations in Latin America

Covering Brazil, Mexico, Colombia and Peru

An essential overview of key requirements for approvals

11 February 2019 London

Benefits of attending:

- **Understand** medical device regulations in LATAM countries
- **Learn** the definition of medical devices and their classification
- **Gain** knowledge of the registration procedures
- **Discuss** recent developments in the LATAM region
- **Opportunities** to meet, network and share experience with other industry colleagues

Expert trainer

Ana Luisa Fritschy
Regulatory Affairs Manager, Aptar and International RA Consultant, France

Includes: Interactive discussion sessions

CPD CERTIFIED The CPD Certification Service

Medical Device Regulations in Latin America

11 February 2019, London

Introduction

This new seminar will provide an essential overview of the key areas of requirements for approvals for medical devices in Latin America.

Focusing on the regulatory requirements and developments in individual countries, the course will include interactive discussion to allow you to exchange experiences with other colleagues.

Who should attend?

This seminar will be of particular interest to:

- Anyone involved in the regulation for medical devices in LATAM
- Those who are new to working with medical devices in the region
- Anyone interested in an update on recent developments

In-house TRAINING

Management Forum in-house events

Elements of this course are also available in-house and can be tailored to your specific needs.
We bring our expert to you and can develop the programme to your team's specific needs at a fraction of the cost of multiple public course fees.

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To find out more please visit: ***management-forum.co.uk***

Expert trainer

Ana Luisa Fritschy, Regulatory Affairs Manager, Aptar, France, has 20 years' experience in the French pharmaceutical industry and health authorities with in-depth knowledge in the development and registration of drugs and medical devices internationally, especially in emerging countries.

Currently, Ana is the co-ordinator of a working group from the French Pharmaceutical Companies Association (Leem) for Brazil. She has developed particular expertise in this country on consultation with ANVISA authorities, transfer of marketing authorization and other aspects related to the establishment of new subsidiaries. In addition, Ana has significant experience in the registration of new drugs and medical devices in Brazil, Mexico, Argentina and Peru.

A certificate of attendance for professional development will be available to each participant who completes the seminar

Group discounts are available upon request. Please contact **customer services** on **+44 (0) 20 7749 4730** or email ***info@management-forum.co.uk***

Programme

- **Welcome and introduction**
- **Introduction to medical devices in the LATAM region**
  - Competitive landscape overview and market opportunities
  - Working with the national authorities
  - How to co-ordinate regulatory operations in the region
  - Mutual recognition and harmonisation
  - Local importation requirements
  - Which countries require permits/licences
  - Working with local consultants and distributors
- **Brazil**
  - Overview of medical device legislation in Brazil
  - ANVISA regulatory approval process
  - Overview of the IVD regulatory requirements in Brazil
  - Medical Device Single Audit Programme (MDSAP)
- **Mexico**
  - Understand the requirements of COFEPRIS regulation for medical devices
  - Medical device classifications
  - COFEPRIS registration routes
  - Post-submission requirements
  - Exploring strategies for bringing a medical device product to market in Mexico
- **Colombia and Peru**
  - Legal overview of medical device regulations in these countries
  - Medical device classifications
  - Registration dossier requirements
  - Renewal and variations
  - Regulatory strategies to access these markets
- **Discussion sessions will take place throughout the day**

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