Regulatory Affairs in Latin America for Medical Devices
Live Online Academy
28-29 April 2021
MEET THE TRAINERS

MARÍA DE LA LUZ LARA MÉNDEZ

María has a Food Engineering Degree from Simon Bolivar University in Mexico City and holds a Master degree in Administration in Productivity and Quality Systems, and Regulatory Improvement diploma. She has more than 15 years of experience in Regulatory affairs in private and public sectors, she worked in the National Regulatory Agency of Mexico (COFEPRIS) for more than 10 years in different areas, as the Marketing Authorization and International affairs areas. She had a key role in the development of official standards, regarding Biotechnological products and pharmacovigilance, and acted as a COFEPRIS representative at various international forums. Currently, she is the CEO at Udelá, a regulatory consulting company in Mexico with presence in Central America and LATAM. She is responsible of the business development of the company.

IVÁN CALDERÓN

Iván is a pharmacist who graduated from UNAM, where he was also awarded a master’s degree for his studies focused on nanotechnology and unconventional routes of administration.

Iván has worked for the pharmaceutical industry in inspections for the compliance of GMPs in the Republic of China with producers of active ingredients (APIs). He has collaborated in the field of clinical studies, focused on bioequivalence and collaborated as an academic.

Iván has worked for the Mexican regulatory agency, has been a member of the Controlled Release Society (CRS) and recently of The Association for Clinical Research Professionals (ACRP); he has participated in international initiatives such as the International Generic Drug Regulators Pilot (IGDRP), the International Pharmaceutical Regulators Forum (IPRF), Dengue Vaccine Initiative (DVI) and in the International Regulatory Cooperation for Herbal Medicines (IRCH).
Day One

Session 1: Introduction to Medical Devices in Latin America
- Working with the national authorities in the region
- Strategies for coordinating regulatory operations in Latin America
- Overview of the competitive landscape in the region
- Mutual recognition agreements and harmonisation in the region

Session 2: Overcoming regulatory challenges in Brazil, Mexico and Argentina
- Evaluating the regulatory requirements and procedures in Brazil: FDA/EMA vs ANMAT vs COFEPRIS vs ANVISA
- Managing future changes to the regulations
- Classification of devices
- Strategic guidance on device registration, including dossier preparation:
  - Dossier requirements
  - Data requirements
  - Timelines
Day One

- Lifecycle management including variations and renewals: managing material, design and manufacturing changes
- Interpreting labelling and packaging requirements
- PMS and Vigilance
- Reporting and follow-up responsibilities

Interactive exercise
Delegates will work through a medical device dossier for one of the countries discussed, either Brazil, Mexico or Argentina, overcoming the problems that have been addressed.

Session 3: Overcoming regulatory challenges in Brazil, Mexico and Argentina

- The GMP inspection for class II and III devices
  - Why is this process so time consuming?
  - Assessing the Medical Device Single Audit Program (MDSAP) led by the IMDRF: how will it speed up the inspection process?
- Exploring how approval in the US, Canada, Japan and Korea will speed up your application in Mexico
Day Two

Session 4: Overview of regulatory procedures and device registration in Colombia, Venezuela, Chile, Peru, Ecuador, Paraguay and Costa Rica

- Comparing local requirements and regulations with Brazil/Mexico/Argentina/EU/US
- Evaluating the differences in device classification
- Developing effective strategies to manage regulatory developments
- Tackling variations and renewals in the region
- Registering your device: Dossier preparation/Translation/Data requirements/Timelines
- Lifecycle management including variations and renewals: managing material, design and manufacturing changes
- Examining labelling requirements
- PMS and Vigilance
  - Reporting and follow-up responsibilities

Session 5: Working with local consultants, host companies and distributors in Latin America

- Examining the importance of having local contacts and how to manage those relationships
- Why use host companies and distributors?
- Assessing the advantages and disadvantages of using a host company/distributor
  - Providing guidance in a challenging country
  - Representing you in the country: Registration and import license holder
  - What happens when this relationship breaks down?
- Methods for finding local contacts that you can trust: how do you evaluate them?
Day Two

Session 6: Importation requirements in Latin America
- Examining local importation requirements in the region
- Discover which countries require a permit/license and the timelines involved
- Developing success strategies for importing devices manufactured overseas using real life case studies

Session 7: Examining specific device issues
- IVD’s
- Combination products
- Using animal derivatives
- Electronic devices
- Software

Interactive case study and group discussion
- Delegates will examine various examples where the relationship between a device company and their local representative has broken down, discussing preventative measures and solutions.
For information or to book a course please contact our Training Consultants

Jessica Purnell
Jessica.Purnell@informa.com
+44 (0)20 7551 9521

Book now>>