ECA Academy
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Speakers

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Ms van Dalen is the global regulatory specialist in the regulatory group dedicated to APIs, with almost 35 years of experience in the regulatory field. She is a board member of APIC, the European API Industry organization, and she participates in the Japan task force, Emerging markets task force and the China task force. She frequently represents APIC in meetings and conferences organized by EMA, EDQM, ICH etc.

How to register APIs in Brazil

Live Online Training on 03 March 2022 from 13:30 - 16:30 h CET

Highlights

- Specifics of the Brazilian Registration File
- Handling Changes in Brazil
- Obtaining the Brazilian GMP Certificate

Programme

Objectives / Background

Since August 2020, the "CADIFA Manual of Administrative Procedures" of the Brazilian Health Regulatory Agency (Anvisa) is valid and needs to be followed for API dossiers. Now, the new version of the "CADIFA Manual" is published and available in Portuguese and in English language.[1]

According to the agency, the DIFA (Active Pharmaceutical Ingredient dossier) must be submitted to Anvisa by the DIFA holder to receive a CADIFA (letter of suitability of the active pharmaceutical ingredient). It shows the compliance of a DIFA with the regulatory requirements. A valid CADIFA and GMP certificate are necessary for the approval of an associated marketing authorization or post-approval change application.[1]

The understanding of Brazilian Registration Procedures for APIs is thus important to know. This Live Online Training provides an overview of the regulatory and GMP requirements for registering APIs in Brazil and obtaining the Brazilian GMP certificate.

[1] Source: CADIFA Manual for Administrative Procedures, CADIFA Manual n° 01, 2nd Version

Target Audience

This Live Online Training has been developed for all who are dealing with API Sourcing, Manufacturing, Quality Assurance and Regulatory Affairs.

Programme

Specifics of the Brazilian Registration File

- The CADIFA system
- The DIFA (API dossier)
- What is different from other regions?

Handling Changes in Brazil

- Relevant guidelines
- How does it work in practice

Obtaining the Brazilian GMP Certificate

- Starting the GMP certificate procedure
- Different sites & different classes of products

Date of the Live Online Training

Thursday, 03 March 2022, 13:30 h – 16:30 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 490
APIC Members € 540
Non-ECA Members € 590
EU GMP Inspectorates € 490
The fee is payable in advance after receipt of invoice.

Registration

Please register register online at **www.gmp-compliance.org.**

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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