ECA Academy
Your GMP/GDP Information Source

Speakers

Marieke van Dalen
MARA Consultancy,
The Netherlands
Ms van Dalen is a global API regulatory specialist leading her own small consultancy in the Netherlands. She has 38 years of experience in the API industry, always in the regulatory field. Her latest position was with Aspen API in the Netherlands, as Global Regulatory Specialist. She was for a long time a Board member of APIC (the European API organisation) and represented APIC often in meetings and symposia with health Authorities all around the world.

Susan Swiggers
Aspen Oss, The Netherlands
Ms Swiggers has a background in molecular biology and more fundamental research at the Rotterdam Erasmus University in The Netherlands. After leaving the lab behind she entered the pharmaceutical regulatory field. At first in drug product regulatory affairs, thereafter switching to drug substance. At Aspen she's involved in the registration of API's in many countries worldwide and providing regulatory support to customers for registration of their drug products, with an additional focus on the changing legislation regarding API registration in Brazil.

How to register APIs in Brazil

Focus on CADIFA and obtaining a Brazilian GMP Certificate

Live Online Training on 13 February 2025 from 10:30 - 15:45 h CET

Highlights

- How to handle Brazilian registrations
- Content of the registration file
- Handling changes in Brazil
- Obtaining the Brazilian GMP (CBPF) certificate

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

How to Handle Brazilian Registrations

- Different ways of submitting API information
- Procedural aspects
- Guidelines

Content of the Registration File

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

Handling Changes in Brazil

- Relevant guidelines
- How does it work in practice?

Obtaining the Brazilian GMP (CBPF) Certificate

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

Date of the Live Online Training

Thursday, 13 February 2025, 10:30 h – 15:45 h CET

Technical Requirements

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 690
APIC Members € 740
Non-ECA Members € 790
EU GMP Inspectorates € 690
The fee is payable in advance after receipt of invoice.

Registration

Please 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

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Phone +49(0) 62 21/84 44-0
Fax +49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content please contact:
Ms Anne Günster (Operations Director) at
+49(0) 62 21/84 44 50, or at
guenster@concept-heidelberg.de

For questions regarding organisation please contact:
Ms Isabell Helm (Organisation Manager) at
+49(0)62 21/84 44 49 or at
helm@concept-heidelberg.de

WA/28022024