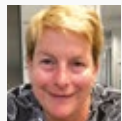


Speakers



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 24 February 2026
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) has been 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

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

Tuesday, 24 February 2026, 10.30 h - 15.45 h

All times mentioned are CET.

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 790

APIC Members € 840

Non-ECA Members € 890

EU GMP Inspectorates € 790

The fee is payable in advance after receipt of invoice.

Registration

By e-mail or by fax – or [search and register directly at www.gmp-compliance.org](https://www.gmp-compliance.org) under the number 22188.

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

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Organisation and Contact

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

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