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.*

**Cristina Jimenez Sala**
Centrient Pharmaceuticals, Spain
*Ms Jiménez is a pharmacist and holds a master's degree in Pharmaceutical Industry. She has been working on different regulatory affairs positions dedicated to the life cycle management of the dossiers for final dosage forms and active principle ingredients for internal and external customers.*

**Andrea Melloni**
European Directorate for the Quality of Medicines (EDQM & Health Care), France
*Mr Melloni has a master's degree in industrial pharmacy (PharmD) from the University of Ferrara, Italy. Since 2020, he has been a Certification of Suitability (CEP) assessor in the Certification of Substances Department at the EDQM. The assessment of chemical and sterile CEP applications falls under the responsibility of his section.*

**Olaf Ludek**
Lyfjastofnun - Icelandic Medicines Agency, Iceland
*Dr Ludek studied chemistry at the University of Hamburg and received a Ph.D. (Dr. rer. nat.) in organic chemistry in 2005. He is working as a quality assessor at the Icelandic Medicines Agency (Lyfjastofnun) since 2010. Since 2012, he is an external expert in the framework of the Certification Procedure of the EDQM in Strasbourg. He was member of the Technical Advisory Board (EDQM) from 2016 until 2022, serving as chairperson from 2020 until 2022. He is member of the CVMP/CHMP (EMA) Quality Working Party since 2012.*

# CEP 2.0

## How to use and prepare an MA with a CEP 2.0

## Live Online Training on 21 May 2025

## Highlights

- EDQM's and National Authority's view on the CEP 2.0
- What information is specific for the CEP 2.0?
- How to use the CEP 2.0?
- Using the CEP outside of Europe

# Programme

## Objectives

This Live Online Training is intended to provide guidance on the format, content and submission procedures for drug substances within the newly implemented CEP 2.0.

You will be informed about the following topics linked to the CEP 2.0:

- What's new? Comparison of CEP and CEP 2.0
- What's expected by the authorities?
- How to obtain a CEP 2.0?
- How to use a CEP 2.0 outside and inside Europe?

Furthermore, you will have the opportunity to reach clarification on ambiguous issues by bringing your questions up for discussion. Take advantage of the experiences of our speakers and send us your questions and challenges prior to the Live Online Training.

## Background

The implementation phase of the new CEP 2.0 was finalized in 2023 and replaced the formerly valid CEP (Certification of Suitability). From now onwards, applicants of a new dossier or renewals will receive a CEP 2.0. This will be available as a PDF file in the so-called sharing tool "DCEP" and will be signed electronically only. For revisions, that affected the content of the CEP, a so called "Hybrid CEP" will be issued. A switch from a valid CEP to a CEP 2.0 is now also possible for CEP holders.

## Target Audience

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

## Programme

### EDQM's View on the CEP 2.0

- Why do we need the CEP 2.0? What is new?
- Cooperation with other authorities
- Outlook to the future

### How to obtain a CEP 2.0 and how to deal with the Users

- What information is specific for the CEP 2.0?
- Information to be provided to the customers
- Wishful thinking about the future

### National Competent Authority´s View on the CEP 2.0

- Experiences with the new CEP 2.0
- Are the current processes working?
- Pitfalls

### How to use the CEP in the Marketing Application in and outside of Europe

- How to use the CEP 2.0?
- Obtaining information from the holder of the CEP
- Using the CEP outside of Europe

### Date of the Live Online Training

Wednesday, 21 May 2025, 10:00 h – 16.00 h CEST

### 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 € 790
APIC Members € 890
Non-ECA Members € 990
EU GMP Inspectorates € 495
The fee is payable in advance after receipt of invoice.

### Registration

By e-mail or you search and register directly at www.gmp-compliance.org under the number 21816.

### 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.

### Organisation and Contact

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

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