



2024 EDQM VIRTUAL TRAINING PROGRAMME

Independent modules on the Ph. Eur., reference standards and the CEP Procedure (CHEMICALLY DEFINED ACTIVE SUBSTANCES)

Week 1 - Programme

Monday, 2 December - Module 1: General methods, general chapters and general monographs (live webinar)

Duration: 1 hour 30 mins

10:00-11:00 General methods, general chapters and general monographs

11:00-11:30 Live Q&A Session

Tuesday, 3 December - Module 2: Individual monographs - Focus on chemically defined active substances and medicinal products containing chemically defined active substances (live webinar)

Duration: 1 hour 30 mins

10:00-10:30 Individual monographs for chemically defined active substances

10:30-11:00 Individual monographs for medicinal products containing chemically defined active substances

11:00-11:30 Live Q&A Session

Thursday, 5 December - Module 3: Impurity control in the Ph. Eur. (live webinar)

Duration: 1 hour 30 mins

10:00-11:00 Impurity control in the Ph. Eur.: theory and practical examples

11:00-11:30 Live Q&A Session

Friday, 6 December - Module 4: Ph. Eur. reference standards (live webinar)

Duration: 2 hours 10 mins

10:00-10:40 Ph. Eur. Reference Standards: establishment and use

10:40-10:50 What GMP inspectors expect concerning RS

10:50-11:40 Handling, dispatch, where to find useful information and other practicalities

11:40-12:10 Live Q&A Session



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Week 2 - Programme

Monday, 9 December - Module 5: Fundamentals of the CEP Procedure (live webinar)

Duration: 1 hour 45 mins

10:00-10:30 General overview of the CEP Procedure

10:30-11:15 Use of a CEP

11:15-11:45 Live Q&A Session

Tuesday, 10 December - Module 6: Building successful CEP dossiers (live webinar)

Duration: 1 hour 30 mins

10:00-11:00 How to build a good new CEP application

11:00-11:30 Live Q&A Session

Tuesday, 10 December - Module 7: Building successful CEP revision applications (live webinar)

Duration: 1 hour 30 mins

14:30-15:30 How to build a good CEP revision application

15:30-16:00 Live Q&A Session

Thursday, 12 December - Module 8: Control of impurities: CEP approach (live webinar)

Duration: 1 hour 30 mins

10:00-11:00 Control of impurities: CEP approach

11:00-11:30 Live Q&A Session

Friday, 13 December- Module 9: The EDQM inspection programme (live webinar)

Duration: 2 hours

10:00-11:00 Introduction to the EDQM inspection programme

11:00-11:30 How to prepare for an inspection – Most common GMP deficiencies

11:30-12:00 Live Q&A Session