



2025 EDQM VIRTUAL TRAINING PROGRAMME

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

Week 1 - Programme

Monday, 1 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, 2 December - Module 2: Individual monographs - Focus on chemically defined active substances and medicinal products containing them (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, 4 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, 5 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*

Week 2 - Programme

Monday, 8 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, 9 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, 9 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, 11 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, 12 December - Module 9: The EDQM inspection programme (live webinar)

Duration: 2 hours

10:00-10:45 *Introduction to the EDQM inspection programme*

10:45-11:30 *How to prepare for an inspection – Most common GMP deficiencies*

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