2021 EDQM VIRTUAL TRAINING PROGRAMME

Independent modules on Ph. Eur., Reference Standards and CEP Procedure
(CHEMICALLY DEFINED ACTIVE SUBSTANCES)

Week 1 - Draft Programme (subject to change)

Monday, 28 June - Module 1: General Methods, General Chapters & General Monographs (Live webinar)
Duration: 1.5 hour
13:00-13:05 Technical Introduction
13:05-14:00 General Methods, General Chapters & General Monographs
14:00-14:25 Live Q&A Session
14:30 Close of module

Tuesday, 29 June - Module 2: Individual Monographs - Focus on Chemically Defined Active Substances & Medicinal Products containing chemically defined active substances (Live webinar) Duration: 1.5 hour
13:00-13:05 Technical introduction
13:05-14:00 Individual Monographs - Focus on Chemically Defined Active Substances & Medicinal Products containing chemically defined active substances
14:00-14:25 Live Q&A Session
14:30 Close of module

Thursday, 1 July - Module 3: Impurity Control in the Ph. Eur. (Live webinar)
Duration: 1.5 hour
13:00-13:05 Technical Introduction
13:05-14:00 Impurity control in the Ph. Eur.: theory and practical examples
14:00-14:25 Live Q&A Session
14:30 Close of module

Friday 2 July - Module 4: Ph. Eur. Reference Standards (Live webinar)
Duration: 1 hour 45 mins
13:00-13:05 Technical Introduction
13:05-13:20 Reference Standards (RS) for chemical and medicinal product monographs
13:20-13:35 RS for general chapters
13:35-13:45 What GMP inspectors expect on RS
13:45-14:25 Handling, dispatch, where to find useful information and other practicalities
14:25-14:45 Live Q&A Session
14:45 Close of module

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Week 2 - Draft Programme (subject to change)

Monday 5 July - Module 5: Fundamentals of the CEP Procedure (Live webinar) Duration: 1.5 hours

13:00-13:05 Technical Introduction
13:05-13:35 General overview of the CEP Procedure
13:35-14:05 Use of a CEP
14:05-14:35 Live Q&A Session
14:35 Close of module

Tuesday 6 July - Module 6: Building successful CEP dossiers (Live webinar) Duration: 1.5 hours

13:00-13:05 Technical Introduction
13:05-13:35 How to build a good new CEP application
13:35-14:05 Introduction to preparing a revision application
14:05-14:35 Live Q&A Session
14:35 Close of module

Thursday 8 July - Module 7: Control of impurities: CEP approach (Live webinar) Duration: 1.5 hours

13:00-13:05 Technical Introduction
13:05-14:05 Control of impurities: CEP approach
14:05-14:35 Live Q&A Session
14:35 Close of module

Friday 9 July- Module 8: The EDQM Inspection Programme (Live webinar) Duration: 1.5 hours

13:00-13:05 Technical Introduction
13:05-13:35 Introduction to the EDQM inspection programme
13:35-14:05 How to prepare for an inspection - most common GMP deficiencies
14:05-14:35 Live Q&A Session
14:35 Close of module