

2023 EDQM VIRTUAL TRAINING PROGRAMME

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

Week 1 - Programme

Monday, 26 June - Module 1: General Methods, General Chapters & General Monographs (Live webinar)

Duration: 1.5 hour

10:00-10:05 Technical Introduction

10:05-11:00 General Methods, General Chapters & General Monographs

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

Tuesday, 27 June - Module 2: Individual Monographs - Focus on Chemically Defined Active Substances & Medicinal Products containing chemically defined active substances (Live webinar)

Duration: 1.5 hour

10:00-10:05 Technical introduction

10:05-10:35 Individual monographs for chemically defined active substances

10:35-11:00 Individual monographs for medicinal products containing chemically defined active substances

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

Thursday, 29 June - Module 3: Impurity Control in the Ph. Eur. (Live webinar)

Duration: 1.5 hour

10:00-10:05 Technical Introduction

10:05-11:00 Impurity control in the Ph. Eur.: theory and practical examples

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

Friday 30 June - Module 4: Ph. Eur. reference standards (Live webinar)

Duration: 2 hours 10 mins

10:00-10:05 Technical Introduction

10:05-10:45 Ph. Eur. Reference Standards: establishment and use

10:45-10:55 What GMP inspectors expect on RS

10:55-11:45 Handling, dispatch, where to find useful information and other practicalities

11:45-12:10 Live Q&A Session

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Week 2 - Programme

Monday 3 July - Module 5: Fundamentals of the CEP Procedure (Live webinar)

Duration: 1.5 hours

10:00-10:05 Technical Introduction

10:05-10:35 General overview of the CEP Procedure

10:35-11:15 Use of a CEP

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

Tuesday 4 July - Module 6: Building successful CEP dossiers (Live webinar)

Duration: 1.5 hours

10:00-10:05 Technical Introduction

10:05-10:35 How to build a good new CEP application

10:35-11:05 Introduction to preparing a revision application

11:05-11:35 Live Q&A Session

Thursday 6 July - Module 7: Control of impurities: CEP approach (Live webinar)

Duration: 1.5 hours

10:00-10:05 Technical Introduction

10:05-11:05 Control of impurities: CEP approach

11:05-11:35 Live Q&A Session

Friday 7 July- Module 8: The EDQM Inspection Programme (Live webinar)

Duration: 1.5 hours

10:00-10:05 Technical Introduction

10:05-10:35 Introduction to the EDQM inspection programme

10:35-11:05 How to prepare for an inspection - most common GMP deficiencies

11:05-11:35 Live Q&A Session