

## 2022 EDQM VIRTUAL TRAINING PROGRAMME

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

#### **Week 1 - Programme**

#### **Monday, 27 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, 28 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

#### **Wednesday, 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

#### **Wednesday 29 June - Module 4: Ph. Eur. reference standards (Live webinar) Duration: 2 hour 10 mins**

**13:00-13:05** Technical Introduction

**13:05-13:30** Ph. Eur. Reference Standards: establishment and use

**13:30-13:45** RS for general chapters

**13:45-13:55** What GMP inspectors expect on RS

**13:55-14:45** Handling, dispatch, where to find useful information and other practicalities

**14:45-15:10** Live Q&A Session

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

#### **Week 2 - Programme**

##### **Monday 4 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 5 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 7 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 8 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