Certified for success:
using the CEP Procedure to elevate quality and drive trust
23-24 September 2025, Budapest, Hungary

Tuesday, 23 September 2025

Draft Programme *(subject to change, 23/05/25)*

08:00 - 09:00 **Registration**

09:00 - 09:30 **Welcome addresses**

Petra Doerr, EDQM, Council of Europe
Rita Pálffy-Poór, National Center for Public Health and Pharmacy (NNGYK)
Susanne Keitel, Chair of the CEP Steering Committee

09:30 - 10:00 **Keynote speech**

Building Trust in a Challenging Public Health Environment

Speaker invited - World Health Organization (WHO)

10:00 - 10:30 **Coffee break**

10:30 - 12:30 **Session I**

Navigating CEP 2.0: A Game Changer

Moderator: Sarah-Taïssir Bencharif, Medical Doctor and Health Care Reporter

10:30 - 10:50 CEP 2.0: where do we stand today
Andrea Melloni, EDQM, Council of Europe

10:50 - 11:10 CEP 2.0: the CEP holder's perspective
Speaker invited - Industry representative

11:10 - 11:30 **CEP 2.0: the pharmaceutical industry perspective**
Karina Boszko, Medicines for Europe

11:30 - 11:50 **CEP 2.0: the regulatory authorities perspective**
Speaker invited - Regulatory Authority representative

11:50 - 12:30 **Panel discussion and Q&A: has the CEP 2.0 achieved its goals?**

12:30 - 13:30 **Lunch break**

13:30 - 15:30 **Session II**

Get ready! New Developments on the Horizon

Moderator: **Sarah-Taïssir Bencharif**

13:30 - 13:50 **Applying modern technologies on well-established APIs**
Stéphanie Girard, Seqens

13:50 - 14:10 **Modernising the CEP procedure**
Hélène Bruguera, EDQM, Council of Europe

14:10 - 14:30 **Finding your way with the new eCTD (ICH-M4Q)**
Ivica Malnar, Agency for Medicinal Products and Medical Devices (HALMED)

14:30 - 14:50 **The potential use of AI for CEP assessments**
Richard Weissmahr, Swissmedic

14:50 -15:30 **Panel discussion and Q&A**

15:30 - 16:00 Coffee break

16:00 - 17:30 Session III
The power of GMP inspections
Moderator: Sarah-Taïssir Bencharif

16:00 - 16:20 **The EDQM Inspection programme: the past, the present and the future!**
Thomas Hecker, EDQM, Council of Europe

16:20 - 16:40 **International Collaboration GMP inspections of API manufacturers**
Speaker invited - European Medicines Agency (EMA)

16:40 - 17:00 **The role of PIC/S to enhance inspections of API manufacturers globally**
Hirofumi Suzuki, PMDA secondee at Pharmaceutical Inspection Co-operation Scheme (PIC/S)

17:00 **Panel discussion and Q&A**

17:30 Close of day 1

19:00 Official Dinner

Wednesday, 24 September 2025

09:00 - 10:30 Session IV
Maximising the Potential of CEPs
Moderator: Sarah-Taïssir Bencharif

09:00 - 09:20 **Relying on CEPs: ANVISA's experience**
Speaker invited - Agência Nacional de Vigilância Sanitária (ANVISA), Brazil

09:20 - 09:40 **Reliance is the key - Perspective of WHO and good reliance practices**
Marie Valentin, World Health Organization (WHO)

09:40 - 10:00 **CEP Acceptance – a global achievement (Industry views)**
Melanie Ramsimmer, Sandoz

10:00 - 10:30 **Panel – multi-stakeholder discussion and Q&A**

10:30 - 11:00 Coffee break

11:00 - 12:15 Panel Discussion - Q&A

Future place of certification in the European Regulatory landscape

Moderator: Sarah-Taïssir Bencharif

Members of the panel will include:

Susanne Keitel, Chair of the CEP Steering Committee
Petra Doerr, EDQM, Council of Europe
EU Commission
European Medicines Agency
European Chemical Industry Council / Active Pharmaceutical Ingredients Committee (APIC/Cefic)
Medicines for Europe

12:15 - 12:30 Closing addresses / Closing remarks

Petra Doerr