

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, 06/06/25)*

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 - 12:10 CEP 2.0: the regulatory authorities perspective

Zuzana Fliegerova, State Institute for Drug Control (SUKL)

Richard Weissmahr, Swissmedic

12:10 - 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**

Speaker invited – Authority

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