

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

Tuesday, 23 September 2025

08:00 - 09:00 Registration

09:00 - 09:30 Welcome addresses

09:30 - 10:00 Keynote speech

Building Trust in a Challenging Public Health Environment

10:00 - 10:30 Coffee break

10:30 - 12:30 Session I: Navigating CEP 2.0: A Game Changer

10:30 - 10:50 CEP 2.0: where do we stand today

10:50 - 11:10 CEP 2.0: the CEP holder's perspective

11:10 - 11:30 CEP 2.0: the pharmaceutical industry perspective

11:30 - 11:50 CEP 2.0: the regulatory authorities perspective

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

13:30 - 13:50 Applying modern technologies on well-established APIs

13:50 - 14:10 Modernising the CEP procedure

14:10 - 14:30 Finding your way with the new eCTD (ICH-M4Q)

14:30 - 14:50 The potential use of AI for CEP assessments

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

16:00 - 16:20 EDQM inspection programme and its impact

16:20 - 16:40 **International Collaboration GMP inspections of API manufacturers**

16:40 - 17:00 **The role of PIC/S to enhance inspections of API manufacturers globally**

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

09:00 - 09:20 **Relying on CEPs: ANVISA's experience**

09:20 - 09:40 **Reliance is the key - Perspective of WHO and good reliance practices**

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

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

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