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Using the CEP Procedure to elevate quality and drive trust

23-24 September 2025 | Budapest, Hungary

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Get ready ! Modernising the CEP Procedure

Hélène BRUGUERA, EDQM, Council of Europe

September 2025

CEP procedure as an attractive regulatory option

Since its creation more than 30 years ago, the CEP procedure has evolved with scientific knowledge and regulatory requirements as well as stakeholders' needs

It is widely used globally, with an increasing number of regulatory authorities accepting CEPs worldwide

Continuous improvement is in the procedure's DNA

Strengths of the CEP procedure

- A robust governance and experts' network to perform the activities
- An efficient process to grant a CEP (and manage the lifecycle) while ensuring the quality and safety of pharmaceutical substances
- A robust GMP inspection programme
- Transparency and Trust to enable Reliance and global acceptance

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In the work programme

Guidance for CEP holders

- ★ Revised EDQM guideline “Revisions/renewals of CEPs”
  - ★ Alignment with recently revised EU classification guideline
  - ★ Additional clarifications
  - ★ Draft document to undergo (short) public consultation Q4 2025
- ★ Revised EDQM guideline “Management of CEP applications”
  - ★ Minor updates to process and timelines to reflect current practices
  - ★ Simplification and modernisation of content
  - ★ Availability Q4 2025
- ★ Revised EDQM guideline “Use of a CEP in a CEP dossier”
  - ★ Minor updates to reflect CEP 2.0 implementation
  - ★ Availability Q4 2025
- ★ And more to come in 2026…

➔ **Monitor the EDQM website and social media**

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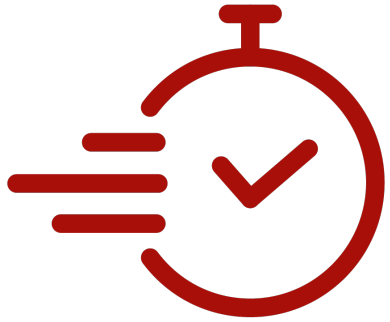
Fast-Track and Reliance

To facilitate access to quality medicines for patients



Fast-Track:

expedited assessment
for some applications

Reliance:

increased use of assessments
of trusted authorities

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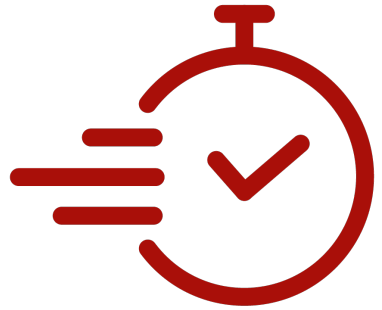
Fast-Track



- As part of EDQM's portfolio of actions to:
  - Contribute to mitigating risks of shortages of medicines
  - Align with the aims of the EU Critical Medicines Act

- Expedited assessment
  - For new applications or revisions of CEPs
  - Upon justified requests from authorities or applicants
  - Establishment of pre-defined criteria (e.g. Union list, etc)
  - Dedicated process
  - Shortened timelines

Reliance as a core strategy

- To make best use of assessors' resources and enhance convergence of assessments
- Already used for a while
  - Mainly for new CEP applications – 5% to 10%
  - CEP applicants declare via the application form whether their substance has been approved by means of an ASMF/DMF (conditions apply)
  - EDQM gets (confidentially) the relevant Assessment Report from the authority and uses it as a reference for own assessment
- Increased opportunities to use reliance
  - Review of criteria
  - Dedicated process and promotion
  - Shortened timelines

Digitalisation

- e-submissions of CEP applications
  - Q4 2025: Automation of upload of e-submissions at the EDQM – **Phase 1**
    - **Immediate impact for applicants:** strict implementation of requirements for e-submissions (eCTD validation)
  - 2026: **Phase 2 -** e-Application Form / interface to enable:
    - Integration with SPOR OMS database for companies' information
    - Automation of recording of procedures

  - 2026 onwards: exploring applicants' space:
    - Submission of applications, file status tracking
    - Hosting documents including CEP certificates
    - Communication between applicants/holders and the EDQM

Digitalisation (2)

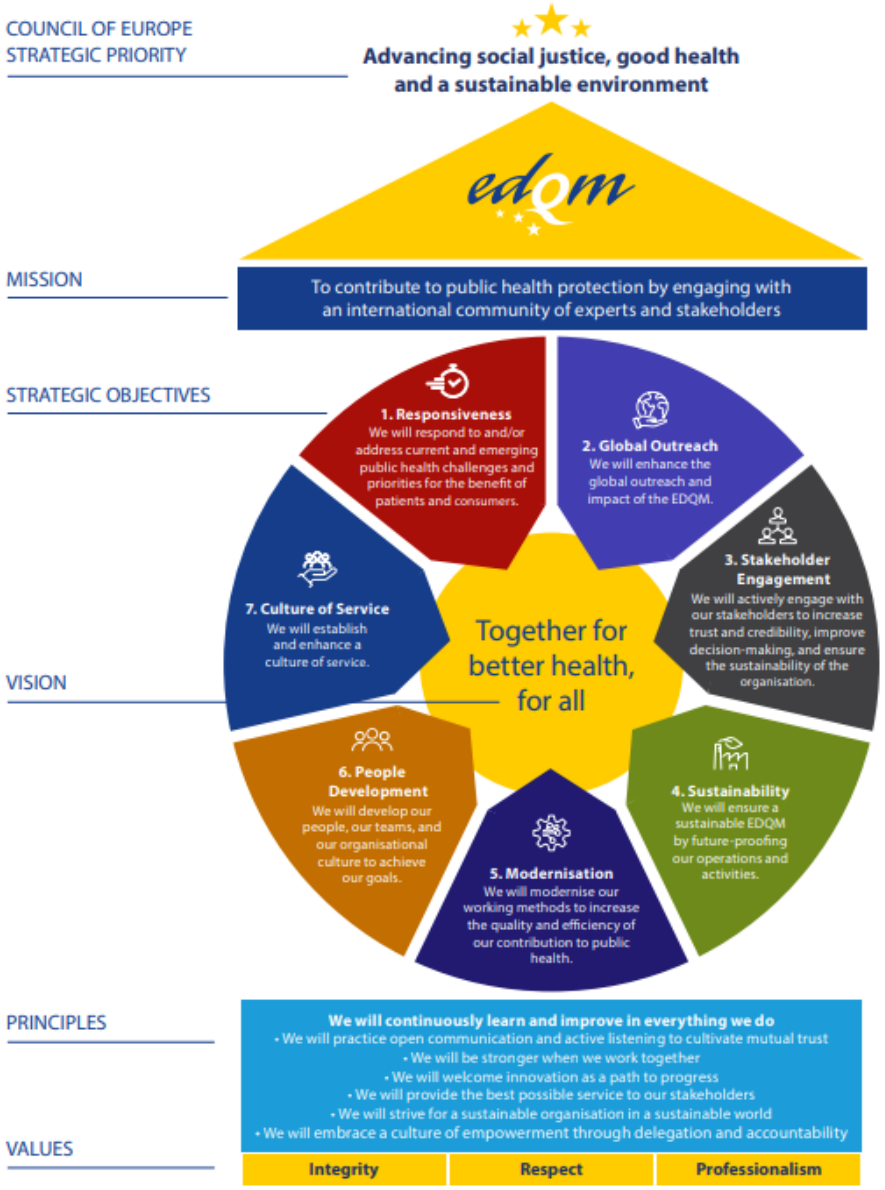
- CEP certificate as **100% digital document**
  - to enable searches in content of CEPs including annexes (copies from dossiers)
  - to facilitate import of metadata by regulatory authorities for CEPs included in marketing applications
  - to integrate with SPOR OMS + reduced level of details for companies' information

  Impact for applicants ➔ reduce or eliminate scanned documents in CEP applications

- Prepare for ICH M4Q(R2) and SPQS

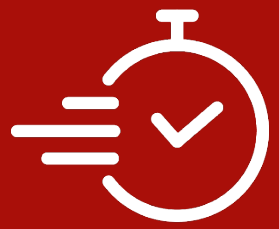
- Exploring use of AI to support CEP processes

EDQM Mid-Term Strategy (2024-2027)



[on EDQM website]

The “CEP for excipients”



1. Responsiveness

We will respond to and/or address current and emerging public health challenges and priorities to the benefit of patients and consumers

Rationale

- ★ Excipients already in scope of the procedure however most CEPs are for active substances
- ★ Feedback from stakeholders that the procedure is not fit for excipients (unclear requirements and risks of misuse)

Scope

- ★ **Explore specific CEP type for excipient** with appropriate requirements and making clear that the substance may be used as an excipient and not as an API

Expected benefits

- ★ Increased adherence to requirements for excipients
- ★ Increased transparency, mitigation of risks of misuse
- ★ Increased attractiveness of the CEP procedure

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Project milestones

End 2024
Detailed SWOT
and internal validation

Q1 2025
Prepare high-level proposal
to be discussed with
stakeholders

26 June 2025
Stakeholder meeting(s) to discuss proposals:

- Content of the dossier
- Content of the CEP certificate
- GMP/Quality system

For endorsement by CEP Steering Committee Q4 2025

End 2025
Develop proposal

- ★ Guidelines, templates
- ★ IT tool
- ★ Communication with stakeholders

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The EDQM inspection programme

2. Global outreach

We will enhance the global outreach and impact of the EDQM

Rationale

- ★ High number of sites (> 1200) and limited capacity (including within national authorities)
- ★ EDQM highly dependent on EU/EEA/MRA inspectors

Scope

- ★ Increased number of on-site or distant GMP inspections for API manufacturers (involved in CEPs)
- ★ Increase Reliance mechanisms and international cooperation
- ★ Explore scenarios for the EDQM to be recognised as inspectorate and to issue GMP certificates (e.g. PIC/S membership)

Expected benefits

- ★ Increased GMP supervision and impact
- ★ Strengthened CEP procedure

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Sustainability at the EDQM

4. Sustainability

We will ensure a sustainable EDQM by future proofing its operations and activities – 6 Projects

Assets/Equipment & Infrastructure

- Future proofing our infrastructure (construction of a 3rd building and refurbishing/renovating existing building)

Employees

- Moving towards workforce planning to ensure sustainability in our workforce

Environment & health

- Environmental sustainability within our organisation (internal)
- Environmental sustainability within our activities for our stakeholders (external)

Stakeholders

- Consolidating & future proofing our IT architecture and tools

Business model

- Securing the EDQM's long term financial sustainability

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Environmental sustainability

- ★**Reduction of environmental impact** (e.g. minimise ecological footprint, managing waste efficiently, using resources sustainably)
- ★**Sustainable innovation** (e.g. greener processes)
- ★**Transparency** (e.g. communicate on sustainability efforts and commitment)
- ★**Social responsibility** (e.g. promote sustainability efforts, build trust with users and stakeholders)

These expectations have moved from “nice-to-have” to mandatory criteria

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Environmental sustainability (« external »)

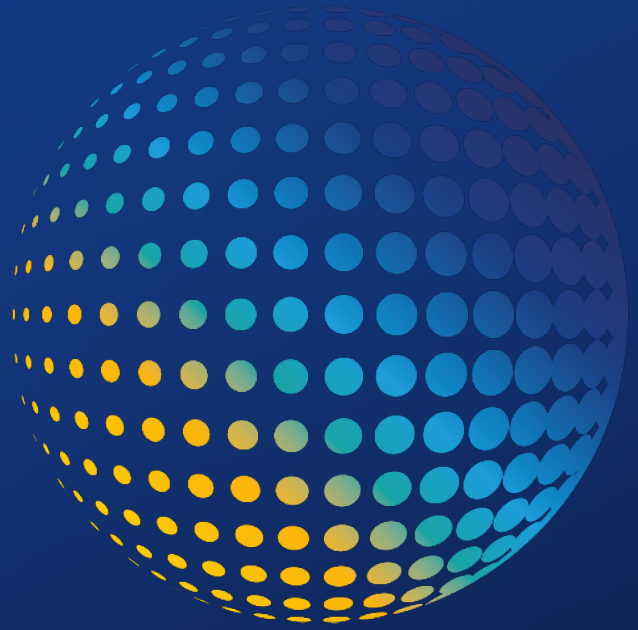
What CEP holders can do:

- ★ Avoid and reduce use of hazardous materials for production and in analytical testing
- ★ Reduce amounts of solvents (including water) in processes and in analytical testing
- ★ Use green(er) technologies to produce substances (enzymatic processes, flow chemistry, etc.)
- ★ Etc.

What the EDQM can do:

- ★ Update Ph. Eur. monographs and reference standards to incorporate sustainable approaches
- ★ Support CEP holders in implementing sustainable initiatives
  - ➔ Preparedness for assessments
  - ➔ **Technical Advice meetings** as a good tool for innovative initiatives

THANK YOU FOR YOUR ATTENTION



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