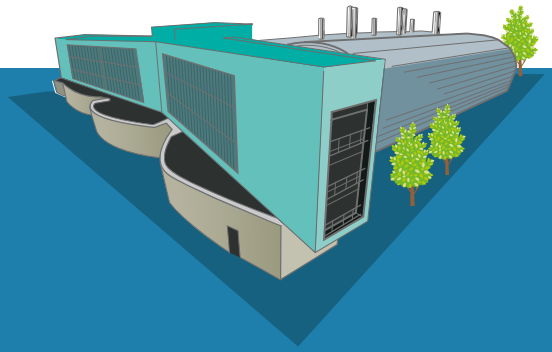
EDQM Certificate of Suitability (CEP): A robust procedure, which exists for 30 years

What is the CEP?

Certificate of Suitability

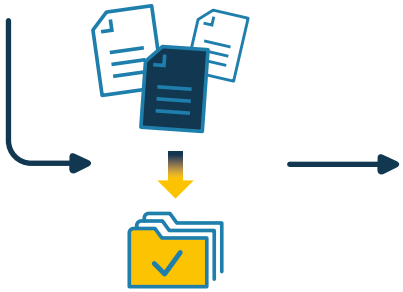
- Assess and conclude that the quality of a substance* is controlled by the Ph. Eur.monograph and additional tests if needed
  *except for biologicals
- Check compliance with GMP at manufacturing sites



European Directorate for the Quality of Medicines and HealthCare (EDQM)

The CEP procedure centralises the evaluation of the quality of pharmaceutical substances for the benefit of regulatory authorities and industry alike, thus saving time and resources and ensuring harmonisation in the assessment of data.

Regulatory Authorities accepting CEPs



Centralised assessment:
saves time and resources

CEP
Marketing Application evaluation

FOR MORE INFORMATION
https://go.edqm.eu/CEPProcedure

The CEP: Actors

Steering Committee (SC)
(Representatives/
Chairs of key European
regulatory bodies & actors)

Assessors from
- **Authorities members of European Pharmacopoeia Convention**
- **EDQM**

→ **CEP certificate granted after evaluation**

Technical Advisory Boards (TABs)

GMP inspectors from
- **National competent authorities from the EU/EEA**
- **EDQM**

→ **Check compliance with GMP and CEP application at sites**

FOR MORE INFORMATION
https://go.edqm.eu/CEPProcedure

How the CEP assessment procedure works for applicants

edqm European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

CEP Application
Additional information

Evaluation

Request for additional information

CEP granted

Request for inspection

Inspection

Renewal

Revision

Request for Ph. Eur. monograph revision

Transfer to the Ph. Eur. experts group

Ph. Eur. monograph revision

FOR MORE INFORMATION
https://go.edqm.eu/CEPProcedure

The EDQM inspection programme

Mission:

verify the compliance with:

- submitted CEP dossier
- EU GMP Part II & any applicable annex

Framework:

- Integral part of the CEP procedure
- For manufacturing sites of active substances (APIs) involved in CEP(s)
- Risk based approach to select sites

Tools:

- On-site inspections
- Documentation based GMP assessment using reliance principles
- Real Time Remote Inspection (RTEMIS)

FOR MORE INFORMATION
https://go.edqm.eu/CEPProcedure

The CEP: Features & benefits

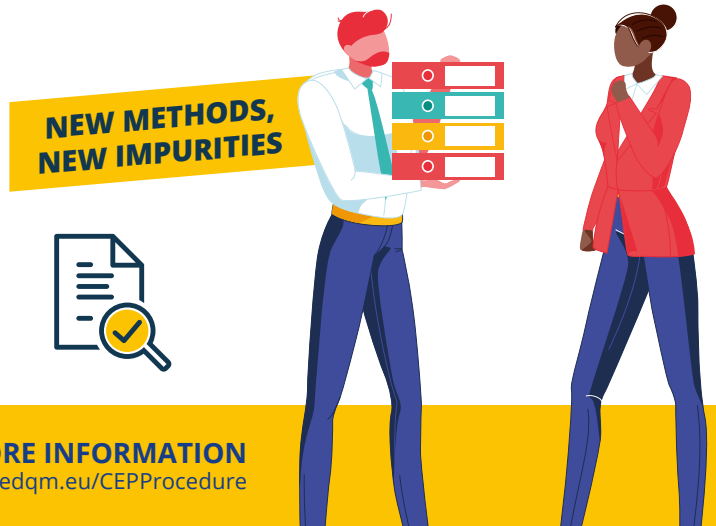
Acceptance and mutual reliance

CEPs are widely accepted in the Ph. Eur. member states and beyond, for example: Australia, Canada, Ghana, Morocco, Saudi Arabia, Singapore, South Africa, Chinese Taipei, WHO (World Health Organisation)

Easier Management of Marketing Authorisation Applications and variations

> The CEP replaces part of the data in the MAA dossier, section 3.2.S

> Single assessment (harmonised decision) of CEP dossiers and variations to it.



Generation of evidence for the revision of the Ph. Eur.

CEP procedure contributes to the revision of **Ph. Eur. monographs.**

FOR MORE INFORMATION
https://go.edqm.eu/CEPProcedure