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

What is the CEP?
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

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.

Centralised assessment: saves time and resources

European Directorate for the Quality of Medicines and HealthCare (EDQM)
Regulatory Authorities accepting CEPs

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

Technical Advisory Boards (TABs)

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

CEP certificate granted after evaluation

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

- **CEP Application**
  - Additional information

- **CEP granted**
  - Request for Ph. Eur. monograph revision
  - Renewal
  - Revision

- **Evaluation**
  - Request for additional information
  - Request for inspection

- **Inspection**

- **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
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.