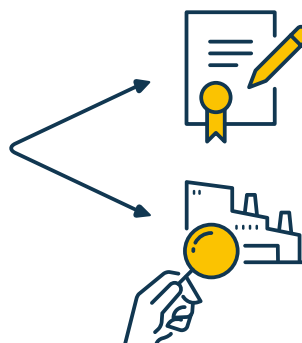


EDQM Certificate of Suitability (CEP): A robust procedure, which exists for 30 years

What is the CEP?



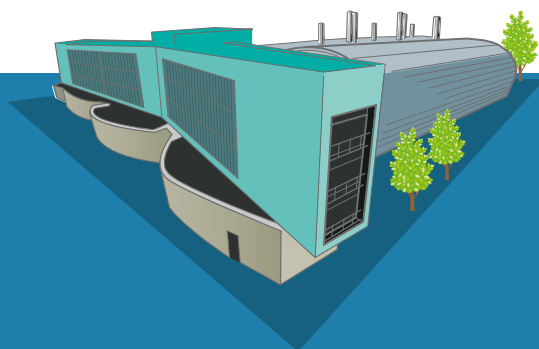
Certificate
of Suitability



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

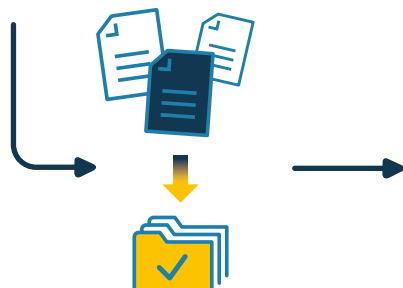


European Directorate for
the Quality of Medicines
and HealthCare (EDQM)

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.



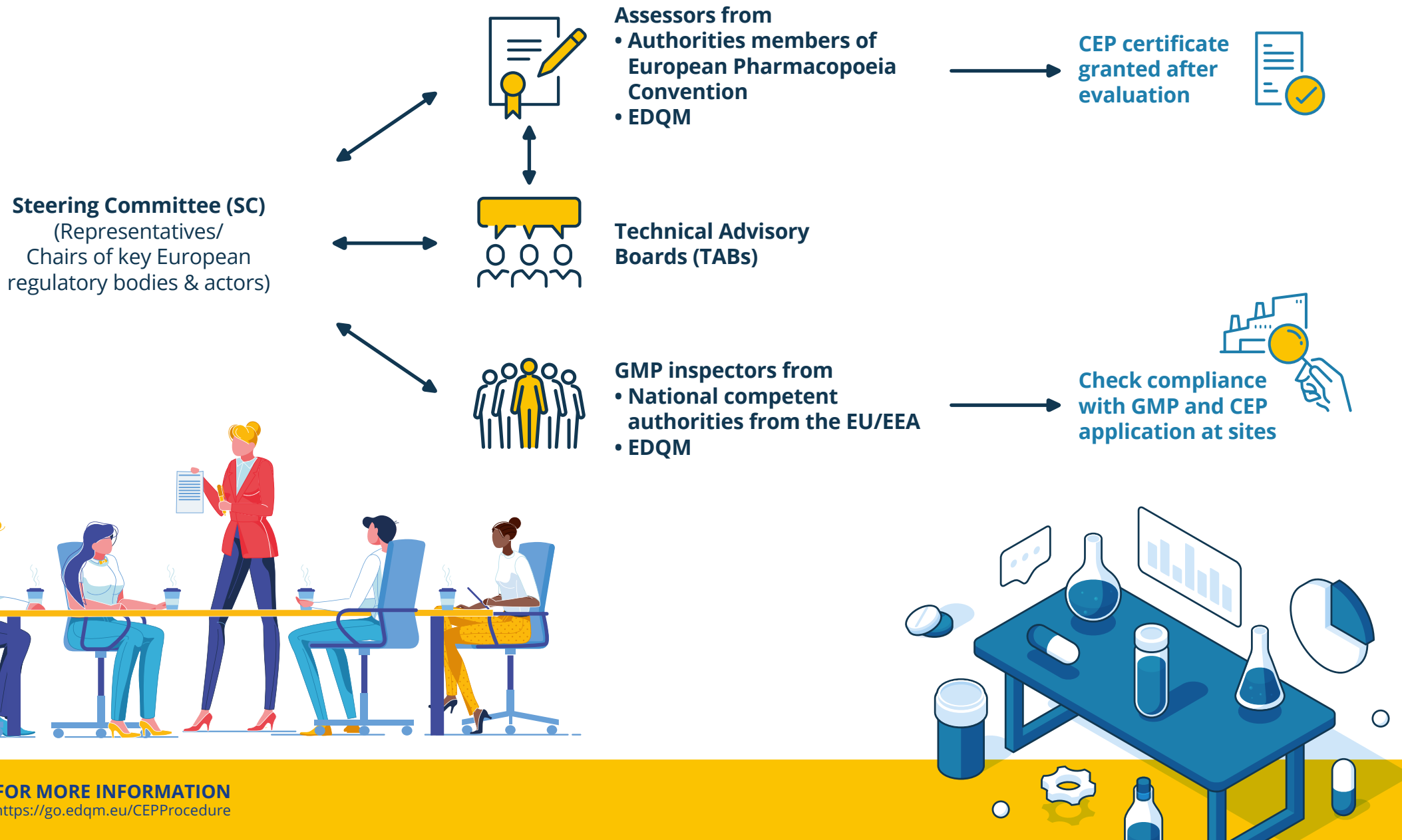
Regulatory Authorities
accepting CEPs



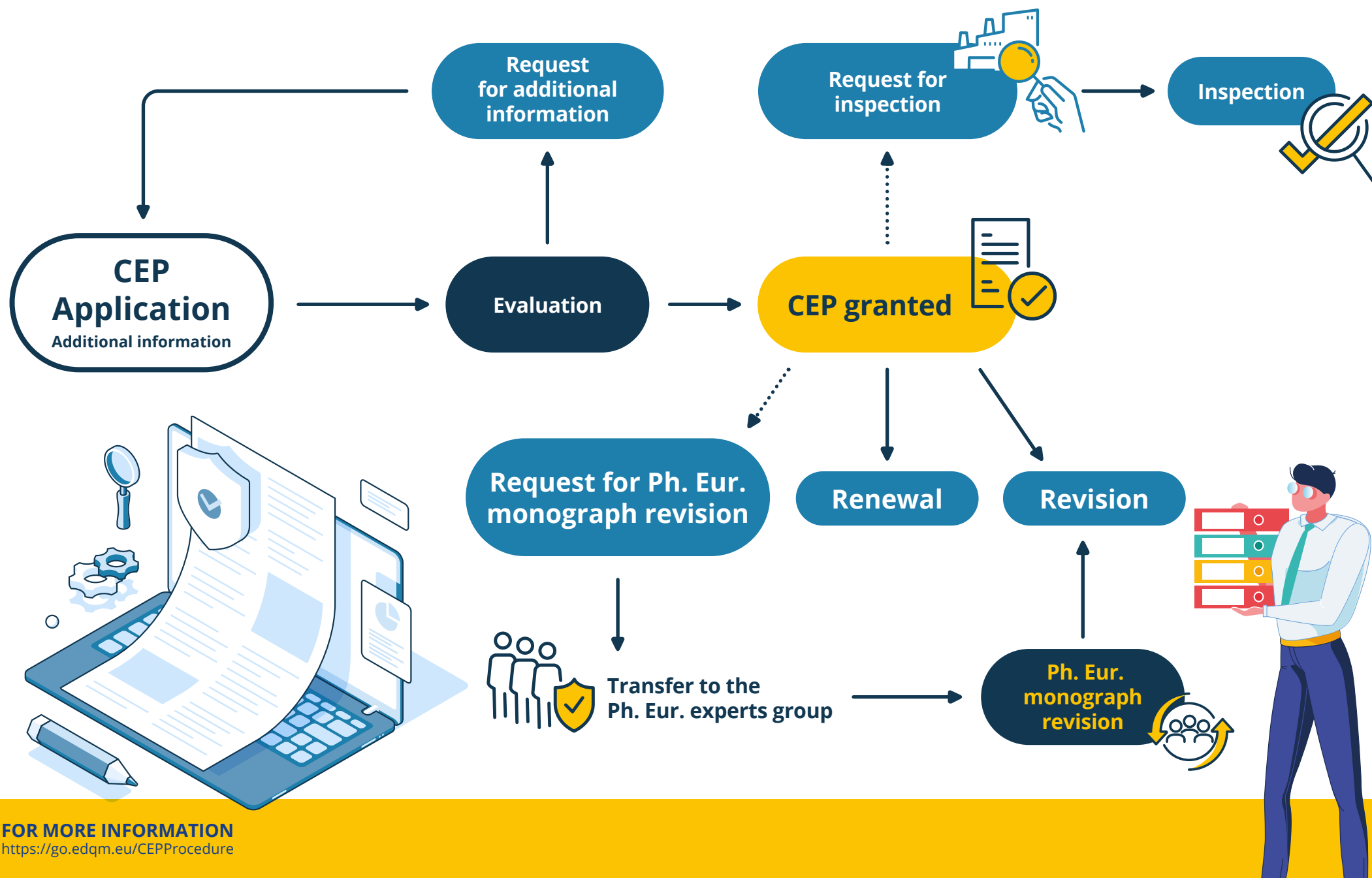
Centralised assessment:
saves time and resources



The CEP: Actors



How the CEP assessment procedure works for applicants



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)



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 3.2.5
- > 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.