Is CEP mandatory for marketing a substance in EU countries?

Answer:

No. CEP is an official procedure implemented by EU Directive; it is one possible option for applying for marketing authorisation in Europe.

Nevertheless, it is the preferred option for demonstrating that a substance used in the preparation of medicinal products complies with the European Pharmacopoeia specifications according to the Note for Guidance on summary requirements for active substances in the quality part of the dossier (CPMP/QWP/297/97 Rev 1 corr; EMEA/CVMP/1069/02).

It is also the preferred option for demonstrating compliance with the requirements concerning TSE risk (general chapter *5.2.8* of Ph. Eur. = EMA NfG 410/01 on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products).