

Certification of Substances Department

PPR/CB

PUBLIC DOCUMENT
(LEVEL 1)

PA/PH/CEP (23) 08

Strasbourg, February 2023

Certification of suitability to the Monographs of the European Pharmacopoeia

Consultation phase for EDQM CEP documents: How to proceed?

1. Background

The EDQM has updated its policy for the elaboration of documents related to the Certification of Suitability (CEP) procedure by introducing a consultation phase for some documents (PA/PH/CEP (22) 44: Management of CEP guidelines and operational documents for the CEP procedure). During the consultation phase stakeholders have the opportunity to provide input and comments, via a specific consultation form in order to facilitate the handling of comments received.

The documents for consultation and the form to submit comments are available for a defined period of time in the dedicated consultation space on the EDQM website.

2. Participating in the consultation phase

To facilitate the management of the consultation, stakeholders are strongly encouraged to use the specific form available in the consultation space to submit their input. The following information should be mentioned.

- Date of submission of the comments
- Title of the document that is commented and its number
- Name of the organisation commenting

The form includes two tables:

- A table for general comments on the document and their rationale
- Another table for specific comments where comments are identified in the first column by their corresponding line number(s) in the document to be commented. In the second column changes proposed are made in track change mode and comments may be added. The rationale for these comments and changes have to be added in the third column to facilitate the compilation.

3. Sending comments

The dully filled consultation form should be sent to the following email: cep@edqm.eu with the following title CONSULTATION - DOCUMENT NUMBER.

4. Collection of comments

Any comments received after the consultation deadline are not taken into account.

The comments are used to finalise the document subject to the consultation phase, as described in the document PA/PH/CEP (22) 44: Management of CEP guidelines and operational documents for the CEP procedure.

Compilations of comments received, including justifications for any decisions made, are prepared and are made available to the groups in charge of approving and adopting the document.
