

Certification of Substances Division

HB/CB

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Certification of suitability to Monographs of the European Pharmacopoeia

Explanatory note: updated EDQM procedures related to paper and electronic submissions for CEP applications

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The Certification of Substances Division (DCEP) at EDQM has revised the requirements for e-submissions for the applicants, in order to implement electronic submissions for CEP applications fully in accordance with ICH M2 EWG and EMA requirements. E-submissions are expected to allow a better handling of dossier by improving the workflow of documents and the lifecycle management of applications.

Applicants are strongly encouraged to submit electronic applications, which do no longer need to be accompanied by paper documentation. The applicant will have to choose between an electronic or a paper application; this choice has to be selected in the relevant application form.

The revised guideline will be applicable as soon as published.

Electronic submissions:

Electronic applications should be either in eCTD format (preferred format), NeeS format, or a single PDF file for module 3. This is applicable to new and existing dossiers and to all kinds of submissions.

The EDQM guideline has been updated to meet current requirements of ICH M2 EWG (Electronic Common Technical Documentation Specification), and it describes specific instructions depending on the format of the application. Beyond the structure of the application, some key aspects of an electronic submission should be highlighted and include:

- The need to use the EDQM template for the QOS, and to provide it as a PDF document. Word documents are no longer accepted.
- The need to submit updated sections of Module 3 each time they are affected (e.g. Answer to a deficiency letter, request for revision,...)
- For eCTDs, the content of the envelope for a CEP application is described.

The new requirements apply to any new application, notification, request for revision or renewal. It is possible to switch to an e-submission for a request for revision, even if the original documentation was not submitted electronically. However, once an electronic dossier is sent, any future data related to the application should then also be in electronic format: no mixture of paper/electronic data is allowed.

It should be stressed that when the first e-submission is a request for revision/renewal, it is highly recommended to provide a full module 3. This will facilitate the management of the lifecycle of the dossier for future requests.

The answers to EDQM deficiency letters related to applications submitted before September 1, 2009 may also be switched to electronic format only. In this context, it is expected that the answer contains:

- i) the cover letter addressing the questions and answers and containing the supportive documentation (e.g. analytical validations) and
- ii) updated sections of Module 3 for those which are affected by the Question and Answer process. Once the CEP has been granted, any further request for revision will then have to be submitted in electronic format.

Paper submissions:

Paper submissions are still accepted, but in this case, NO electronic files should be sent to EDQM. Any update to paper submissions (i.e. Answers to EDQM deficiency letters, or requests for revision) should also include copies of updated sections of the CTD which are affected by the changes, with the changes being highlighted.

Paper submissions will be scanned by EDQM before validation of the application and then destroyed, therefore the clock start for the dossier may be delayed accordingly.

These new instructions have been put in place for an efficient treatment of CEP applications. Failure to comply with them may lead to the rejection of an application.

For any question regarding submission process, EDQM offers assistance. Please post your request at cep@edqm.eu or through the EDQM helpdesk on our website <http://www.edqm.eu> .