Can a valid CEP be used to describe a starting material in another CEP application?

Answer:

For active substances, the use of a valid CEP to describe a starting material is acceptable only when it can be demonstrated compellingly that the proposed starting material complies with the requirements of ICH Q11 and its related Q&A.

If the requirements of ICH Q11 can be demonstrated as having been suitably addressed for the proposed starting material, then the CEP applicant should:

- make clear in their cover letter that the substance covered by a valid CEP (CEP X) is to be considered as a starting material in the manufacture of a different substance that is the subject of the CEP application/revision (CEP Y);
- provide compelling justification in section 3.2.S.2.3 of the CEP application in support of the suitability of this substance as a starting material based on the requirements of ICH Q11;
- include a copy of CEP X in section 3.2.S.2.3 of the CEP Y submission. In addition,
    - if CEP X is in hybrid or 2.0 format, a “letter of access” for CEP X must be enclosed;
    - if CEP X is in the old format, the “declaration of access box” for CEP X must be completed.

The full specification described in CEP X must be typically applied to the starting material for use in the manufacturing process described in the CEP Y application, unless otherwise justified.

The dossier for CEP Y should not include other information in section 3.2.S.2.3 related to CEP X. This information has already been provided in the context of that CEP and is maintained appropriately by its holder.

The holder of CEP X and the applicant of CEP Y should liaise appropriately to ensure that the CEP Y applicant has sufficient information to conduct their own due diligence on actual and potential impurities that might be carried over into their substance. Impurities that have been addressed in CEP X should generally not be mentioned in sections 3.2.S.2.3 and/or 3.2.S.3.2 of the CEP Y dossier unless there is a risk that they will potentially be carried over into the final substance.

A final decision on the acceptability of the proposed starting material will be made by the EDQM during the CEP Y evaluation.