Application dossier

- Are alternative methods accepted?
- Are analytical procedures appended to a CEP considered equivalent to a European Pharmacopoeia monograph method?
- Can some tests be omitted?
- Should all tests referred to in a CEP be performed for routine analysis/batch release?
- Is a certificate of suitability equivalent to a certificate of analysis?
- How should I deal with different grades of the same substance?
- How should I deal with recovery of materials in a dossier?
- Can a valid CEP be used to describe a starting material in another CEP application?
- What should we do if we use peptones in the manufacture an active substance?
- Is it possible to apply for a Chemical CEP with reference to a specific polymorphic form when no statement on polymorphism is included in the corresponding individual Ph. Eur. monograph?
- In our CEP application, is it possible to claim that the quality of our substance complies with a specific degree of hydration when degree of hydration is not defined in the corresponding individual Ph. Eur. monograph?
- In the revised Ph. Eur. monograph, a degree of hydration has been either removed from / clarified in the title of the substance. Will EDQM issue a new certificate of suitability to reflect this?
- How to present the specification for a substance in a CEP application?
- Is it possible to submit changes during the dossier assessment phase?
- What does the removal of the rabbit pyrogen test (RPT) from the European Pharmacopoeia mean for CEP holders?