ICHQ3D and Finished Pharmaceutical Products (FPPs) prequalification procedures

The ICHQ3D guideline presents a process to assess and control elemental impurities (EI) in finished pharmaceutical products (FPPs) using the principles of risk assessment (RA). This RA includes consideration of the impurity profile of the API, as well as the contribution of excipients, facilities, equipment and containers as outlined in ICHQ3D documents. PQTm has decided to apply the ICHQ3D guideline to FPP dossier applications. Note that PQTm implemented ICHQ3D on a voluntary basis for APIs in 2018, with supplemental guidance published on the website in October 2019.

The FPP risk management summary (RMS) should be a standalone assessment, but may be supported in part by component RMSs conducted for the API(s), excipients and other elements.

For all FPPs submitted after 1 January 2020, the applicant should ensure that they have completed an RMS during the PQTm assessment process (i.e. prior to prequalification). This RMS should be available if requested by WHO PQTm assessors or the PQTm inspection team. See ICHQ3D training module 5 for approaches and illustrative examples for implementation of the ICHQ3D guideline.

For those FPPs that have been accepted for assessment prior to 2020 and for which an FPP RA is not yet conducted, the applicant should plan to complete an FPP RMS by 2021 and this should then be available if requested by WHO PQTm assessors or the PQTm inspection team. At this time, the above is not a requirement for those FPP prequalified prior to 1 January 2020.

Until otherwise notified, it is not compulsory to include the RMS in the FPP dossier; however, if an RMS is provided in the dossier submitted for prequalification, this RMS may be considered on audit basis as part of an assessment in line with ICHQ3D.

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