ICH Q4: Pharmacopoeias

Q6A activity provided the framework on how to set specifications for drug substances to address how regulators and manufacturers might avoid setting or agreeing to conflicting standards for the same product, as part of the registration in different regions. The resulting ICH Q6A Guideline provides harmonised guidance in this area. With the passage of the Chemical Substances (Q6A) ICH Guideline, the harmonisation of about 10 compendial test chapters has been considered as critical by the ICH Steering Committee. These chapters are at various stages of harmonisation among the three pharmacopeial organisations (USP, JP & EP). The three organisations conduct their harmonisation efforts through a tripartite pharmacopeial harmonisation program known as the Pharmacopoeial Discussion Group (PDG).