COMPARABILITY AND SIMILARITY PROTOCOLS FOR BIOTECHNOLOGY PRODUCTS

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Over lifecycle, from development through all industrialization stages and then over manufacturing history across multiple sites, a biotechnology product must show very high levels of quality consistency, as that is a pre-requisite for safety and efficacy to patients (cf. ICH Q5E, 2004).

Recently, FDA defined different levels of similarity (Draft Guidance, May 2014, “Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product”) namely the concepts of (1) “highly similar with fingerprint-like similarity” and that of (2) “residual uncertainty” in regard to similarity.

Here we present a new approach to combine whole analytical domains from different techniques used in comparability protocols (to support change management for same product and process) that also is applicable to assess similarity in biocomparability investigations.

Our approach ensures much higher levels of confidence in Comparability Protocols by not overlooking differences that might be unnoticed or overlooked due to incomplete prior-knowledge in regards to methods used and attributes considered. Our approach can (a) detect very small differences, (b) establish therefore the exact level of comparability / similarity and (c) provides a sound statistical foundation to assess residual uncertainties. We will illustrate our approach on reference products over their lifecycle and to compare reference with putatively similar products. The outcome of assessments (a) through (c) can then be linked to pharmacological performance or both types of biotechnology products, and support regulatory or other decisions related to managing filings.