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Fingerprint-like similarity: Making the connection between product characteristics and clinical outcomes

Analytical similarity assessments typically focus on comparing the physical, chemical and functional properties of a biosimilars product to the reference product, to understand where the two products are similar and where they are not similar. An attempt is then made to justify why observed differences will or will not impact the clinical outcomes (e.g. safety, including immunogenicity, efficacy, PD or PK). The justification typically requires making a bridge between an observed difference and a clinical outcome via some type of a functional assay. This type of assessment is only as good as the assays being used (e.g. what level of difference would have to be present in order to observe a difference in the functional response). When differences are observed, new or more sensitive assays may be developed, independent of a relationship between the observed difference and a clinical outcome. We argue that if one starts from a detail understanding of the product, clinical indications, and safety profile of the reference product and other similar products, then one can a priori determine which physical, chemical and functional attributes are either known to impact or likely to impact the clinical outcomes. Using this knowledge, attributes can be identified that may require a detailed understanding of the relationship and interrelationship(s) between the attribute and the clinical outcomes as well as between attributes and the clinical outcomes (e.g. is there a relationship between high mannose and sialic acid levels on PK?). With this knowledge first, methods are developed, along with the appropriate controls, that have the sensitivity required to detect meaningful differences. The assessment of fingerprint like similarity can then be based on (1) both the full physical and chemical comparison of the product to the RPP and (2) the detailed analysis of the key properties, with sensitive assays, that allow linkage between key product attributes and clinical outcomes. We will provide an overview of our view on fingerprint-like similarity and how it can be applied to biosimilars development.

Biography

Peter Bernhard is a Biotechnology professional with significant technical leadership experience and a proven track record in Analytical and CMC Development. He quickly and fearlessly gets to the heart of situations, identify areas for improvement, and then seek to implement creative and efficient solutions that generate value. His continuous improvement mindset and drive towards future possibilities, combined with his action-oriented nature and ability to navigate around obstacles, allowed him to excel at initiating and executing new projects or developing and refining business processes. He is a quick thinker and learner who can assimilate information from multiple sources and then communicate this information effectively and clearly to the target audience.

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