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The need for a reference product database for biosimilars

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Abstract

The current Draft Guidance from the FDA, "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product" provides guidance for the burden of proof necessary to obtain a biosimilar approval via section 351(k). The Draft Guidance recommends that a Sponsor apply a stepwise approach, which will not necessarily be the same for all products. Furthermore, The Draft Guidance recommends "... the stepwise approach should start with extensive structural and functional characterization of both the proposed product and the reference product, which serves as the foundation of the biosimilar development program." It is also recommended that multiple manufacturing lots from multiple locations be analyzed and compared for the proposed and reference products. Accordingly, a reference product will have extensive structural characterization performed multiple times in a single biosimilar development program. Additionally, it is reasonably expected that multiple development programs will exist (from different companies) for a given reference compound. As a result, the reference compound will have been extensively analyzed many times over. A Reference Product Database, consisting of structural and functional data for approved products, would enable biosimilar programs to realize significant reductions in total research effort and overall development expenditures. The impact would be faster times to market, lower costs, more competition, and ultimately lower costs to consumers and payers.

Based on the above premise, a Reference Product Database clearly seems logical. This begs the question, why does a universal yardstick for reference compounds not exist today? This presentation will explore the challenges to building an industry-wide database, how it could be developed, what data points should be included, and finally, stakeholders and their interests.

Biography

Jeff Lyons obtained a B.S. in Finance (University of North Carolina at Wilmington) and Accounting (University of North Carolina at Greensboro) in 1994. He entered into Public Accounting as an auditor focusing on banking and government. Jeff acquired his CPA license and worked in Public Accounting for five years with Perry-Smith & Co. and KPMG. A career change took Jeff into sales of telecommunications and networking equipment, where he worked for SBC Global and Nortel Networks. Jeff then transitioned into pharmaceuticals and worked for Fort Dodge / Wyeth. In 2004, Jeff was hired by Absorption Systems for Business Development. He was promoted to Director of the Business Development team until 2009 when Absorption Systems acquired its *in vivo* facilities in San Diego. Jeff was promoted to General Manager of the facility, an AAALAC-accredited, GLP-compliant vivarium that performs preclinical research in support of biological, pharmaceutical, and medical device research and development programs.