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Compliance and thoughtfulness from idea to commercial production

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Abstract

The usefulness and depth of a biosimilar to forward a program can be measured by the complexity of how it is understood and documented within the FDA guidelines for evidence of association to the reference product.

The scientific information and the federal regulatory framework are two areas that need to be developed in-concert with each other. The exclusion of one for the other will lead to more complications and time lost.

The idea of a biosimilar is inventive and a major step forward in the advancement of biotechnology and pharmaceutical sciences. The idea of this technology being underserved by the lack of understanding in the regulatory area can be resolved with a comprehensive focus that will ensure understanding.

How to get there? This approach will be discussed in the presentation focus for this talk. The guidelines will be analyzed to provide the framework for compliance that is practical and useful to the development world.

Biography

Deborah Thibodeaux, M.S., has been with DKT Lab Consulting, LLC since its inception. She is the president for this unique Consulting Service. She has published papers in reputed journals and is a founding member of the consortium, “The Cerneos Group, LLC”. She has worked in many aspects of the Biotechnology field and brings the comprehensive analysis of challenges to DKTLC.