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Challenges and approaches in demonstrating biosimilarity at the physicochemical and biological level

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The Biologics Price Competition and Innovation Act of 2009 created an abbreviated pathway for biological products to be biosimilar or interchangeable with an FDA-licensed product in the US. The BPCI Act and subsequent guidance from both the FDA and EU regulatory authorities has catalyzed a surge in the development of biosimilars, as well as the first biosimilar approval by the FDA in 2015. A key component to any submission is the extent to which physicochemical and biological characterization data are applied to analytical similarity. This presentation will describe the challenges in obtaining data to assure characterization of both the brand product and the biosimilar being developed and how these data can be applied during process development. Lessons learned from approved complex generics will be discussed. The choice of a broad set of analytics, both physicochemical and biological, as well as the complementary and orthogonal nature of those analytics will be described. Key characteristics that define both the brand product and the biosimilar will be discussed and will include different approaches to establish equivalence criteria as well as statistical methods which may be used to evaluate the data. The challenges such as the diversity of the brand product as well as lot age will also be addressed.

Biography

Jill A Myers leads CMC efforts in Regulatory Communications in biosimilars and novel biologics at Momenta Pharmaceuticals. Previously, she built an independent consulting firm with multiple operational and strategic projects. Before that, she started a process development and manufacturing department at Applied Molecular Evolution and prior to that, she was a Program Executive at and ran the Process Biochemistry group at Biogen. She earned her PhD in Biochemistry from UCLA and was a Post-Doctoral Fellow at Harvard Medical School and has served on multiple industry committees including past Chair of the Board of the Recovery of Biological Products Conference Series.

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