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Why aren't biosimilars generics - regulatory challenges

Biological products, derived from mammalian, bacterial, or from animal origins constitute many of today's important medications. As numerous patents protecting originator biological products are expiring, the development of 'Generic Biologics' products aka biosimilars become a lucrative and exciting opportunity for many "traditional generic" and international pharmaceutical companies. Unlike small molecule drugs, generally targeted by the "traditional generic" industry, biological products are usually highly complex in structure.

This presentation will highlight the differences between the regulation covering generic "small molecule" drugs and biosimilar-based drugs and focus on the regulatory challenges in implementing the new regulations.

Biography

Adam Sabouni is the Managing Partner for PharmaConsultz. He was the Chief Development Officer at Novan Therapeutics. He has served as the Global VP, Pharmaceutical Sciences and Process Development at Stiefel Laboratories. He was responsible for 5 R&D sites and supported 6 Manufacturing facilities in 4 continents. He has ~25 years of experience in PD, manufacturing, compliance, and remediation. At Pfizer, he was responsible for the remediation action plan to lift the cGMP-related consent decree. He is a Pharmacist and has a PhD in pharmaceutical sciences from the University of Bonn.

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