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Why aren't biosimilars generics-regulatory challenges?

A consent decree is an agreement between the FDA and a pharmaceutical manufacturer that usually bars the drugmaker from manufacturing and distribution product(s) until the company has implemented timely and sustainable changes, through a series of steps, to bring the drug manufacturer in alignment with the FDA's vision of GMPs. While there is no set formula for what triggers a consent decree, it is safe to assume that many consent decrees were/are caused by FDA inspections in which a company is found not following GMPs, followed by a warning letter. This presentation provides an overview and practical examples of what causes a company to fall under a consent decree, how to avoid it, and what is the best action plan to get out of it.

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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