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Journey through the evolution of biosimilars

In this talk, I will take you along on my exciting journey from this first attempt all the way to developing biosimilar monoclonal antibodies. It will shed light on how much the attitude of the European regulators changed from then to now. The requirements were inflated due to the little experience both on the side of the sponsor and the regulators. After the first products were approved and first guidelines were issued the situation calmed and requirements were based on science and evidence. Then followed the desperate attempts of the originator companies to discredit the biosimilar movement. All sorts of arguments were presented to delay and prevent the dawn of biosimilar. The originators fought on legal grounds and countered with semi-scientific argumentation which culminated in a final push to force biosimilar developers to do Phase III interchangeability studies. Finally, all these efforts will have been in vain, hundreds of millions of dollars will have been wasted. But the Biosimilars will prevail. The originators will finally go back to what they are supposed to do, innovate!

Biography

Peter Kalinka is a Biosimilar developer of the first hour. He was fortunate enough to be in charge of the first Biosimilar to be developed, a recombinant human Growth hormone, Omnitrope. Meanwhile, He has been involved in the development of more than 17 Biosimilars and Biobetters.

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