



Seminars in Biotechnology BTEC 591 & BTEC 691

“Biosimilarity and biosimilar development”

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13:30

MBG Conference Hall

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Emine YILMAZ graduated from Istanbul Technical University, Department of physics and literature with BSc degree in Chemistry.

She joined Sanovel Pharmaceutical Company after graduation and studied in quality control of generic drugs. She worked in raw materials team in QC for 5 years. Afterwards she transferred to the Biotechnology division and worked in the all development and regulatory registration process of the first biosimilar product produced in Turkey from cell to the finished product. After Arven invested in a high technology drug production facility in Kırklareli she started to lead the Biotechnology QC team in Arven Kırklareli facility. After the system for Biotechnology QC was settled up she transferred to the R&D team for new Biosimilar projects.

Abstract

Biological drugs are used in different therapeutic fields and very efficient in clinical therapy resulting being a part of mostly used top 10 drugs world wide in 2018. Biologic drugs are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. A biosimilar is a biologic medical product highly similar to another already approved biological medicine (the 'reference medicine') and for which there are no clinically meaningful differences in terms of safety, purity, and potency. As biological drugs are very complex molecules, it is very difficult to characterize them and as living systems are the starting material for the drug it is not possible to produce exactly the same product. As a result of complexity of Biologicals “Biosimilarity” is born in order to express the similarity between the original product and the “generic?”biologics.

Biosimilarity is also hot topic in Turkey for several years and investments are started to produce different biosimilar drugs in Turkey. As biosimilar drug development is very complicated and takes longer time than generic drug development only one product that is produced from cell to finished product is on the market yet. The other biosimilars are only fill finish products. However Pharmaceutical companies are developing new biosimilar drugs and in the future more companies will produce biosimilars from cell to the finished product .

This talk will focus on Biosimilars and biosimilar development. Biologics and biosimilars definitions and their differences from generic drugs will be discussed. The important points to consider in development of biosimilars will be discussed.