Danish Pharmaceutical Society
The Biopharmaceutical Section
&
Department of Pharmacy

Biosimilars – how similar ?

January 9th 2019, 14:00-17:15
Benzon Auditorium
Faculty of Pharmaceutical Sciences, University of Copenhagen
Universitetsparken 2, 2100 Copenhagen Ø

As patents for many of the marketed biologics expire, new competing and complementary biosimilar products will be filed for registration.

A biosimilar product is by definition highly similar to another already approved biological medicine (reference medicine), hence approved according to the same standards in terms of pharmaceutical quality, safety and efficacy. The question is however, what is "highly similar"? In this seminar, we will get an introduction to the regulatory landscape of biosimilars, an introduction to biosimilar manufacturing and finally how such products are implemented in the clinic.

Program

14.00-14.15 Introduction to biosimilars
Prof. Hanne Mørck Nielsen/ Postdoc Stine Harloff-Helleberg,
Drug Delivery and Biophysics of Biopharmaceuticals/ BioDelivery Center,
University of Copenhagen

14.15-14.45 Development and characterization of biosimilars
Claus Kristensen, CEO Glycodisplay Aps

14.45-15.15 Break with refreshments

15.15-15.45 Introduction to the regulatory landscape of biosimilars
Nanna Kruse Aaby, Danish Medicines Agency

15.45-16.15 Clinical implementation of biosimilars
Dorthe Bartels, Amgros

16.15-16.30 Discussion and wrap up

Registration no later than 6th of January via www.farmaceutisk-selskab.dk.
No entry fee, non-members are also welcome to participate in the meeting.