



14 – 18 AUGUST 2017 / UNIVERSITY OF COPENHAGEN

BIOPHARMACEUTICALS DRUG DEVELOPMENT

The complexity of drug development, in particular pharmaceutical development and safety assessment, poses large challenges in the overall development of novel biopharmaceuticals. This course relies on leading experts in the field and to a large extent uses a case-based approach to introduce the newest advances in our ability progress the to development effective biopharmaceuticals.

The commercial and scientific prominence of biopharmaceuticals is beyond dispute. This course provides an overview of the drug development process and highlights crucial aspects of specific importance for our ability to develop biologically active macromolecules into effective biopharmaceuticals.

At first sight, utilization of biologically active macromolecules as drugs appears straightforward since the biology of endogenous compounds, such as peptides and proteins, are given (e.g. hormones, coagulation factors). Further, due to the tremendous recent advances in genetic understanding and knowledge of protein function in the biology of diseases, an explosion of novel opportunities for new and improved development of biopharmaceuticals has occurred. Advanced (bio) technological tools provide opportunities for tailoring macromolecules to improve drug ability of these compounds, and new insight into formulation design and delivery approaches are continuously emerging. However, due to the structural complexity of this high molecular weight, labile compounds, drug development including predictable sufficient efficacy and safety assessment in appropriate models still pose significant challenges in the overall development of novel biopharmaceuticals.

WHAT YOU WILL LEARN

In this course, you will learn to:

- Understand and address potential major issues during development of biopharmaceuticals regarding pharmaceutical formulation development, safety and efficacy testing
- Identify key challenges and suggest solutions for addressing critical issues in the development and testing of biopharmaceuticals
- Design and develop novel interdisciplinary approaches thereby improving current practice in the development of biopharmaceuticals
- Communicate field-specific issues and solutions regarding development of biopharmaceuticals to other specialists, and project stakeholders
- Cooperate within a multi-disciplinary development project team

COURSE CONTENT

The course will address and highlight characteristics and procedures of relevance for the design and development of biopharmaceuticals. Experts from relevant fields will lecture on and discuss both fundamental concepts and specific selected issues related to biopharmaceuticals drug development. Topics of special attention are picked from the discovery phase through development and assessment, and include peptide and protein engineering, pharmaceutical drug design and formulation, experimental models, efficacy and safety assessment and regulatory aspects. Case studies will form the basis for interactive discussion sessions.

It has been a very inspiring week!

*Nanna Maria Junker Nielsen, Principal Scientist,
Novo Nordisk A/S*



**”I think this course is relevant for many people in the biopharm industry!
I sincerely hope, that you are able to continue this course in the future.”**

Anne Charlotte Hegelund, Senior Scientist, Novo Nordisk A/S

PARTICIPANTS

The course is aimed for professionals in the pharmaceutical industry who need an interdisciplinary overview of the specific requirements for development of biopharmaceuticals.

Participants should:

- Hold a relevant bachelor degree or equivalent
- Have a minimum of 2 years of relevant job experience within drug development
- Be proficient in English

COURSE DATES

5 days, 14 – 18 August 2017, 9:00 – 16:30 at the University of Copenhagen, Frederiksberg Campus.

COURSE DIRECTORS

Hanne Mørck Nielsen, Professor, Department of Pharmacy, University of Copenhagen

Stine Harloff-Helleberg, Postdoc, Department of Pharmacy, University of Copenhagen

OTHER COURSE TEACHERS

Guest lectures include experts in biopharmaceutical drug development from the Nordic pharmaceutical industry, authorities/agencies and academia. For more information: www.copenhagensummeruniversity.dk

COURSE FEE

EUR 2,600/DKK 19,000. Fee includes teaching, course materials, all meals during the course and examination.

It would be valuable for many other companies outside Denmark!

*Chiara Nenci, Senior Research Scientist,
Elanco Animal Health*

EXAMINATION

Type of exam assessment: Written assignment

A written report based on a case story. The report must be based on the common course syllabus and an individual selection of literature (scientific articles, regulatory documents, etc.) relevant for the selected case. Deadline for submission in *Digital Eksamen*: 23 October 2017 at 2 p.m.



FOR VIDEOCLIP, MORE INFORMATION AND REGISTRATION:
copenhagensummeruniversity.ku.dk

