



Copenhagen
Summer
University



19 – 23 AUGUST 2019, 9:00 – 16:30



EUR 2,680 / DKK 19,900 EXCL. DANISH VAT

Copenhagen Summer University

BIPHARMACEUTICAL DRUG DEVELOPMENT

At first sight, utilizing biologically active macromolecules as drugs would appear to be pretty straightforward, since the biological effects of endogenous compounds such as peptides and proteins is well known (e.g. hormones, coagulation factors). Further, due to the recent tremendous advances in genetic profiling and increased knowledge of how protein functions in the biology of diseases, there has been a dramatic increase in the number of new opportunities for novel and improved biopharmaceuticals. In addition, new insights into formulation design and delivery approaches are emerging all the time. Despite these major advances, however, the complexity of pharmaceutical formulation design, development and safety assessment still poses huge challenges in the overall development of novel biopharmaceuticals.

“I got a great overview of the topic and many great talks!”

Pier Giorgio Amendola, Postdoc, Biotech Research & Innovation Centre, University of Copenhagen

This course provides you with an overview of the stages involved in the drug development process and highlights aspects of crucial importance for our ability to develop biologically active macromolecules. In order to help you fully understand these aspects, we have invited several leading experts in the field as guest lecturers. In addition, we take a case-based approach to introduce you to some of the latest advances in the development of effective biopharmaceuticals.

WHAT YOU WILL LEARN

After the course, you will be able to:

- Understand and address major issues in the development of biopharmaceuticals including 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 in the development of biopharmaceuticals to other specialists and project stakeholders
- Cooperate within a multi-disciplinary development project team

COURSE CONTENT

The course will highlight characteristics and procedures that are crucial for the effective design and development of biopharmaceuticals. Through a mix of lectures and discussions, experts from relevant fields will share their knowledge on both fundamental concepts and specific selected issues related to biopharmaceutical drug development. Key topics requiring special attention will be selected from the discovery phase through to the development and assessment phases, and will 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 discussion sessions.

PARTICIPANTS

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

The University of Copenhagen has preapproved the course as an elective in the Master of Industrial Drug Development (MIND) programme and the Master of Medicines Regulatory Affairs (MRA) programme.

Participants must:

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

COURSE DIRECTORS

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

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

Lene Jørgensen, Associate Professor, Department of Pharmacy, University of Copenhagen

OTHER COURSE TEACHERS

Guest lecturers include experts in biopharmaceutical drug development from the Nordic pharmaceutical industry, authorities/agencies and academia.

COURSE FEE

EUR 2,680/DKK 19,900 excl. Danish VAT. Fee includes teaching, course materials, examination and all meals during the course.

EXAMINATION

An optional examination is available (3 ECTS credits at Master's level). The examination is a written report based on a selected case or topic. 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: 23rd October 2019 at 2 p.m.

For more information and registration

W	COPENHAGENSUMMERUNIVERSITY.DK		csu@adm.ku.dk		+45 35 33 34 23
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