At first sight, utilizing biologically active macromolecules as drugs appears to be fairly straightforward since the biology of endogenous compounds such as peptides and proteins is something of a given (e.g. hormones, coagulation factors). Further, due to the recent tremendous advances in our genetic understanding and increased knowledge of 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 insight into formulation design and delivery approaches is continuously emerging. However, the complexity of pharmaceutical formulation design, development and safety assessment still poses huge challenges in the overall development of novel biopharmaceuticals.

This course provides you with an overview of the stages in the drug development process and highlights aspects of crucial importance for our ability to develop biologically active macromolecules. To further understand these aspects, the course has invited several leading experts in the field as guest lecturers. The course’s case-based approach will also 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 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 biopharmaceutical drug development. Key topics requiring special attention will be selected from the discovery phase through development and assessment, 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.

“Very Nice. Fantastic skills and ability to wrap up over the week.”

Thomas Gilberg, Outsourcing Manager,
LEO Pharma A/S
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 at English

COURSE DATES
5 days, August 13 – 17, 2018, 9:00 – 16:30 at the University of Copenhagen, South Campus.

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. For more information: www.copenhagensummeruniversity.dk

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: 22nd October 2018 at 14:00.

FOR MORE INFORMATION AND REGISTRATION: copenhagensummeruniversity.ku.dk

"Great course! I learned a lot and enjoyed discussing with the other participants”
Paula Dencher, Scientific Data Specialist, Janssen Vaccines and Prevention B.V.

"It has been a very inspiring week!”
Nanna Maria Junker Nielsen, Principal Scientist, Novo Nordisk A/S

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