Medical Biotechnology and Drug Development, Spring 2017
Section A

Course Schedule
Monday and Thursday
8:30-9:50
Classroom: V10-A12

Instructor
Jeanette Erbo Wern

Senior Scientist 2013 – 2016 (Dept. of Infectious Disease Immunology, Statens Serum Institute, Denmark). Senior Scientist 2010 – 2013 (Immune Targeting Group, Bioneer, Denmark) Post doc 2006 - 2009 (Inst. Of International Health, Immunology and Microbiology, University of Copenhagen, Denmark) Ph.D Immunology 2001 – 2005 (Inst. Of International Health, Immunology and Microbiology, University of Copenhagen, Denmark) M.Sc. 2001 (Inst. Of International Health, Immunology and Microbiology, University of Copenhagen, Denmark). With DIS since 2016.

DIS Contacts
Lisbeth Borbye, Program Director,
Susana Dietrich, Assistant Pram Director,
Ryan Polito:

Course Description
The emphasis of the course will be on biomedicine and drug discovery & development, showcased through a focus on the European pharmaceutical and biotech research community.

You will learn about the general principles of drug discovery & development, including safety, toxicology, formulation, and clinical trials. Furthermore, the course will explore the opportunities and challenges biotechnology has for medicine, such as the different new types of biotechnological drugs, gene therapy, personalized medicine, delivery problems, stem cells, etc.

Additionally, and especially through academic visits both in Denmark and in the UK, you will get a good overview of the different players involved in the drug discovery and development process, including research laboratories, start-up companies, biotech companies, contract research organizations, and pharmaceutical companies.

The course will incorporate some group work in class and will finish with a group project, in which you will focus on drug development in Scandinavia and prepare and present a report on this.

Group work helps you prepare for the way work is organized in professional life and can improve the quality of the work produced, by adding the different strengths of the students.

Prerequisites
One year of biology and one year of chemistry at the university level.

Learning objectives
Upon completion of this course, students will be able to:

- Give a basic explanation of biomedical drug discovery and development
- Review characteristics and principles of biotechnological tools, methods, and classes of drugs
- Research biotechnological information and present it in a clear and critical way
- Participate actively and critically in discussions of biotechnology and different types of drugs in class and with biomedical professionals
- Assess the challenges that researchers and people working in the biopharmaceutical area are faced with when dealing with drug discovery and development

Required readings
- Edited by Daan J. A. Crommeling and Robert D. Sinclair: *Pharmaceutical Biotechnology – An Introduction for Pharmacists and Pharmaceutical Scientists*. Third Edition, 2007, Taylor and Francis. (hereafter referred to as **PB**)
- Edited by Raymond G. Hill and Humphrey P. Rang: "*Drug discovery and development – technology in transition*", Churchill Livingstone/Elsevier, 2013. (hereafter referred to as **DDD**)
- Reading compendium (hereafter referred to as **RC**)
- Extra material posted on Canvas

Elements
Lectures, class discussions, solution sessions (alone/in groups), case studies, group presentations of case studies, field studies visiting pharmaceutical and biotech companies, and the group project with presentation.

Evaluation

Tests (1 x 15%, 2 x 20% each)	55%
Study tour assignment	15%
Drug Development Project Report	12,5%
Drug Development Project Presentation	7,5%
Participation	10%

The three tests are spaced as evenly as possible throughout the semester. There is no final, but instead the class wraps up with the *Drug Development in Scandinavia Project.* The project report is graded as a group effort, while grades for the project presentation are a combination of group and individual performance.

Participation

To prepare for each day, you are required to read all assigned material, using the study questions for that day as well as take a survey on Canvas and vote on the study questions that were more challenging. Based on those results, more focus will be given in class to certain areas of study.

Participation is determined by attendance, tardiness and engagement in class. You are expected to attend all DIS classes and activities when scheduled, and we will actively monitor attendance. Absences will jeopardize your grade and your standing at DIS. Allowances will be made in cases of illness, but you will need to **email your instructor** in advance. If you miss multiple classes the Director of Academic Support, and the Director of Student Affairs will be notified and they will follow-up with you to make sure that all is well.

Students will also be asked to address some of the study questions in class: this will be a part of the evaluation parameter, "preparation." Additionally, for those students that did not have a chance to give their input in class, you will have the opportunity to do so on Canvas: a) on the discussion board there will be an open "Continue today's class discussion/debate", where students can share thoughts/questions related to the topic discussed in class, b) if relevant, there will also be a specific question/topic related to the day's class, to which students can address/answer/debate on Canvas. The participation of the students in these debates will be taken into consideration when the student's participation assessment is made.

Tests

Test 1: Monday, February 20
Test 2: Thursday, March 9
Test 3: Monday, April 10

There are three tests throughout the semester, on these topics:

- Drug discovery and development
- Peptides and nucleotides as biopharmaceuticals
- Immune-defense related biopharmaceuticals

You will take the tests in class. They will be a combination of information recall, concept explanation and synthesis (five questions), and problem analysis (one question). *Tests will generally last 40 minutes, unless otherwise stated*.

Drug Development Project (you will receive detailed information separately)

In groups of 4 to 6, you will investigate the clinical drug development of a Scandinavian biopharmaceutical company. Focusing on a current or recent pharmaceutical product, you will explore the science, research, methodology, and challenges of developing the product, culminating in a paper and presentation. More information will be provided at a later date.

Core Course Week and Study Tours

Core Course week and study tours are an integral part of the core course as we take the classroom on the road and see how theory presented in the classroom is translated to practice in the field. You will travel with your classmates and DIS faculty/staff on two study tours: a short study tour during Core Course Week and a long study tour to a relevant European destination.

Expectations for study tours:

- Participate in all activities
- Engage in discussions, ask questions, and contribute to achieving the learning objectives
- Respect the destination, the speakers, DIS staff, and your fellow classmates
- Represent yourself, your home university and DIS in a positive light

Learning Objectives:

- To learn about the newest and most innovative biotechnology-based methods for diagnosis and treatment of disease through academic visits
- To observe the dynamics of drug discovery and development through visiting biomedicine and biotech research facilities
- To meet some of the players active in the transfer of technology from university to business and explore their work
- To explore the differences between Denmark, the US and UK within the Biomedicine field
- To visit cultural landmarks and institutions in the historical cities of Denmark and Europe
- To develop questions for further learning/research
- To engage in your personal learning process outside the classroom by actively participating and challenging your current ideas and assumptions.
- To get to know your fellow students and professor in an educational and social setting outside DIS.

While on a program study tour DIS will provide hostel/hotel accommodation, transportation to/from the destination(s), approx. 2 meals per day and entrances, guides, and visits relevant to your area of study or the destination. You will receive a more detailed itinerary prior to departure.

The dates for core course week, including short study tour, and your long study tour are below for your reference.

Core Course Week: February 6 – 10 (Including Short Study Tour to Odense/Aarhus, Sept. 6-8)
Long Study tour to London, UK: February 26 – March 3

Travel policies:
You are required to travel with your group to the destination. If you have to deviate from the group travel plans, you need approval from the program director and the study tours office.

Study tour assignment (You will receive a more detailed ST Assignment document)

Before your short study tour, you will be organized into groups of 2-3 people. Within these groups, you will construct a group paper, topic areas from which to choose include:

1. In-depth exploration of a biotech research topic encountered on the study tours
2. Relationship between academia and private enterprise
3. Collaboration and/or competition – relationships between groups and companies
4. Careers and work-life in biotechnology: niches, educations and different fields

Each group will decide on a specific subject on which to focus their paper. Please note that the themes above are general and the final paper topic/research question should be more refined and related to study tour visits.

It is recommended that you research your visits prior to the study tour to raise the quality of your questions and observations on the trips. More information will be provided prior to Long Study Tour.

Study Tour Assignment Due on **Friday, March 17th**.

Field studies

Wednesday, March 15th: 8:30-12:30
Biopharmaceutical Company Visits

- In assigned groups, you will visit the company whose product you're researching for the *Drug Development* Project; the exact companies will be announced later.

Practical Information

The Science & Health department faculty and staff have put many hours into selecting and organizing the readings and material for this course. Please make sure to read all the material assigned; the reading material and the websites have been carefully chosen and are pertinent to your success in Medical Biotechnology and Drug Development. You have an obligation to your fellow classmates and yourself to come prepared to class.

Questions and feedback

If you have questions to the readings, lectures, or assignments, you are always welcome to contact me by email. Alternatively you can email program assistant Ryan Polito at to setup an appointment or ask a question. The program director for this course is Lisbeth Borbye,. The program assistant and the program director can be found in the Science and Health office in Vestergade 10-B12.

Academic Honesty: Plagiarism and Violating the Rules of an Assignment

DIS expects that students abide by the highest standards of intellectual honesty in all academic work. DIS assumes that all students do their own work and credit all work or thought taken from others. Academic dishonesty will result in a final course grade of "F" and can result in dismissal. The student's home universities will be notified. DIS reserves the right to request that written student assignments be turned in electronic form for submission to plagiarism detection software. See the Academic Handbook for more information, or ask your instructor if you have questions.

Disability resources: Any student who has a need for disability accommodations should contact Academic Support (acadsupp@dis.dk) to coordinate this. Upon DIS approval, students should inform the instructor of accommodations within the first 2 weeks of class.

Use of Laptops or Phones in Class: Use of phones in class is not allowed. Laptop use is allowed for group and project work only and when authorised.

Policy on late papers and/or assignments: Late papers will be accepted, but your grade for the paper will be reduced by half a letter grade for each day that it is late.

Canvas

Canvas is a web-based system that allows you to access course resources and communicate with your classmates and faculty. To access Canvas, you can go to the DIS homepage and click the 'Canvas' link on the bottom of the website, or go to: https://canvas.disabroad.org/login/canvas. You can also download the Canvas App (By: Instructure) on iPhone and Android mobile smart phones.

For each class there is a set of study questions related to the topic. These are to help you go through the material. There is a survey on "which questions were challenging" for each set of study questions. Before each class, you are expected to use the survey to indicate which study questions you found difficult. This helps the teacher to during class to focus on the areas perceived as most challenging.

Announcements will be posted with relevant information on the front page and emails can also be directed toward you from this page regarding the class.

Awards

Academic Excellence Award

Each semester we recognize one outstanding student from the Biomedicine Program with an Award of Academic Excellence. It is reserved for a student who has distinguished him- or herself through diligence, commitment, academic performance, and ideally a student who contributes to a good, collaborative learning environment in class.

	DATE	LECTURE	TEXT
	Wednesday, January 18	**BMD Program Orientation V10-A22 8:30-9:50**	
1	Thursday, January 19	**Introduction to the course** - What is biotech? - History of biotech - Why biotech in Denmark? **Overview of drug discovery and development process** - Phases in DD & DD - Introduction to pharmacology - Terms and concepts - Small molecules vs. biopharmaceuticals	**DDD:** - Chapter 1: "The Development of the pharmaceutical industry", p. 14-18 (Concluding remarks) - Chapter 3: "Therapeutic modalities", p. 34-40 (from conventional therapeutic drugs). - Chapter 4: "The Drug discovery process: general principles and some case histories", p. 43-46 (until "Some case stories") + p. 50 ("Comments and Conclusions"). - Chapter 14: "Drug development: introduction", p. 203-209. **Links on Canvas**: Biotechnology industry - E&Y Report 2013
2	Monday, January 23	**Drug development** - Formulation - Delivery - Storage - Small molecule **Please bring compendium to class** *Introduction to Study Tour Assignment* **Elect Class Representatives**	**DDD:** - Chapter 12: "Biopharmaceuticals", p. 184-186 (from "Pharmacological, Toxicological and Drug-Delivery issues with Proteins and Peptides"). - Chapter 14: "Drug development: introduction", p. 203-209. - Chapter 16: "Pharmaceutical development", p. 231-237 (Principles of Drug Delivery Systems). - Chapter 22: "Drug discovery and development – facts and figures", p. 329-330 (from "Pipelines and attrition rates") **RC:** Chapter 3 by R. Lipp and E. Punger: "Formulation of Biotech products", p. 173-185. **Links on Canvas**: Pharmacokinetic properties (from "As discussed in Chapter 8")
	Monday, January 23	**BMD Welcome Social 18:30 – 20:00**	
3	Thursday, January 26 **Guest lecturer** **Both**	**Drug discovery** *Guest lecturer: Morten Grunnet from Lundbeck* - Target identification - Disease models - Screening	**DDD**: - Chapter 2: "The nature of disease and the purpose of therapy" p. 24-27 (until "Pharmacoepidemiology and Pharmacoeconomics). - Chapter 4: "The Drug discovery process: general principles and some case histories", p. 50-54 (from "The Stages of Drug Discovery until Project Planning).

	sections	- Small molecule pharmacy contrasted with biotech	- Chapter 6: "Choosing the target", p. 63-65 (until Conventional Strategies for Finding New Drug Targets). - Chapter 11: Pharmacology: its role in drug discovery", p. 157-59 (until "Interpretation of binding assays") + p. 161 (until "In vitro profiling") + p. 164-169.
4	Monday, January 30	**Patent law** - General principles - Special concerns regarding biopharmaceuticals **Core Course Week (including Short Study Tour) orientation, in class**	**RC**: Chapter 4: "Patents in the Pharmaceutical Biotechnology Industry: Legal and Ethical Issues", p. 187-197. **Link on Canvas:** - "U.S. Says Genes Should Not Be Eligible for Patents" - "Pigs Fly: Federal Court Invalidates Myriad's Patent Claims" - "Myriad can patent breast cancer genes" - "Myriad Genetics Wins and Loses in Latest Court Ruling" - "US Supreme Court Rules Genes Cannot be Patented"
	Thursday, February 2 **Guest speaker** **Both sections**	**Gert Mølegaard** Moelgaard Consulting "Future Trends in the Pharmaceutical Industry" Having worked in the pharmaceutical industry for more than 25 years, Mølgaard has experience from a number of major engineering, automation and validation projects within pharmaceutical manufacturing as well as senior management positions. Gert Mølgaard was part of the team that created the GAMP (good automated manufacturing practice) guide and he has been actively involved in new guidance for process validation, PAT, manufacturing excellence and Quality by Design. He has contributed to numerous conferences, books and technical guidelines. Gert Mølgaard is also a former chairman of ISPE (International Society of Pharmaceutical Engineering)	
	Thursday, February 2	**Fact sheets for short tour academic visits due by 15:00 on canvas**	
February 6-8 **Core Course Week** incl. Short Study Tour to Odense/Aarhus (Feb 6-8) See end of syllabus for the Copenhagen programme (Feb 9-10, including lectures 5 and 6)			
7	Monday, February 13	**Peptides** - Properties - Pharmacokinetics - PEGylation - Hormones as example	**PB**: Chapter 5: "Pharmacokinetics and Pharmacodynamics of Peptide and Protein Drugs", p. 95-108. **PB:** Chapter 7: "Genomics, Other "Omics" Technologies, Personalized." p. 161-162. **RC**: Chapter 8: "Hormones", p. 209-214.

8	Thursday, February 16	**Genetics in target identification** - Genomics and other "-omics " - Microarrays - Bioinformatics - Knockout mice **Long Study Tour Orientation In Class**	**DDD**: - Chapter 6: "Choosing the target", p. 67-72 (from "New strategies for identifying drug targets" until "Target Validation"). - Chapter 7: "The role of information, bioinformatics and genomics", p. 82-89 (until "Phase 0 clinical studies…). - Chapter 7: "The role of information, bioinformatics and genomics", p. 77-79 (until "General principles for data mining"). **PB**: Chapter 7: "Genomics, Other "Omics" Technologies, Personalized..", p. 133-135 .
	Friday, February 17	**Send reflection write up for CCW by e-mail**	
9	Monday, February 20	**Test 1: Drug discovery and development (40 minutes)** **Microarrays: group exercise**	
10	Thursday, February 23	**Nucleotides** - Antisense, triple helix, Transcription factor decoys - RNAi - Aptamers	**PB**: Chapter 9: "Oligonucleotides", p. 211-222. **RC**: Chapter 5: "Aptamers as therapeutics" Note: the "Aptamers in the clinic" should be considered as examples alone
	Thursday, February 23	**Fact sheets for short tour academic visits due by 15:00 on canvas**	
	Friday, February 24	**Send preliminary research question by e-mail**	
Long Study Tour to London February 26 – March 4			
11	Monday, March 6	**Gene therapy** - Vectors, viral and non-viral - *Ex vivo* vs. *in vivo* - Disease targets and examples of applications	**PB**: Chapter 8: "Gene therapy", p. 175-185 (till Adenoviruses) + 193-198 (till The role of drug metabolism…). **RC**: Chapter 6: Box 14.2 from "Nucleic-acid and cell-based therapeutics" – Product case study: Gendicine. **Links on Canvas:** "Hemophilia B Gene Therapy Breakthrough" "A Shield Against Chemotherapy"
12	Thursday, March 9	**Test 2: Peptides and nucleotides as biopharmaceuticals (40 minutes)** Long Study Tour wrap up with Jeanette	
	Friday, March 10	**Send refection write up for LST by e-mail**	

13	Monday, March 13	**Drug Development in Scandinavia Biopharmaceutical Company Presentations**	
Wednesday, March 15 Field Study *Biopharmaceutical Company Visits* 08:30-12:30			
14	Thursday, March 16	**Immunology I** - General and specific immunity - Cells of the immune defense	”Basic concepts in Immunology”: - RC: Chapter 1: p. 1-13 - Canvas: p.14-17 (until end of 1-14) - RC: Chapter 1:,p.14 (from 1-16) to 24 (until end of 1-20) - Canvas: p.35 and 36 (Summary to Chapter 1)
	Friday, March 17	**Study Tour Assignment Due**	
Break March 18 – 26			
15	Monday, March 27	**Immunology II** - Interplay of the immune defence cells - Immunogenicity of biopharmaceuticals	**PB**: Chapter 6: “Immunogenicity of Therapeutic Proteins”: p. 125-132.
16	Thursday, March 30	**Antibodies** - Structure and production - Therapeutic uses of antibodies - Examples	**Links on Canvas:** “Monoclonal Antibodies” **PB**: Chapter 15: “Monoclonal antibodies: From structure to therapeutic Application”, 309+312-319; Chapter 16: “Monoclonal antibodies in cancer”, p. 354-356 (until Cetuximab).
17	Monday, April 3 **Guest lecturer Both sections**	**Vaccines I** *Guest lecturer: Jes Dietrich* - Conventional vs. modern vaccines - Adjuvants	**Canvas material**: Immunobiology’s “Modulating the immune response to fight infection”: - p. 577 – 586 (until 14.23) - p.587 – 588 (14.24) - p.589 – 590 (14.26) - p.591 – 592 (14.28 and summary)
18	Thursday, April 6	**Vaccines II** - Antigen discovery - Disease model - Vaccine development - Therapeutic vaccine examples - Vaccines recap	**PB**: Chapter 21: p.412 (Conventional vaccines onwards) – 425.
	Friday, April 7th	***Preliminary Drug Development Assignment Due***	

19	Monday, April 10	**Test 3: Immune defence-related biopharmaceuticals (50 minutes)**
		Break April 12 - 17
	Thursday, April 20	**No Lecture** Students are advised to use this time to work on their Drug Development Project report
	Monday, April 24	**No Lecture** Students are advised to use this time to work on their Drug Development Project report
	Thursday, April 27	**No Lecture** Students are advised to use this time to work on their Drug Development Project report
	Friday, April 28	***Drug Development Assignment Due***
	Monday, May 1	**No class**
	Wednesday, May 3	**Final class** - **Presentations of Drug Development** - **Evaluation and wrap-up** Time: 13:00-17:00 Location: TBA **Concluding Social** Time: 17.00-19.00 Location: TBA

DIS STUDY ABROAD IN SCANDINAVIA

Core Course Week Schedule		
Thursday, February 9		
08:50 – 10:10 **The stem cell hour**	**Stem Cells** **Introduction to stem cells** - Types of stem cells - Sources and uses of stem cells **Paper debate/discussion** **- Nat Methods paper**	**PB:** Chapter 7: "Genomics, Other "Omics" Technologies, Personalized", p. 162-165 **RC:** Chapter 9: Regulatory Issues for Personalized Pluripotent Cells **Links on Canvas**: "Small molecules facilitate rapid and synchronous iPSC generation", Abstract, Introduction and Discussion
	Take public transportation to go to Novo Nordisk	
12:00-15:00 **Novo Nordisk**	**Visit to Novo Nordisk** **Host: Johan Henrik Faber** Head of the Protein Characterization Department	
15:00-16:00	**Return to Copenhagen**	
Friday, February 10		
09:00-10:20 **Lecture 5**	**Clinical trials** - Ethics - Organization and planning - Clinical trial from hell: TeGenero	**RC**: Chapter 2: "The drug development process", p. 84-88. **Links on Canvas**: - "Q&A: Drug trials" - "Drug volunteers' 'living hell'" - "Doubt cast over drug trial safety" - "Horror clinical trial in test tube recreation"
10:40-12:00 **Lecture 6**	**Safety assessment and toxicology** *Guest lecturer: Louise Lauritsen* - From animal testing to clinical trials - Small molecule pharmacy contrasted with biotech	**DDD**: - Chapter 15: "Assessing drug safety", p. 211-222 (until other studies). - Chapter 20: "Regulatory affairs", p. 294-296 (until "Environmental considerations"). **RC**: Chapter 2: "The drug development process", p. 80-85.
12:00-13:00 **Drug Development Project**	**Introduction to the Drug Development Project** **Scientific Manuscripts: Referencing & Citing** **(Lunch provided by DIS)**	
13:00-14:00	**CCW wrap up**	