Life science track

Biomedicine- Master program Course coordinator: Fredrik Ek and Marcus Järås

BIMM04- Drug Development and Clinical Trials, 7.5 credits BIMM82- Research Project in drug development, 45 credits



Fredrik Ek



Marcus Järås



Life science track - outline

Second year Master program



March-	May	Sept	End Oct
Start looking for project	 Academic track	Initiate formulation/signing of contract. Documents accessible on Ortrac	All documents Signed and Uploaded before Start of the project

Get started with the contract as soon as possible already before summer or in the beginning of the autumn semester – long process time in the industry. Updated contract will be ready in May and sent out to students.

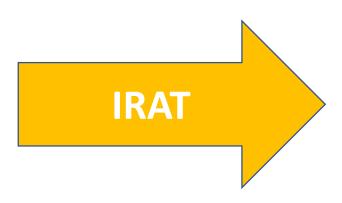
BIMM04

Course content

- The course covers the general process for development of a new drug from preclinical discovery via pre-clinical development and clinical trials.
- The course will address scientific, strategic and regulatory challenges from discovery to approval of a new drug and also includes key methods and terminology.
- It also covers the importance of the professional groups that are involved in the different phases of the development of a new drug.
- This course will prepare the students for subsequent degree projects and future work in the pharmaceutical industry as well as work in academia regarding innovations, early drug development and entrepreneurship.

BIMM 04 layout

Lectures and mandatory TBLs 2 weeks



TBL application – Project plan 2 weeks

BIMM04 – preliminary schedule from previous year

V40				30-sep	01-okt
Tid	mån	tis	ons	tors	fre
8.15-9					
9.15-10					
10.15-11					
11.15-12					
13.15-14					Screening-early discovery Small molecules (Fredrik Ek) BMC I1345
14.15-15				Course introduction (Marcus Järås/Fredrik Ek) GK-salen	Screening-early discovery Antibodies (Marcus Järäs) BMC I1345
15.15-16				Preclinical phase-overview Target selection Antibody/Small molecules	
16.15-17				(Marcus Järås/Fredrik Ek) GK-salen	
Wa1	Q4-okt	05-okt	06-okt	07-okt	Q8-okt
792					UO-UKI.
Tid	mån	tis	ons	tors	lre
8.15-9					
9.15-10					
10.15-11	LU Innovation - how can we help you? (Cecilia J, LU Innovation) BMC 11345	Hit to lead small molecule (Fredrik Ek) BMC 11345	Administration and Formulation, (Nils Ove Gustavsson, Camurus) BMC 11345	Proof of concept in vivo (Karin von Wackenfeldt, Truly Translational) BMC I1345	Clinical trials design (Ana Carneiro) BMC 11345
11.15-12	Patent strategy in life science (Jerry Olsson) BMC I1345	Hit to lead antibody (Peter Ellmark, Alligator Bioscience) BMC 11345	Toxicology studies (Maria Askmyr, Hansa Biopharma) BMC I1345	Preclinial data documentation and IND application (Martina Kvist Reimer, Red	Clinical trials funding/ endpoints Arvid Söderhäll, Empros Pharma) BMC I1345
	UISSUITY BINIC 11343	biodelice) biie 1245	biophiamily owic 1250	Glead) BMC 11345	Sociali, Empros Harria) directions
13.15-14		TBL-Preclinical discovery (Fredrik		TBL-Preclinical development (Fredrik	TBL From preclinical data to First in Man
14.15-15		Ek/Marcus Järås) MNO:0104		Ek/Marcus Järås) HSC C302	(Ana Carneiro) HSC C315
14.15-15 15.15-16		Ek/Marcus Järås) MNO:0104		Ek/Marcus Järås) HSC C302	(Ana Carneiro) HSC C315
15.15-16		Ek/Marcus Järås) MNO:0104		Ek/Marcus Järås) HSC C302	(Ana Carneiro) HSC C315
		Ek/Marcus Jārās) MNO:0104		Ek/Marcus Järås) HSC C302	(Ana Carneiro) HSC C315
15.15-16		Ek/Marcus Jārās) MNO-0104		Ek/Marcus Järås) HSC C302	(Ana Carneiro) HSC C315
15.15-16		Ek/Marcus Järås) MNO-0104		Ek/Marcus Jārās) HSC C302	(Ana Carneiro) HSC C315
15.15-16		Ek/Marcus Järås) MNO-0104		Ek/Marcus SHrkh) HSC C302	(Ana Carneiro) HSC C315
15.15-16		Ek/Marcus Järås) MNO-0104		Ek/Marcus Járáb) HSC C302	(Ana Carneiro) HSC C315
15.15-16	11-okt	Ek/Marcus Järås) MNO-0104	13-okt	Ek/Marcus Birkh) HSC C302	(Ana Carneiro) HSC C315
15.15-16 16.15-17	13-okt		13-okt	Bk/Marcus Birlish HSC C302	
15.15-16 16.15-17 V42			13-okt	Bk/Marcus Birlish HSC C302	
15.15-16 16.15-17 V42 Tid			13-okt	Bk/Marcus Birlish HSC C302	
15.15-16 16.15-17 V42 Tid 6.15-9	mån Protocol development (Andres	12-okt US Regulatory aspects (Susanne	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 6.15-9 9.15-10	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb	12-okt 85 Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 6.15-9 9.15-10	mån Protocol development (Andres	12-okt 85 Regulatory aspects (Susanne Magnusson, Cantarga) 8Mr. Rune Grubb Quality assurance/control (Annelis Teddersen, NovoNordsk) BMK fune	13-ckt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 V42 Tid 6.15-9 9.15-10	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	12-okt 15 Begulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annells	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 8.15-9 9.15-10 10.15-11	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annelis Feddersen, NovoNordisk) BMC Rune Grubb	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 V42 Tid 6.15-9 9.15-10	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	12-okt 15: Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annelis Feddersen, NovoNordisk) BMC Rune Grubb TBL-tribical aspects, vulnable populations, research breach, orotocol	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 8.15-9 9.15-10 10.15-11	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	12-okt 15. Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annelis Rune Grubb TBL-tthical aspects, volnable populations, research Darchap Corporations, research Cataco, protocol deviations (Racerch Darchap Corporations)	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 8.15-9 0.15-10 10.15-11	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	12-okt 15: Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annelis Feddersen, NovoNordisk) BMC Rune Grubb TBL-tribical aspects, vulnable populations, research breach, orotocol	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 8.15-9 0.15-10 10.15-11 11.15-12	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	12-okt 15. Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annelis Rune Grubb TBL-tthical aspects, volnable populations, research Darchap Corporations, research Cataco, protocol deviations (Racerch Darchap Corporations)	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 8.15-9 0.15-10 10.15-11 11.15-12 13.15-14 14.15-15 15.15-16	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	12-okt 15. Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annelis Rune Grubb TBL-tthical aspects, volnable populations, research Darchap Corporations, research Cataco, protocol deviations (Racerch Darchap Corporations)	13-okt	BE/Marcus Birlish HSC C302	15-okt fre
15.15-16 16.15-17 V42 Tid 8.15-9 0.15-10 10.15-11 11.15-12 13.15-14 14.15-15 15.15-16	mån Protocol development (Andres McAllister Bioinvent) BMC Rune Grubb Trial Management (Eva Lindgvist,	12-okt 15. Regulatory aspects (Susanne Magnusson, Cantargia) BMC Rune Grubb Quality assurance/control (Annelis Rune Grubb TBL-tthical aspects, volnable populations, research Darchap Corporations, research Cataco, protocol deviations (Racerch Darchap Corporations)	13-okt	BE/Marcus Birlish HSC C302	15-okt fre

V43	18-okt	19-okt	20-okt	21-okt	22-okt
Tid	mån	tis	ons	tors	fre
8.15-9					
9.15-10			TBL re-iRATMNO:0104		
10.15-11					
11.15-12					
13.15-14					
14.15-15					
15.15-16					
16.15-17					
V44	25-okt	26-okt	27-okt	28-okt	29-okt
Tid	mån	tis	ons	tors	fre
8.15-9					
9.15-10					
	TBL HSC C180			TBL Redovisning BMC D15 Dora Jacobsohn	TBL Redovisning MC D15 Dora Jacobsohn
10.15-11	TBL HSC C180				TBL Redovisning MC D15 Dora Jacobsohn
10.15-11	TBL HSC C180				TBL Redovisning MC D15 Dora Jacobsohn Course ending
10.15-11	TBL HSC C180			Jacobsohn -	Jacobsohn
10.15-11 11.15-12 13.15-14	TBL HSC C180				Jacobsohn
10.15-11 11.15-12 13.15-14 14.15-15	TBL HSC C180			Jacobsohn TBL Redovisning MC D15 Dora	Jacobsohn
10.15-11 11.15-12 13.15-14 14.15-15	TBL HSC C180			Jacobsohn TBL Redovisning MC D15 Dora	Jacobsohn
10.15-11 11.15-12 13.15-14	TBL HSC C180			Jacobsohn TBL Redovisning MC D15 Dora	Jacobsohn
10.15-11 11.15-12 13.15-14 14.15-15	TBL HSC C180			Jacobsohn TBL Redovisning MC D15 Dora	Jacobsohn
10.15-11 11.15-12 13.15-14 14.15-15	TBL HSC C180			Jacobsohn TBL Redovisning MC D15 Dora	Jacobsohn

Part one – lectures and TBLs Part two – group project

Two courses in one

BIMM04 7.5 credits

Master students

Drug Development & Clinical Trials 3 credits
PhD & PostDocs

Together Lectures+TBLs+iRAT



Promote networking and interaction students-researchers Course lunch

Unique course at LU – learn from the experts

Mainly lecturers from the industry – good opportunity for networking



Lecturers planned for 2024

Marcus Järås, Senior Associate professor, antibody based therapies

Fredrik Ek, Associate professor Chemical Biology

Cecilia Jägert, PhD, business development LU Innovation

Jerry Olsson, PhD, Patent consultant Acadia Pharmaceuticals/Camurus

Peter Ellmark, Associate professor, CSO Alligator Bioscience

Nils Ove Gustafsson, Civ ing, VP late stage development Camurus

Maria Asmyr, PhD, Senior Scientist Toxicology Hansa Biopharma

Karin von Wackenfeldt, CEO Truly labs

Liselotte Larsson, COO Cantargia

Martina Kvist Reimer, Region Skåne and Red Glead Discovery

Johan Flygare, Senior Associate professor and coordinator ATMP research program

Ana Carneiro, MD Associate professor, Clinical lead SUS

Arvid Söderhäll, PhD, CEO Empros Pharma

Andres McAllister, MD PhD, CMO BioInvent International

Ewa Lindqvist, BSc, Director Delivery THREAD

Susanne Magnusson, PhD, Director Clinical development Cantargia

Annelis Feddersen, MSc, Head of Clinical Research Novo Nordisk



















Evaluations of BIMM04

Overall the course was well received, the graded questions of the course evaluation, the average on all 18 questions was **5.4** (out of 6).



BIMM82 project in drug devlopment

Course content

- During the course, the student will carry out a delimited project at an organisation in the life-science industry that has a clear connection to biomedical research and development.
- The project is to have a clear issue that is summarised in the project plan.
- The student will, in addition to the workplace-based project period, devote time to analysing completed project work and summarise this in a written report that is also to be presented orally at a seminar.
- The student will also review and publicly discuss and examine other student's report.

Project topic within the scope of drug discovery and development or similar



Research & Development 3-6 years Preclinical Studies
1 year

Clinical Trials 4-7 years Review & Approval 1-2 years



- Target identification
- · Compound screening
- Lead identification



- In vitro studies
- In vivo studies
- · Toxicity testing



- Phase I, II, III trials
- Dosage & safety monitoring



- Safety & efficacy evaluation
- Approval & manufacture
- · Post-release monitoring

Titles previous thesis

Investigating cDC1 Reprogramming in Multicellular Patient-Derived Tumor Spheroids

Regional Correlation of Medication Errors in Diabetes with Injectable Glucose Lowering Drugs and the Covid-19 Pandemic

PATIENT DIVERSIFICATION AND INCLUSION IN CLINICAL TRIAL RECRUITMENT

The HoloMonitor® Fluorescence Prototype Enables Tracking of Fluorescent Cells Through the Combination of Holographic and Fluorescence Microscopy

Optimization of an in vitro IgG B cell assay for evaluating immunogenicity of the next generation IgG-cleaving enzymes

Assessment of project course BIMM82

Project plan **Company work Oral Presentation** Defense Written report **Peer analysis**

Portfolio 30 credits and written report 15 credits

Finding supervisors at companies

- Contact HR at the company or potential supervisors directly.
- When a supervisor has been identified and you have been accepted, a contract between the company and LU needs to be established.
- Design and write a project proposal with the supervisor at the company.

Why choosing the Life science track?

- Contact with the life science industry companies and people.
- You will be more attractive for the Life science industry.
- You will learn about drug development and clinical trials, knowledge that will be useful also for academic research.

Reflections from students that have taken the life science track

I chose the Life science track because the Biomedicine programme overall is quite directed to academia, and I wanted to know more about the industry. The first course; Drug Development and Clinical trials gave me a real insight into what drug development looks like and made me very interested in the pharmaceutical industry. During this course we had lectures from people representing different companies in life science, which was great and kick-started our networking! The project in the course included taking a fictive drug through discovery, development, pre-clinical and clinical trials, which I learned so much from, and became very invested. It was very "learning by doing".

I then did my Master thesis project at a CRO company. It was a very high tempo workplace which I love! You really learn a lot about the industry working in a company, and you get prepared for the working life. The main difference from doing your project in academia is that you can be more independent and take responsibility for your project management yourself, since your supervisor (and everyone else) is also busy with their own projects. You become more a part of the team, a colleague, and you are the project leader. In the company I also had the opportunity to learn so much more outside of my project, because there is always a need of people, I was eager to learn and it creates a possibility for a future position at the company (which I now have).

After this track I feel very ready to start my career as an independent scientist!

Choosing a specialization in industrial research allowed me to get a better understanding of the drug development process as well as the purpose and structure of clinical trials, from first-in-human studies to Phase IV. The course on drug development and clinical trials offered a new perspective that I hadn't encountered previously at the Biomedicine Master's program, where subjects such as patient safety and consumer tendencies were discussed in relation to research and drug development. I feel that this helped me gain an understanding for how drug development is approached outside of academia, which provided me with a unique perspective on the life science industry when transitioning from student to young professional. Moreover, performing my master thesis project at a company allowed me to observe and take part in the inner workings of a biotechnology company, where I got to witness the different career paths that exist for someone with a background in cell biology. My thesis work within the industry also gave me a good understanding for how the life science industry interacts with customer demand and scientific development. I would recommend the Industrial Research track to any student who wishes to get a better understanding of the drug development process as well as the life science industry in general.

"When I started my master's degree program, I knew I wanted to work in a pharmaceutical company once I graduated. During the third semester, we were given the option to choose either the life sciences track or the academic track. Without a doubt, I chose the life sciences track and I can proudly say that I made the best decision. During this course, we were taught about drug discovery to post-marketing of the developed drug. To give us real-life examples, we had lecturers from different pharmaceutical companies who helped us to understand how the pharmaceutical industry works. This course also helped us to broaden our network within the industry. The life sciences track prepared me well for my thesis project. I have been given a chance to do my master thesis project at Sanofi, Amsterdam where I performed a research project about diversity in clinical trials. Since I learned quite a lot about the pharmaceutical industry, I was able to use the knowledge I obtained from the course in my internship project and in the company. Moreover, it also helped me to integrate smoothly into the company environment. At the end of the course, I felt that I am completely ready to get myself into the industry as I have trained with the necessary skills to be a successful scientist."

Questions

- Can I still be a PhD student?
 - Yes!

Companies to contact

Lund/Malmö

Lund/Malmö

Alligator Bioscience

Acousort Maria Agemark <u>maria.agemark@acousort.com</u>

Active Biotech

Camurus

Truly Translational (contact Karin von Wachenfeldt) karin@trulylabs.com

Cellavision

Abliva

Asgard Therapeutics cristiana.pires@asgardthx.com

Bioinvent International

Bonesupport

Cantargia

Carbiotix

Cellavate

Combigene

Cyxone

Follicum

Hamlet Pharma

Hemocue Mirjam Andreasson Mirjam. Andreasson@hemocue.se

Idogen

In2cure

IVRS Contact Ramin Massoumi ramin.Massoumi@ivrs.se

Hansa Biopharma

Klifo

TFS Oncorena

PRA Health sciences

Pharmiva

Phase Holographic imaging (PHI) Patrik Eschricht patrik.eschricht@phiab.se

Qlucore

Redoxis Contact malin.hultqvist@redoxis.com

Saga Diagnostics Lao Saal <u>lao.saal@med.lu.se</u>

Senzagen

THREAD (contact Ewa Lindqvist evachod@gmail.com)

Xintela contact Evy Lundgren-Åkerlund

SMILE Incubator Several companies

Sweden/Copenhagen

NovoNordisk Sweden Annelis Feddersen aefe@novonordisk.com

Leo Pharma

Lundbeck

Genemab

Novozymes

Symphogen

Ascendis Pharma

Zealand pharma

Bavarian Nordic

Galecto Biotech

Io biotech

Orphazyme

Y-mabs

Pfizer

Ferring

AstraZeneca Göteborg