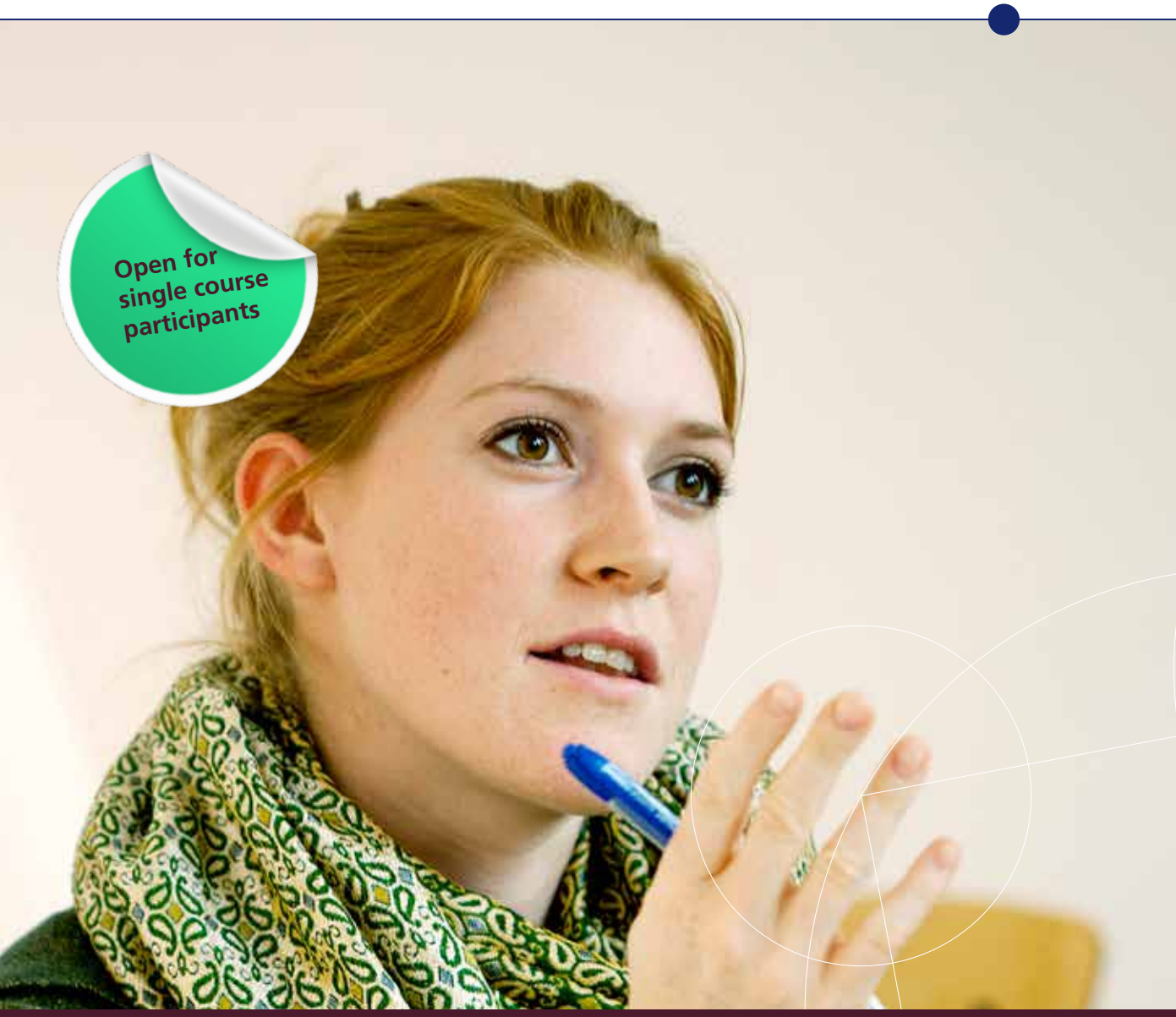
FACULTY OF HEALTH AND MEDICAL SCIENCES
UNIVERSITY OF COPENHAGEN




# MASTER OF INDUSTRIAL DRUG DEVELOPMENT

# MIND

# DRUG DEVELOPMENT FROM A TO Z

Drug development is a long, complex process requiring the interaction of numerous specialist fields. Growing competition in the industry has increased the need to coordinate the many elements involved in order to accelerate the drug development process and smooth the transition of candidate drugs to market. Skilful coordination of all the disciplines involved, from early target identification and validation through safety and efficacy testing to market launch, can streamline the approach to the production of new medicines.

The overall purpose of the MIND programme is to provide the biotech and pharmaceutical industries, pre- and clinical research organisations, medical device industry and related enterprises with academic personnel who are qualified to respond to these challenges.

On completion of the programme, graduates will  have a broad overview of and the ability to understand the connections between all stages of the development process from discovery to clinical trials, registration and marketing.

The MIND programme gives drug developers the professional building blocks to liase with other professionals within the company as well as with external partners, thus ensuring a high and up-to-date scientific level of the work carried out in multidisciplinary project teams. Graduates' ability to effectively and critically evaluate each stage of the drug development process will allow them to predict future bottlenecks.

## THE TYPICAL MIND PARTICIPANT

- **Has a background in fields such as engineering, pharmacy, chemistry, biochemistry or health sciences.**
- **Holds a relevant degree at bachelor level, master level (56%) or PhD level.**
- **Has at least two years of relevant job experience.**




# PARTICIPANTS

Master of Industrial Drug Development is aimed at experienced people in the biotech and pharmaceutical industries, clinical research organisations, and to some extent the medico industry, who are involved in developing drugs and need an overview of the process in its entirety as well as in-depth understanding of the individual elements.

# INTERACTION WITH INDUSTRY AND AUTHORITIES

The MIND programme is based on cutting-edge drug research, while maintaining focus on industrial utility.

The MIND faculty comprises leading professors and experts from pharmaceutical industry and authorities from Denmark and abroad, who are eager to share the latest research as well as case stories from the industrial arena with participants.

The programme objective is a high degree of practical relevance and utility orientation so that employers, who usually finance the programme for participants, gain immediate results.

# MIND AND THE DRUG DEVELOPMENT PROCESS

The Master of Industrial Drug Development programme provides an overview of the entire drug development process from discovery to marketing.

FROM DISCOVERY TO MARKETING →

DISCOVERY

EARLY DEVELOPMENT

PRECLINICAL DEVELOPMENT AND SAFETY

CLINICAL DEVELOPMENT

REGULATORY AFFAIRS

PHARMACEUTICAL MANUFACTURING & QA

MARKETING & INFORMATION

**FROM DISCOVERY TO MARKETING**

With pharmaceutical companies striving to be market leaders, key employees must have a broad overview and the ability to understand the connections between all stages of the development process from discovery to marketing.

On completion of the programme, Masters of Industrial Drug Development will have gained extensive interdisciplinary and practical knowledge of the industrial drug development process. Their ability to effectively and critically evaluate each stage of the drug development process will allow them to predict future bottlenecks.

The MIND programme gives drug developers the professional building blocks to be able to create and lead teams across divisional lines. Masters of Industrial Drug Development will be able to liaise with other professionals within the company as well as with external partners, thus ensuring a high and up-to-date scientific level of the work carried out in multidisciplinary project teams.

# INDIVIDUAL PROGRAMME LAYOUT

Compulsory courses make up about half of the programme. They are designed as intensive one- or two-week courses that require various degrees of preparation. The number of courses followed per year is up to participants and their employers to decide.

Elective courses and the final master's project make up the second half of the programme and are selected by participants in cooperation with a supervisor from the Faculty of Health and Medical Sciences. Employer input is also welcome.

Electives can be courses offered by the Faculty of Health and Medical Sciences or other universities in Denmark or abroad.

The master's project completes the MIND programme. It is a practice-oriented research project on an elective topic which allows the participant to apply the acquired skills and knowledge to the host organisation or company.

The project is supervised by a university lecturer and a supervisor from the participant's host organisation or company.

# FLEXIBILITY

MIND is designed as a part-time programme that can be combined with a busy career and family life. Freelance participants are welcome – all MIND courses can be taken as single courses as needed or desired.

> IT IS IMPORTANT THAT THE PROGRAMME IS AIMED AT PEOPLE WITH A MIXED EDUCATIONAL BACKGROUND IN ORDER TO NETWORK, GET DIFFERENT VIEWS ON TOPICS AND MAKE THE PROGRAMME MORE ATTRACTIVE.
>
> Graduate from 2011 (Graduate Survey 2012)



# THE MIND ADVISORY BOARD

**HELLE BRØNDSTED** MSc (pharm), PhD
Product Specialist
DGM Denmark A/S

**THÓRA BRYNJA BÖDVARSDÓTTIR** MSc (human biology), Master of Medical Product Innovation
Vice President, Diabetes Pharmacology,
Novo Nordisk A/S

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Senior Scientific Advisor, Clinical Pharmacology,
LEO Pharma A/S

**HENRIK FYLKING-NIELSEN** MSc (pharm)
Corporate Vice President
Novo Nordisk A/S

# COMPULSORY COURSES

You may take the courses in your own individually decided order.

Courses are listed in recommended order.

All MIND courses are taught in English.

**OVERVIEW: DISCOVERY AND DEVELOPMENT OF MEDICINES**
A comprehensive overview of drug development and an understanding of the dynamics of drug development and inter-communication across research disciplines.

**DRUG DISCOVERY**
A general comprehension of the elements involved in modern drug discovery including target identification & validation, and identification & optimization of lead compounds.

**PHARMACOLOGY**
Pharmacology concepts applied in the drug development process. Basic concepts and drug classes are introduced. Pharmacokinetics and experimental in vitro and in vivo tools are emphasized.

**NON-CLINICAL SAFETY AND TOXICOLOGY**
The requirements and conclusions to be drawn from the results of non-clinical safety assessment conducted in vivo as well as in vitro.

**DRUG FORMULATION AND DELIVERY**
Understanding the most relevant factors affecting the drug product performance enables the development of an optimal pharmaceutical product.

**CHEMICAL PROCESS DEVELOPMENT AND PRODUCTION OF ACTIVE PHARMACEUTICAL INGREDIENTS (API)**
In-depth knowledge of the different aspects of chemical process development from discovery through pilot plant size to optimized production scale synthesis and preparation of a Drug Master File.

**DRUG REGULATORY AFFAIRS IN DRUG DEVELOPMENT**
How regulatory affairs professionals interact with the specialists involved in the process of drug development, the EU legislative framework, application procedures and the strategic regulatory issues.

**QA, QC, GXP FOR PHARMACEUTICAL PRODUCTION**
Quality assurance and quality control of drug development and manufacture for worldwide distribution.

**CLINICAL PHARMACOLOGY AND BIOSTATISTICS**
The clinical pharmacological and biostatistical considerations involved in conducting clinical trials in drug development.



> ACADEMICS ARE OFTEN ENCOURAGED TO BECOME SPECIALISTS. HOWEVER, DEVELOPING NEW DRUGS IS VERY MUCH AN INTERDISCIPLINARY PROCESS THAT REQUIRES MANY EMPLOYEES WITH AN UNDERSTANDING OF THE ENTIRE PROCESS. MIND IS THE ONLY MASTER'S PROGRAMME IN DENMARK PROVIDING THAT KIND OF OVERVIEW.
>
> Marianne Kock, Senior Vice President Ferring Pharmaceuticals A/S and Vice Managing Director Regulatory Affairs & Pharmacovigilance in Ferring Group, Member of Advisory Board

# ELECTIVES

**BIOPHARMACEUTICALS – PHARMACEUTICAL DEVELOPMENT AND SAFETY ASSESSMENT**
An interdisciplinary introduction to the new advances in our ability to develop macromolecules into effective biopharmaceuticals.

**QUALITY BY DESIGN (QBD) IN PHARMACEUTICAL DEVELOPMENT**
An insight into the key principles of Quality by Design covering quality risk management, formal experimental design and process analytical technology.

**MARKET ACCESS FOR PHARMACEUTICAL PRODUCTS**
Strengthened capacity to understand and deal with crucial market access issues, and ability to systematically and effectively analyse the effect of market access decisions.

# A FLEXIBLE MASTER'S PROGRAMME

**Jeanett Borsdal**
Head of Section, Regional Quality Managers' network
H. Lundbeck A/S
MSc in Pharmacy
Currently working on her master's project

I started the MIND programme to increase my insight into drug development. When I first started my title was Clinical Operations Manager (later Head of Section in Clinical Operations) and I was part of the core team working on development projects. Each core team had members representing all the different steps in the drug development process. Through the programme, I quickly developed a solid theoretical foundation in all the different aspects of drug development, which made it easier for me to engage in conversation with the core teams – even when they got really technical.

Today, I am the Head of Section for our RQM's (Regional Quality Managers) who oversee the phase II and III studies we have outsourced to different CRO's (Contract Research Organisations). As the sponsor, we need to control the quality of both the CRO's and the sites and that is what our RQM's help us do. The RQM's work globally and are located all around the world, reporting directly to me in Denmark. Managing them at a distance makes it more difficult to get input about their challenges and their performance since I do not see them on a daily basis. Distance is not the only challenge, our different cultural backgrounds mean that we have different perceptions of how we think is the right way to act in a given situation.

**THE FLEXIBLE MIND**

Thankfully, the flexibility of the MIND programme has made it possible for me to do my master's project together with a colleague on one of my key professional challenges – distance management and cultural differences/challenges. We are in a very early phase of the work on our project right now and it is really motivating to put a theoretical perspective on something I deal with everyday. The master's project is very relevant to my work and will hopefully also benefit others within Lundbeck.

I think flexibility is one of the real strengths of the MIND programme. In my case, I will have taken four

years to complete my master's degree, by the time I have finished. In that period both my job description and the size of my family has changed. It is one thing to make the job/family equation add up but topping that with a fair amount of travel and a master's programme makes flexibility crucial. Happily, I have been able to take the courses in the order that suited me best and I have been able to change the scope of my master's to reflect changes in my job.

Given the large amount of work and hours a master's degree requires it is crucial that the programme adds value – both for the division and me. And the MIND programme has certainly done that.



# FROM THE EMPLOYER'S PERSPECTIVE

At Lundbeck our most important resources are our employees. That is why it is so important that they are skilled professionals. Their strength and talent defines our market position so investing in our employees is a high priority.

We invest in our employees in a variety of ways, one of them being continuing education. There is formal continuing education like the MIND programme, but we also use short, targeted external courses to learn what the world looks like outside our own organisation. Last but not least we also offer in-house courses to develop our employees qualities to the highest level.  For us, the key is a systematic approach to knowledge sharing.

In Jeanett's case, thanks to the MIND programme, she has been able to focus her master's project on a concrete challenge to our division. She's taking a theoretical approach to a field in which she already has substantial practical experience. And hopefully that will help her develop the way she works – and the way the entire division works.

Another thing Jeanett is taking home from the MIND programme is a more theoretical and systematic approach to her every day challenges, i.e. the ability to take a challenge and present it in a new and better way. And that is valuable to the entire division.

**Dorte Arnbjerg**
Divisional Director, Global Study Management
H. Lundbeck A/S
Jeanett's manager

# THE WHOLE WORLD IS MY WORK PLACE

**Ibrahim Kamara**
Independent consultant

Ibrahim Kamara has 15 years experience in the quality assurance of biological drugs. MIND-training (Master of Industrial Drug Development) has given him insight into the entire drug development process. And academically relevant courses from the University of Copenhagen have set him up for a working life with the whole world as his employer

Ibrahim is from The Netherlands and has a bachelor's degree in Medical Biology from Imperial College, London. He now lives in Spain where he works as an independent, advisory consultant for various European companies. He began the MIND programme in 2007 and is about to complete the programme:

"The MIND programme has given me both insight and an overview of the entire drug development process from molecule to patient. And I have had a chance to meet the leading Danish and international scholars in the field. Unlike many other university-based courses, on our course we get information straight from the protagonists themselves, as many of the guest speakers on the programme spend their days working in the pharmaceutical industry," says Ibrahim Kamara.

He is keen to highlight the network, he has gained on the programme:

"I have met Danish and foreign students with very different functions in the pharma industry. On the courses we share our specialised experience in an industry that is known for keeping its cards close to its chest."

**LARGE MOLECULES WITH GREAT POTENTIAL**
For fifteen years Ibrahim has been working in quality assurance for medicines, especially biological drugs, which present special challenges in the long and difficult process of developing new drugs.

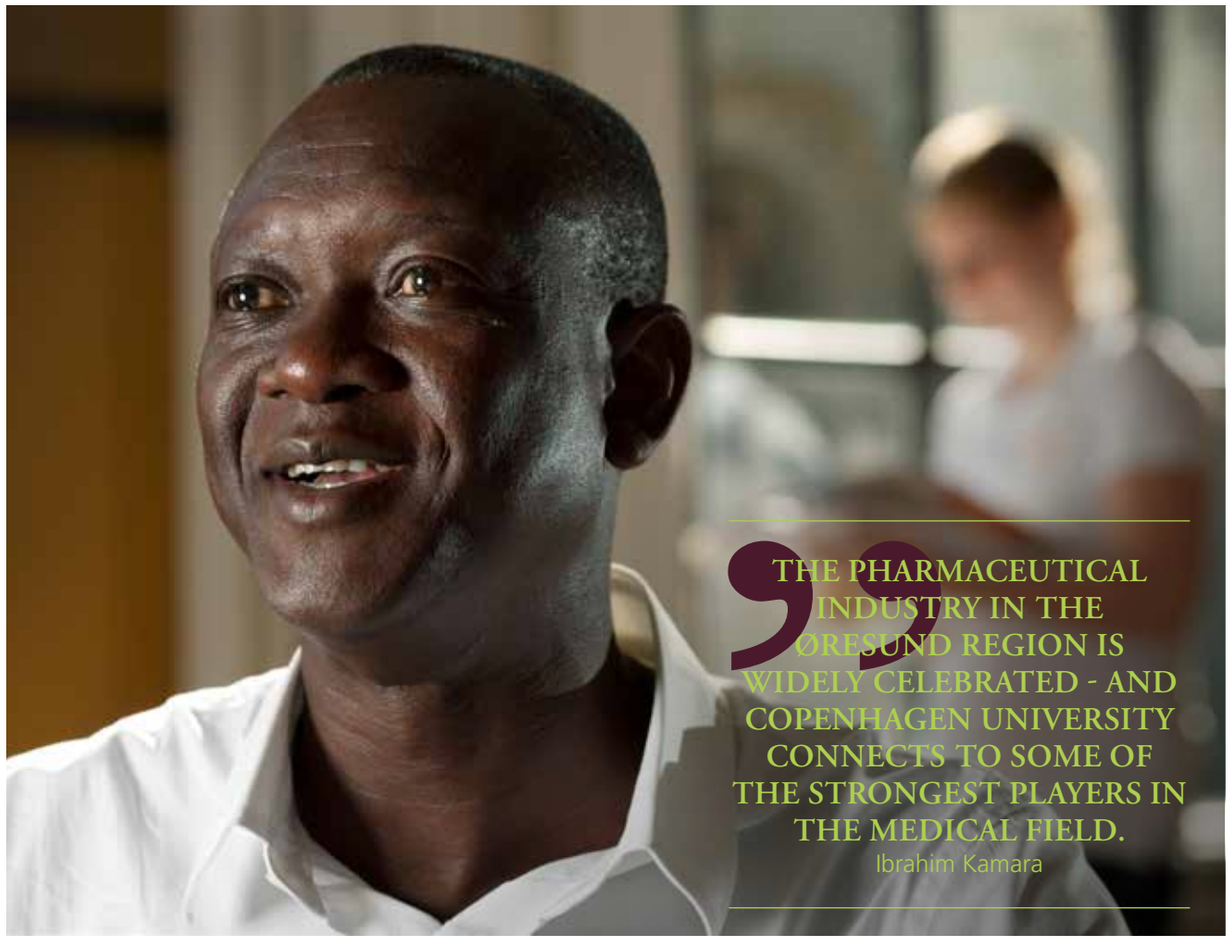
"The new thing in pharma is to think big. Most of today's medicines consist of tiny chemical substances, but research increasingly points towards the use of large protein molecules as drugs. These so-called biological drugs, based on proteins or peptides have great processing potential. They are literally made of natural raw material, so they have targeted power - and very few side effects," says Ibrahim. "However, proteins are also brittle and expensive to manufacture and store. So quality assurance of the potential super drugs is a real challenge."

"Courses like 'Quality by Design' and 'Biopharmaceuticals – pharmaceutical development and safety assessment' on MIND have been a really good foundation for me working with challenging biologics," says Ibrahim.

**MIND POWER AND YOUR AMBITIONS**
The MIND programme is very flexible, a good thing for a man whose job spans Continental Europe: "For someone like me who has lived in several different countries over the years and now has a job that requires a great deal of travel, flexibility is important," says Ibrahim. He considered several continuing education options in 2006 - but quickly realised that the MIND programme at the University of Copenhagen was tailor made for his expectations and ambitions:

"The pharmaceutical industry in the Øresund Region is widely celebrated – and Copenhagen University connects to some of the strongest players in the medical field," says Ibrahim, who worked for several years for Novo Nordisk Engineering in the Copenhagen area.

"Having looked all over the world for appropriate training, I had no doubt that MIND was right for me. The great flexibility, the possibility of a full master's programme and the prosperous Scandinavian pharmaceutical industry next door made all the difference," says Ibrahim.



# NEW SKILLS WITH MIND ON BOARD

**Maria Boese**
Vice President of Regulatory Affairs
Novo Nordisk A/S

Just a few years after qualifying as a chemical engineer Maria Boese has gone from thinking analytically in a lab to thinking strategically as part of the management team of Denmark's largest and most successful pharmaceutical company.

The Regulatory Affairs function is central to the pharmaceutical industry because it brings together and coordinates all aspects of the drug development process, from preclinical development and clinical trials in humans, to production and pharmacovigilance. From the earliest stages of development of a new drug, it is important to get an overview of the regulatory framework. Which challenges should the company take into account in the development of a specific product? Which clinical trials should be organised for drug approval? Which law applies in an international market? Strategic thinking in terms of risk-benefit analysis and a flair for politics are very important when developing drugs.

"When working with regulation and registration in the pharmaceutical field, it is essential to get an overview of the drug development process. Amongst other things, the breadth of the Master of Industrial Drug Development gave me insight into clinical trials and law, two fundamental aspects of all drug development. At the same time the flexible programme has been a great advantage because I have a really busy life. The short intense courses and freedom of choice has been excellent for me. Most MIND courses last a week with an exam on the last day. It is perfect for busy people with lots to do both at work and during leisure time," says Maria Boese.

**FLAIR FOR BUSINESS AND MANAGEMENT AMBITION**
40-year-old Maria is currently vice president of Regulatory Operations at Novo Nordisk A / S. She completed the MIND programme in 2010 and has also taken a Graduate Diploma in Business Administration to increase her business acumen:

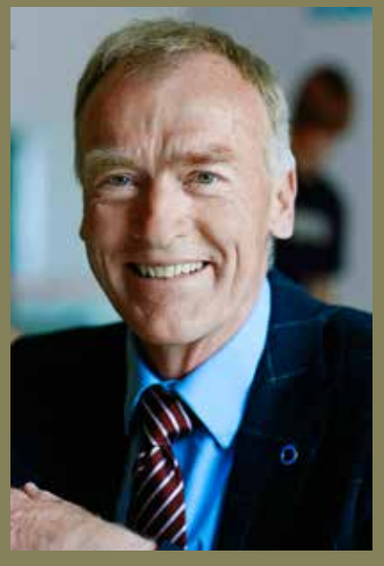
"I work as a manager on a daily basis and the combination of training in marketing management and my master's degree in industrial drug development has given me a strategic overview of business, from a pragmatic drug development point of view. Many teachers at MIND spend their days in the industry – so there is no lack of specific examples in the teaching. The programme has a practical aim, which has been very useful for me. In my management job I work with specialists from all parts of the drug development process and it's great to be able to participate in academic discussions at all levels. The breadth of the MIND programme is really good for that," says Maria Boese.

**A BROAD APPROACH TO DRUG DEVELOPMENT**
Regulatory Affairs professionals are usually responsible for checking that product marketing meets the relevant legislation. Marketing permission is based on the evidence in the registration application, which is produced by the company:

"In my job, I rely on drug professionalism every day, this includes documentation of quality, safety and efficacy. Knowledge of legislation and general understanding of society are also things I draw on all the time. As a chemical engineer I needed a broader professional profile in pharmaceuticals to make the transition to regulatory affairs – the MIND programme has been a very important step," says Maria Boese.

## FROM THE EMPLOYER'S PERSPECTIVE

**Peter Bonne Eriksen**
Senior Vice President
Regulatory Affairs
Novo Nordisk A/S
Maria's manager



> CONTINUING EDUCATION PROGRAMMES SUCH AS MIND ARE REGULARLY ASSESSED TO DETERMINE CONTENT, QUALITY, COSTS AND WHETHER THEY FIT WITH THE REQUIREMENTS LAID DOWN IN EACH EMPLOYEE'S INDIVIDUAL DEVELOPMENT PLAN. THE TIMING OF COMPLETION ALSO NEEDS TO FIT WITH OTHER PRIORITIES AND TASKS.

> MIND HAS PROVIDED A COHERENT INTRODUCTION TO MANY ASPECTS OF MODERN DRUG DEVELOPMENT AND HAS HELPED MARIA DEVELOP HER SKILLS IN HER CURRENT JOB. IT COULD ALSO BE VALUABLE IN MARIA'S FUTURE JOBS.

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# PRACTICAL INFORMATION

### ADMISSION REQUIREMENTS

Relevant bachelor's degree or equivalent (minimum)
Two years of relevant job experience (minimum)
Proficiency in English

### TUITION FEES

A Master of Industrial Drug Develoment degree from the Faculty of Health and Medical Sciences costs a total of DKK 175.000-200.000 (approx. EUR 23.500-26.800) depending on the electives chosen. Expenses for food and materials are extra. The programme is usually employer financed.

### APPLICATION

There is continous enrolment in the programme and hence no fixed application deadline.

### VENUE

The compulsory courses are normally taught at the School of Pharmaceutical Sciences, Universitetsparken 2, 2100 Copenhagen Ø.

### FURTHER INFORMATION

For further information about the programme and individual courses, please see www.mind.ku.dk, or address your query to:

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