2010 Curriculum for the Master programme in Industrial Drug Development at the Faculty of Health and Medical Sciences, University of Copenhagen

This revised curriculum comes into force on 1 September 2024 and shall apply in relation to students admitted after September 2024.

The curriculum was approved by the Dean on 9 December 2010 with changes approved on 25 March 2014, 21 March 2017, 17 April 2018, 12 March 2019, 10 March 2020, 13 April, 2021, on 10 March 2022, 14 March 2023 and 25 April 2024.

This subject-specific curriculum, the course descriptions at www.kurser.ku.dk, and the general programme regulations for professional Master's programmes together comprise the curriculum for the Master programme in Industrial Drug Development**.**

Part 1 Objectives and Competence profile

§ 1 Objectives

The objective of the Master programme in Industrial Drug Development (master i industriel lægemiddeludvikling) is to provide the biotech and pharmaceutical industries, pre- and clinical research organisations, medical device industry and related enterprises with academic personnel who have insight into and understanding of all aspects of the industrial drug development process, and who are qualified to lead multidisciplinary teams across divisional lines to respond to the challenges of the industry.

1.2 Successful completion of the programme gives the right to use the title Master of Industrial Drug Development and the Danish title master i industriel lægemiddeludvikling.
1.3 The degree is worth 60 ECTS credits.
1.4 The programme falls within the scope of the Study Board for the Professional Master's Degree Programmes at the Faculty of Health and Medical Sciences.
1.5 The programme falls within the scope of the corps of external examiners for the pharmaceuticals programmes in Denmark.

§ 2 Admission requirements

2.1 Applications are assessed by an Admissions Committee after the application deadline.
2.2 The programme starts annually on 1st February.
2.3 It is a condition for admission that the full programme and/or single course applicant:

- holds a relevant bachelor's degree, professional bachelor's degree, diploma degree or equivalent. Relevant disciplines would be chemistry, biochemistry, pharmacy, medicine, biomedicine, human biology, molecular biology, veterinary sciences, health sciences, nursing and engineering.
- have at least two years of relevant work experience related to drug development after having completed the qualifying course of study.

- Admission to a professional master's programme requires a mastery of English corresponding to level B English at Danish upper secondary level. Applicants must document proficiency in English as stated in the programme webpage.

2.4 The admissions committee may on the basis of an individual assessment admit applicants who do not hold a relevant degree if the applicant is deemed by the Study Board to possess comparable educational qualifications.
2.5 The courses offered under the Master programme can be taken as single courses. If the number of applicants for a given course exceeds the number of seats, priority will be accorded to students enrolled in the full Master programme.
2.6 The admission committee may grant exemptions from the provisions of paragraph 1 when special circumstances apply.

§ 3 Competence profile
The Master of Industrial Drug Development (MIND) programme equips graduates with the following knowledge, skills and competences:

Knowledge
MIND graduates have demonstrated knowledge and understanding of the following subjects:

- target identification and target validation methods and processes
- lead optimisation methods and processes
- principal steps and methodologies in drug discovery and development including translational steps
- principal steps in discovering, modifying, assessing, producing and patenting new chemical and biological compounds
- the overall development plan involving medicinal chemical, pharmaceutical, non-clinical and clinical development
- quality assurance
- regulatory requirement for medicines
- management of drug safety issues before and after market authorisation
- management of lifecycle activities of a medicine
- ethical and legal provisions in drug development

MIND graduates have in-depth knowledge based on the highest level of international research in one or more subject areas in a selected field. On this scientific basis, graduates are equipped to understand and reflect on the knowledge of the other relevant subject areas and identify scientific issues.

Skills
MIND graduates are able to:

- apply basic computational methods in the areas of bioinformatics and structure-based drug design
- adhere to GMP and GCP guidelines for drug products
- apply knowledge of drug regulatory affairs to work tasks and project strategies
- schedule and integrate non-clinical tests into overall drug development and assess their predictive value

- design early studies in patients: dose-finding and proof-of-concept studies
- design a confirmatory clinical development plan
- perform a benefit/risk assessment throughout the lifecycle management of a medicine
- liaise and communicate professionally, using scientific terminology, with other specialist groups within the drug development industry, as well as with non-specialist

Competences
MIND graduates are able to:

- effectively and critically evaluate each stage of the drug development process and predict future bottlenecks
- critically evaluate validation of drug targets
- manage and develop complex work situations related to drug discovery and development
- independently initiate and carry out discipline-specific and interdisciplinary collaboration related to drug development
- initiate, plan, implement and assume professional responsibility for drug development projects from discovery to clinical trials and registration
- organise the elements of a drug development programme
- take independent responsibility for own professional development.

Part 2 Modules, instruction and maximum duration of study

§ 4 Modules and methods of instruction

The modular structure of the programme is designed to provide students with overall academic qualifications within a prescribed timeframe, which is defined in terms of ECTS points. All courses in the programme are subject to a modular structure.

§ 5 Maximum duration of study

Failure to complete the professional master's programme within six years following enrolment will result in termination of enrolment, unless a longer period of study is allowed in the course specific regulations. The Study Board may grant exemptions from the six-year time limit under extraordinary circumstances.

Part 3 Study and exam activities

§ 6 Study and exam activities

The Master programme comprises the following courses and exams.

View of mandatory courses, fixed elective courses, elective courses, course codes and ECTS

Mandatory	Course title and code	ECTS
	Discovery and Development of Medicines SMIMB1011U/E	5
	Drug Discovery SMIMM1131U/E	3
	Pharmacology SMIMB1041U/E	2,5
	Non-clinical Safety and Toxicology SMIMB1051U/E	2,5
	Drug Formulation and Delivery SMIMA1161U/E	4
	Process Development and Production of Active Pharmaceutical Ingredients (API) SMIMM1151U/E	3
	Drug Regulatory Affairs in Drug Development SMIMA1081U/E	2,5
	QA, QC, GXP for Pharmaceutical Production SMIMA1101U/E	2,5
	Clinical Pharmacology and Biostatistics SMIMB1151U/E	5

Elective courses	Course title and code	ECTS
	Elective courses See the list of elective courses	10-18

Master's project	Course title and code	ECTS
	Master's project SMIMIL014E (12 ECTS)	12-20

§ 7 Compulsory, constituent subject elements and elective elements

7.2 The student can plan the sequence and pace of the courses.

7.3 The course descriptions at www.kurser.ku.dk specify learning outcomes, contents, teaching and learning methods, prerequisites for participation, etc.

7.4 The programme consists of 30 ECTS credits from compulsory study and exam activity. Also the master's project is a compulsory activity.

7.5 The programme consists of 10-18 ECTS credits from elective study and exam activity.

7.6 The programme consists of 12-20 ECTS credits from the master's project.
7.7 The programme's constituent subject elements are all compulsory study and examination activities and the master's project.

§ 8 Group exams
Written papers can be undertaken in groups with other students if stipulated in the course descriptions at www.kurser.ku.dk
8.2 Group examinations can be done for groups of no more than four students, when stipulated in the course descriptions at www.kurser.ku.dk.
8.3 Jointly written papers are permitted provided the contributions made by each member of the group can be identified. A separate and individual grade will be given to each student.
8.4 Oral examination on the basis of jointly written papers should be individual, and a student may attend the examination of other students in the group only if his or her examination has been held.

§ 9 Instruction and exam languages
Instruction is conducted in English, unless only Danish-speaking students and instructors are present. All examinations are held in English.

§ 10 Elective elements
The Master programme includes a compulsory element of elective courses worth a total of 10-18 ECTS credits.
10.2 The Study Board endorses students' access to elective courses. These elective courses are described in the course descriptions at www.kurser.ku.dk and announced no later than 1 May and 1 November in the preceding semester. In addition the student have access to elective courses at the MSc in Pharmaceutical Sciences as well as the opportunity to partake in an Independent Elective Study (see § 12).
10.3 In March the Study Board generally approves the elective course descriptions for the following academic year.
10.4 The Study Board offers elective courses that are aligned with the objective of the Master programme, see 1.1 above.

§ 11 Master's project
11.1 The program concludes with a master's project, as stipulated in § 11, paragraph 1, no. 2 of the master's regulation. The student must have completed and passed all courses and examinations in the program before the oral defense of the master's project; otherwise, the student will be deregistered. The project must demonstrate the student's ability to formulate, analyze, and process issues within a relevant, delimited scientific subject in a qualified manner.
11.2 The master's project is prepared individually or in groups of two students.
11.3 The project must adhere to length guidelines specified in the course description for the master's project and fall within the topic of the approved master's project agreement.
11.4 The project must include a summary in English, not exceeding 1 A4 page. The summary contributes to the overall assessment of the project.
11.5 In assessing the master's project, emphasis is placed not only on the academic content but also on the student's spelling and writing skills. Academic content is given the greatest weight.
11.6 The master's project is worth 12-20 ECTS credits. The student decides the credit size of the master's project.

11.7 The master's project must be written in English. The final oral examination is usually conducted in English, but may be conducted in Danish, if the examinee, examiner and external examiner agree.

Part 4 Specific provisions

§ 12 Independent Elective Study

Students can participate in an independent elective study of 2.5 ECTS or 5 ECTS. Students can participate in independent elective study of a maximum of 5 ECTS. The objective is to give the student an opportunity to organize and carry out an independent study motivated by academic as well as personal interests, under the guidance of a supervisor from the Faculty of Health and Medical Sciences. The study may be carried out in Denmark or abroad.
The course descriptions at www.kurser.ku.dk specify learning outcomes, contents, teaching and learning methods, prerequisites for participation, etc.

§ 13 Prerequisites for establishing courses

In the event that a course attracts fewer than 10 students, the Faculty of Health and Medical Sciences reserves the right to cancel the course. However, if the course is sought after by students admitted at the Master programme the faculty is obligated to run obligatory courses at least every second year.

If a course is to be held with less than 10 enrolled students, the Study Board may offer the course with a revised structure, with fewer class teaching hours.

§ 14 Transitional arrangements

ECTS credit points already earned from passing SMIMM1141U/E Chemical Process Development and Production of Active Pharmaceutical Ingredients (API) replace the ECTS from SMIMM1151U/E Process Development and Production of Active Pharmaceutical Ingredients (API).

Part 5 Concluding remarks

§ 15 Exemptions from these provisions

In exceptional circumstances, the Study Board may grant exemptions from any curriculum provisions within the sole remit of the Study Board.

§ 16 Date of commencement

This revised curriculum comes into force on 1 September 2024 and shall apply in relation to students admitted after September 2024.