



Curriculum for
Part time Master Programme in Industrial Drug Development
2010 (revision 2025)

University of Copenhagen

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Chapter 1. Description of the programme

1.1 Title

A passed master's degree entitles the holder to the designation Part time Master of Industrial Drug Development.

1.2 Standardising ECTS credits

The scope of the master's degree programme is calculated in ECTS credits (European Credit Transfer and Accumulation System). One year of full-time studies amounts to 60 ECTS credits, corresponding to a workload for the student of 1650 hours.

The master's programme is standardised to 60 ECTS credits.

1.3 Affiliation

The programme falls under Study Board for the Professional Master's Degree Programmes at the Faculty of Health and Medical Sciences and the students have the right to vote and stand for election to this Study Board.

The programme is affiliated with corps of external examiners for the pharmaceuticals programmes in Denmark.

The programme is offered by the Faculty of Health and Medical Sciences in Copenhagen.

1.4 Language

The programme is offered in English.

1.5 Academic profile

1.5.1 Purpose

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.

1.5.2 Competency profile

After graduation, the student will have acquired the following:

Knowledge:

- 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:

- 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:

- 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.

Chapter 2. Admission requirements

2.1 Admission to the master's degree programme

Admission to the master's degree programme in Industrial Drug Development requires that the applicant has

- completed a qualifying Bachelor's degree, including a professional Bachelor's degree, a relevant medium-term higher education, a relevant diploma degree completed as a regulated course or other Danish or foreign education at the same level
- Minimum 2 years of relevant work experience after completing the qualifying education
- Meets language requirements

Deadlines for admission to the programme can be found on the programme's website.

2.2 Qualifying education

The following programmes are eligible:

Bachelor's degree, professional bachelor's degree, diploma degree or equivalent:

- Chemistry
- Biochemistry
- Pharmacy
- medicine
- biomedicine
- human biology
- molecular biology
- veterinary sciences
- health sciences
- nursing
- engineering

Applicants who do not meet the requirements, but who, on the basis of a specific individual assessment, are deemed to have educational qualifications that can be equated with a qualifying education, may be admitted.

2.3 Relevant work experience

Relevant work experience is defined as:

having at least two years of relevant work experience related to drug development after having completed the qualifying course of study.

2.4 Language requirements

Applicants must be able to document English proficiency equivalent to one of the requirements below:

- upper secondary school B-level

- upper secondary school A-level

2.5 Capacity

Up to 25 students can be admitted to the master's programme once every year.

2.6 Ranking of applicants

If there are more qualified applicants than study places, applicants are ranked according to the following criteria:

- Qualified applications are prioritized in order of submission date, with the earliest applications ranked highest.

Chapter 3. Structure of the education

3.1 Outline of the programme

The programme is standardized to 60 ECTS credits and consists of the following elements:

- Compulsory subject elements of 30 ECTS credits including a Master's project of 12-20 ECTS credits
- Delimited electives of 10-18 ECTS credits

Compulsory subject elements comprise the constituent part of the programme.

Recommended course of study

Year	Autumn semester		Spring semester	
1st year	Discovery and Development of Medicines	1 mandatory courses + elective	1 mandatory course + 1 elective	1 mandatory course + 1 elective
2nd year	1 mandatory course + 1 elective	1 mandatory course + 1 elective	1 mandatory course + 1 elective	Master's project

The master's project completes the programme. It is a prerequisite for being able to pass the master's project that all previous exams have been passed.

3.1.1 The compulsory subject elements of the programme

Code	Subject title / LINK	ECTS	External censorship	Form of assessment	Form of examination	Location and possible schedule group	Formal academic requirements for enrolment
SMIMB 1011U	Discovery and Development of Medicines	5	Yes	7-point grading scale	On site-Written Exam	Spring	
SMIMA 1081U	Drug Regulatory Affairs in Drug Development	2,5	Yes	7-point grading scale	Written Assignment	Autumn/Spring	
SMIMA 1101U	QA, QC, GXP for Pharmaceutical Production	2,5	No	Passed/Not Passed	Written Assignment	Autumn/Spring	
SMIMA 1161U	Drug Formulation and Delivery	4	No	7-point grading scale	Written Assignment	Autumn/Spring	
SMIMB 1041U	Pharmacology	2,5	Yes	7-point grading scale	Onsite Written Examination	Autumn/Spring	
SMIMB 1051U	Non-clinical Safety and Toxicology	2,5	Yes	7-point grading scale	Written Assignment	Autumn/Spring	
SMIMB 1151U	Clinical Pharmacology and Biostatistics	5	Yes	7-point grading scale	Home Assignment	Autumn/Spring	
SMIMM 1131U	Drug Discovery	3	Yes	7-point grading scale	Written Assignment	Autumn/Spring	
SMIMM 1151U	Process Development and Production of Active Pharmaceutical Ingredients (API)	3	No	7-point grading scale	Home Assignment	Autumn/Spring	
SMIM24 003U	Master's project	12	Yes	7-point grading scale	Written Assignment with Oral Examination	Autumn/Spring/Summer	

3.1.2 The core electives of the programme

Code	Course title / LINK	ECTS	External censorship	Form of assessment	Form of examination	Location and possible schedule group	Formal academic requirements for enrolment
SMIM20001U	Pharmacoepidemiology and post-authorisation safety studies	5	No	7-point grading scale	Written Assignment	Autumn/Spring	
SMIM20002U	Digital Health	3	No	Passed/Not Passed	Written Assignment	Autumn/Spring/summer	
SMIM22001U	Pharmacovigilance: Signal detection and risk management	5	No	7-point grading scale	Written Assignment	Autumn/Spring	
SMIM22002U	Big data, artificial intelligence and machine learning in drug safety	5	No	7-point grading scale	Written Assignment	Autumn/Spring	
SMIM23004U	Biotherapeutics Drug Development	3	No	Passed/Not Passed	Written Assignment	Autumn/Spring	
SMIM24001U	Pharmacological and Clinical Aspects of Drug Safety	5	No	7-point grading scale	Written Assignment	Autumn/Spring	
SMIM25001U	Pharmacoepidemiology, post-authorisation safety studies and real-world data	5	No	7-point grading scale	Written Assignment	Autumn/Spring	
SMIM25002U	The European Health Technology Assessment (HTA) process – get on the learning curve	2,5	No	Passed/Not Passed	Written Assignment	Autumn/Spring/Summer	

Code	Course title / LINK	ECTS	External censorship	Form of assessment	Form of examination	Location and possible schedule group	Formal academic requirements for enrolment
SMIMA 1091U	Quality by Design (QbD) in Pharmaceutical Development	3	No	Passed/ Not Passed	Written Assignment	Autumn/Spring	
SMI-MIF115U	Market Access for Pharmaceutical Products – trends and challenges	3	No	Passed/ Not Passed	Written Assignment	Autumn/Spring/Summer	
SMI-MIF116U	Value Based Health Care	3	No	Passed/ Not Passed	Written Assignment	Autumn/Spring/Summer	
SMI-MIL02IE	Independent Elective Study	2,5	No	Passed/ Not Passed	Written Assignment	Autumn/Spring/Summer	
SMRM1 8005U	Clinical Development and Documentation	4	No	7-point grading scale	Written Assignment	Autumn/Spring	
SMRM1 8008U	Labelling as driver for Regulatory Strategy	3	Yes	7-point grading scale	Written Assignment	Autumn/Spring	
SMRM1 8009U	Biopharmaceuticals – Quality Development and Documentation	4	No	Passed/ Not Passed	Written Assignment	Autumn/Spring	
SMRM1 8010U	Quality – Drug Substance and Drug Product	4	No	Passed/ Not Passed	Written Assignment	Autumn/Spring	

Chapter 4. General rules

4.1 Maximum programme duration

The student must complete his/her education no later than six years after enrolment.

Students who do not complete the education within the maximum period of study will be discharged by the university.

Students are not entitled to the 2nd and 3rd examination attempts in a subject element if this causes the maximum period of study to be exceeded.

4.2 Rules on teaching

4.2.1 Subject element tender

Subject elements are described in the UCPH course catalogue: kurser.ku.dk.

All subject elements are approved by the dean after recommendation from the Study Board, effective 1 September.

4.2.2 Alteration of subject elements

As a general rule, subject elements descriptions cannot be changed after publication in terms of description of objectives, level, language, ECTS credits, location, form of teaching, and examination form.

4.2.3 Cancellation of subject elements

The University of Copenhagen has the right to cancel a subject element after the application deadline, e.g. if there are too few registered participants. In the event of cancellation of subject elements that are compulsory for students enrolled in full master's degree programmes, the student must be assigned an alternative offer within a reasonable period.

4.3 Rules on examinations

The purpose of an exam, regardless of the type of exam, is to test whether the students meet the criteria for assessment as they appear in the subject element description.

4.3.1 Number of exam attempts

The student has three attempts to pass an exam. If the student does not participate in a registered exam, the student has used an exam attempt.

When a course is offered for the last time, the university determines when the student has the last opportunity to take an exam in the subject element.

Students who have exhausted their exam attempts will be discharged by the university.

4.3.2 Rules on writing and spelling skills

The student's writing and spelling skills are included in the overall assessment of the master's project, although the academic content must be given greatest weight.

If there is a *special* focus on writing and spelling skills in other subject elements, this will be stated in the individual subject element description on kurser.ku.dk.

4.3.3 Group examination

It is stated in the subject element description when group exams are allowed, as well as how many students (max.) can participate in the individual group exam.

In a group exam, each student's performance must be assessed individually and an individual grade is given.

In the case of written group assignments, the individual student's contribution must be stated in the assignment answer, so that an individual assessment is ensured. If an individual assessment is not possible, the assignment cannot be graded, and the assignment will be rejected from assessment.

In the case of an individual oral examination that follows a written group assignment, the other authors of the group assignment may not be present in the examination room before they are to be examined. A grade must be given in connection with an individual oral examination before the next student is examined.

In the case of oral group exams, a group of students are examined at the same time and an individual assessment is made.

4.3.4 Special examination conditions

Upon application, the Study Board may offer special examination conditions on the basis of physical or mental impairment and to students with a mother tongue other than Danish, when the university deems it necessary for the sake of equality of the students in the examination situation. It is a prerequisite that the offer does not change the academic level of the exam.

The university is responsible for ensuring that the exam can be conducted with the assigned special conditions and that the conditions are clearly communicated to the student.

4.3.5 Exam prerequisites

If a subject element contains exam prerequisites, these will appear in the subject element description in the course catalogue on kurser.ku.dk.

Exam prerequisites must be met before the student participates in an exam for the first time.

If the student does not meet the stipulated exam prerequisite(s), the student will be registered for a used exam attempt.

4.3.6 Re-examination

The form of examination for the re-examination is the same as the ordinary examination, unless otherwise stated in the subject element description.

Rules for holding re-examinations are set out in the University of Copenhagen's administrative rules.

4.3.7 Standard Page Definition

A standard page is 2400 characters including spaces. The keynote count includes footnotes, endnotes, tables, equations and formulas. Front page, table of contents, any summary or abstract, bibliography, figures, attachments and appendices do not count.

4.3.8 Complaints about examinations

The student may submit a written complaint about the exam and/or legal deficiencies.

Complaints about the exam must be submitted to the university no later than 2 weeks after the result of the exam has been reported to the student. The deadline is calculated at the earliest from the date on which the deadline for publication of the assessment has been set.

4.4 Pre-approval and credit transfer of subject elements

The Study Board may grant approval of subject elements passed in another uncompleted master's degree programme to replace subject elements in the programme.

It must be pre-approved by the Study Board if:

- The student wishes to replace compulsory subject elements with subject elements from other master's programmes
- The student wishes to replace elective subject elements with subject elements from other programmes at the Part time Master or master's level

Once the student has been granted credit transfer for previous subject elements, the credit transfer cannot subsequently be cancelled or changed.

Credit transfer from foreign universities is transferred with a pass/fail assessment.

4.4.1 Complaints and appeals

Students can submit a written complaint about legal deficiencies in credit transfer decisions. Complaints must be submitted to the faculty.

Students can appeal the academic assessment in decisions on credit transfers.

If the appeal concerns credit transfers from Danish educational institutions or any type of prior approval, the appeal must be brought before a Credit Transfer Appeal Board. The student must submit his/her appeal to the faculty no later than two weeks after receiving the decision.

If the appeal concerns final credit transfer from abroad, the appeal must be brought to the Qualifications Board no later than four weeks after the person in question has received the decision. The student submits his or her appeal to the faculty.

Chapter 5. Formalities

5.1 Possibilities for exemption

The Study Board may, upon application, grant exemptions from the rules in the curriculum that are solely set by the university if there are documented exceptional circumstances.

Complaints regarding legal issues in connection with decisions on students' circumstances made by study boards can be submitted to the Danish Agency for Higher Education and Science.

5.2 Complaints about legal deficiencies

Complaints regarding legal deficiencies in decisions on students' circumstances made by the university can be submitted to the Danish Agency for Higher Education and Science.

5.3 Legal basis

The rules of the curriculum are set in accordance with current executive orders, with the subsequent amendments:

- Ministerial Order no. 19 of 9 January 2020 on Master's Degree Programmes at Universities (the Master's Degree Programme Order).
- Ministerial Order no. 1121 of 19 September 2025 on Examinations and Tests in University Programmes (the Examination Order).
- Ministerial Order no. 1125 of 4 July 2022 on the grading scale for degree programmes within the Ministry of Higher Education and Science (the Grading Scale Order).
- Ministerial Order no. 2272 of 1 December 2021 on part-time university programmes (Order on Part-Time programmes).
- Consolidated Act no. 391 of 10 April 2024 on universities (the University Act).
- Ministerial Order no. 1122 of 19 September 2025 on Credit Transfer in University Programmes (the Credit Transfer Order).

5.4 Authentication

The curriculum was approved by the Dean on 15 March 2026.

5.5 Effective date

The curriculum goes into effect on 1 September 2026 and applies to students who commence their degree programme on this date or later.

Chapter 6. Transitional provisions

There are no transitional provisions for this curriculum.