2006 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 2018 and shall apply in relation to students admitted after 1 November 2006 and before 1 September 2010.

The curriculum was approved by the Dean in September 2006 with changes approved on 25 March 2014, 21 March 2017, and 17 April 2018.

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

Part 1 Objectives and qualification 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
It is a condition for admission that the applicant

- hold 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:
  - Scandinavian applicants (including Danish applicants) are required to document proficiency in English corresponding to at least English B level; cf. Section 11 of the Danish Ministerial Order on Admission at Universities.
  - Applicants from an English-speaking country meet the language requirements and do not need further documentation of English proficiency.
Applicants who have completed a Bachelor’s and/or Master’s degree in English meet the language requirements. Applicants must submit necessary documentation.

Applicants employed at a company with English as working language meet the language requirements. Applicants must submit necessary documentation.

Applicants from outside Scandinavia who speak or write English as a second language must pass the International English Language Testing System (IELTS/Academic) or the Test of English as a Foreign Language (TOEFL) to document their qualifications in English. The minimum acceptable score for IELTS is 6.5 and for TOEFL 560 on the paper test, or 83 on the internet-based test. For more information about the tests: www.ielts.org and www.toefl.org.

2.2 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.

2.3 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.

2.4 The admission committee may grant exemptions from the provisions of 2.1 when special circumstances apply.

§ 3 Qualification 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

§ 4 Modules
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.

Part 3 Study and exam activities

§ 5
The Master programme comprises the following courses and exams:
<table>
<thead>
<tr>
<th>Compulsory courses</th>
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<tr>
<td><strong>Discovery and Development of Medicines</strong></td>
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<td><strong>Drug Discovery</strong></td>
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<td><strong>Pharmacology</strong></td>
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<td><strong>Drug Formulation and Delivery</strong></td>
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<td><strong>Chemical Process Development and Production of Active Pharmaceutical Ingredients (API)</strong></td>
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<tr>
<td><strong>Drug Regulatory Affairs in Drug Development</strong></td>
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<td><strong>QA, QC, GXP for Pharmaceutical Production</strong></td>
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<tr>
<td><strong>Elective courses</strong></td>
<td><strong>Elective courses</strong></td>
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<td>(10-18 ECTS)</td>
<td>(10-18 ECTS)</td>
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<tr>
<td><strong>Master’s project</strong></td>
<td><strong>Master’s project</strong></td>
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<td>(12-20 ECTS)</td>
<td>(12-20 ECTS)</td>
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2.2 The student can plan the sequence and pace of the courses.
2.3 The course descriptions at www.kurser.ku.dk specify learning outcomes, contents, teaching and
learning methods, prerequisites for participation, etc.

§ 6
The programme consists of 30 ECTS credits from compulsory study and exam activity. Also the
master’s project is a compulsory activity.
6.2 The programme consists of 10-18 ECTS credits from elective study and exam activity.
6.3 The programme consists of 12-20 ECTS credits from the master’s project.
6.4 The programme’s constituent subject elements are all compulsory study and examination
activities and the master’s project.

§ 7
The programme includes the following courses and exams:

Course title: Discovery and Development of Medicines
STADS code: SMIMB1011U/ SMIMB1011E
ECTS: 5 ECTS

Course title: Drug Discovery
STADS code: SMIMM1131U/ SMIMM1131E
ECTS: 3 ECTS credits

Course title: Pharmacology
STADS code: SMIMB1041U/ SMIMB1041E
ECTS: 2.5 ECTS credits

Course title: Non-clinical Safety and Toxicology
STADS code: SMIMB1051U/ SMIMB1051E
ECTS: 2.5 ECTS credits

Course title: Drug Formulation and Delivery
STADS code: SMIMA1161U/ SMIMA1161E
ECTS: 4 ECTS credits

Course title: Chemical Process Development and Production of Active Pharmaceutical Ingredients (API)
STADS code: SMIMM1141U/ SMIMM1141E
ECTS: 3 ECTS credits

Course title: Drug Regulatory Affairs in Drug Development
STADS code: SMIMA1081U/ SMIMA1081E
ECTS: 2.5 ECTS credits

Course title: QA, QC, GXP for Pharmaceutical Production
STADS code: SMIMA1101U/ SMIMA1101E
ECTS: 2.5 ECTS credits

Course title: Clinical Pharmacology and Biostatistics
STADS code: SMIMB1151U/ SMIMB1151E
ECTS: 5 ECTS credits

Elective courses worth a total of 10-18 ECTS credits.

Course title: Master’s project
STADS code (12 ECTS): SMIMB0014E
ECTS: 12-20 ECTS

§ 8 Group examinations
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 element
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 students 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
Students must complete a master’s project. The project must demonstrate the student’s ability to formulate, analyse and process issues within a relevant, defined scientific subject in a qualified way.

11.2 The master’s project may be prepared individually or by groups of 2 students.
11.3 The project must be completed in accordance with the approved master’s project agreement and comprise the equivalent of c. 25-40 pages A4 pages (using 12 point Times Roman). The project must be accompanied by an abstract in English of no more than one A4 page. The abstract must summarize the problem formulations, the methods used, significant results/findings, a discussion if relevant, and a conclusion. The abstract will be included in the overall assessment of the master’s project.

11.4 When assessing the master’s project, emphasis must, in addition to the academic content, also be placed on the student’s spelling and writing skills.

11.5 The master’s project is worth 12-20 ECTS credits. The student decides the credit size of the master’s project.

Part 4 Concluding remarks

§ 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 15 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 15 enrolled students, the Study Board may offer the course with a revised structure, with fewer class teaching hours and/or another type of examination.
§ 14 Transitional arrangements
The Study Board will specify transitional arrangements in regards to students (enrolled prior to 1 November 2006) who have not yet passed all compulsory courses laid down in the 2004 programme Curriculum. The individual implications of the transitional arrangements will be announced to each student in writing.

§ 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 2018 and shall apply in relation to students admitted after November 2006 and before 1 September 2010.