2011 Curriculum for the Master programme in Pharmaceutical Regulatory Affairs at the Faculty of Health and Medical Sciences, University of Copenhagen

This revised curriculum comes into force on 1 September 2014 and shall apply in relation to students admitted after April 2011.

The curriculum was approved by the Dean in March 2011 with changes approved on 25 March 2014.

This subject-specific curriculum, the course descriptions at www.kurser.ku.dk, and the general curriculum provisions together comprise the curriculum for the Master programme in Pharmaceutical Regulatory Affairs.

Part 1 Objectives and qualification profile

§ 1 Objectives
This programme is an international master’s programme concerning the registration of drugs and biological and biotechnological products and aimed at employees in the pharmaceutical sector. The programme targets individuals involved in the regulatory and legislative areas of the pharmaceutical industry, as well as employees in healthcare and biotech companies or in regulatory bodies. Programme participants will gain a comprehensive and detailed knowledge of the procedures related to the application, registration and approval of drugs and biological and biotechnological products that will qualify them to specialize in the entire process of drug registration from the initial stages of discovery to final approval. Programme participants will thus be qualified to advise and involve professional groups in the development process surrounding the regulatory and statutory requirements governing drug registration, potentially shortening the length of time it takes for companies to obtain a marketing approval and managing the drug on the international market.

1.2 Successful completion of the programme gives the right to use the title Master of Pharmaceutical Regulatory Affairs and the Danish title master i lægemiddelregistrering.

1.3 The degree is worth 60 ECTS credits.

1.4 The programme falls within the scope of the Study Board for Part-time Pharmaceutical Master programmes.

1.5 The programme falls within the scope of the Corps of External Examiners for the Pharmaceuticals Programmes in Denmark.

§ 2 Admission requirements
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 within regulatory affairs or equivalent after having completed the qualifying course of study.
- meet the language requirements as stipulated in the general curriculum provisions.
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 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. The same admission requirements apply to students taking 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 Pharmaceutical Regulatory Affairs (MPRA) programme equips graduates with the following knowledge, skills and competences:

Knowledge
MPRA graduates have demonstrated knowledge and understanding of the following:

- The principles of drug discovery and drug development
- EU regulation and legislation
- EU regulatory procedures
- Marketing authorization applications
- Pharmaceutical regulatory affairs aspects of Pharmaceutical quality
- Pharmaceutical regulatory affairs aspects of Non-clinical development
- Pharmaceutical regulatory affairs aspects of Clinical development
- Pharmaceutical regulatory affairs aspects of Quality management
- The future directions in global pharmaceutical and health economics and their implications for product development and evaluation

Skills
MPRA graduates are able to:

- Choose the most appropriate marketing authorization application (MAA) procedure for a given medicinal product
- Adhere to European legislation and regulation guidelines
- Identify when consultation (e.g. scientific advice) with the regulatory authorities is needed
- Integrate the interface between chemistry, manufacturing and control (CMC), pharmaceutical development and non-clinical and clinical data
- Participate in product information development
- Perform an adequate audit- and inspection follow-up
- Perform ongoing risk/benefit assessment throughout the lifecycle of a medicinal product

Competences
MPRA graduates are able to:

- Independently initiate and carry out proper actions between regulatory authorities and the marketing application authorization applicant/holder.
• Critically examine and evaluate scientific data and conclusions intended for regulatory review
• Enable application of new methods, tools and strategies to aid successful drug development and regulatory review
• Enable improvement of the regulatory environment by implementing and upholding good regulatory practices
• Enable regulatory compliance in pharmacovigilance
• Train leaders and employees in regulatory aspects of drug development
• 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>
<th>Discovery and Development of Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Regulatory Affairs in the EU</td>
</tr>
<tr>
<td></td>
<td>Quality – Drug Substance and Drug Product</td>
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<td></td>
<td>Product Life Cycle Activities</td>
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<td></td>
<td>Non-Clinical Documentation</td>
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<td></td>
<td>Regulatory Strategic Considerations during Global Drug Development</td>
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<tr>
<td></td>
<td>Clinical Development and Documentation</td>
</tr>
<tr>
<td></td>
<td>Role and Responsibilities of a Regulatory Affairs Professional</td>
</tr>
<tr>
<td>Elective courses</td>
<td>Elective courses (0-8 ECTS)</td>
</tr>
<tr>
<td>Master’s project</td>
<td>Master’s project (12-20 ECTS)</td>
</tr>
</tbody>
</table>

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 40 ECTS credits from compulsory study and exam activity. Also the master’s project is a compulsory activity.
6.2 The programme consists of 0-8 ECTS credits from elective study and exam activity.
6.3 The programme consists of 12-20 ECTS credits from 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

Course title: Regulatory Affairs in the EU
STADS code: SMPMA3141U/ SMPMA3141E
ECTS: 6

Course title: Quality – Drug Substance and Drug Product
STADS code: SMPMA3161U/ SMPMA3161E
ECTS: 4

Course title: Product Life Cycle Activities
STADS code: SMPMA3191U/ SMPMA3191E
ECTS: 5

Course title: Non-Clinical Documentation
STADS code: SMPMA3171U/ SMPMA3171E
ECTS: 5

Course title: Regulatory Strategic Considerations during Global Drug Development
STADS code: SMPMA3151U/ SMPMA3151E
ECTS: 4

Course title: Clinical Development and Documentation
STADS code: SMPMA3181U/ SMPMA3181E
ECTS: 6

Course title: Role and Responsibilities of a Regulatory Affairs Professional
STADS code: SMPMA3201U/ SMPMA3201E
ECTS: 5
Elective courses 0-8 ECTS credits.

Course title: Master’s project
STADS code (17.5 ECTS): SMPMA0014E
ECTS: 12-20

§ 8
All compulsory courses except “Discovery and Development of Medicines” are offered in
collaboration between the Faculty of Health and Medical Sciences and Medicademy. Students enroll in the courses at Medicademy. After passing the courses at Medicademy, students enroll for a supervised project report at the Faculty of Health and Medical Sciences. The course descriptions at www.kurser.ku.dk offer further information on this matter.

§ 9 Group examinations
Written papers can be undertaken in groups with other students if stipulated in the course descriptions at www.kurser.ku.dk.
9.2 Group examinations can be carried out in groups of no more than four students, when stipulated in the course descriptions at www.kurser.ku.dk.
9.3 A joint written work is 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.
9.4 An oral examination on the basis of joint written work 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.

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

§ 11 Elective element
The Master programme includes an element of elective courses worth a total of 0-8 ECTS credits.
11.2 The Study Board must ensure that Master students have 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 § 11)
11.3 In March the Study Board generally approves the elective course descriptions for the following academic year.
11.4 The Study Board offers elective courses in keeping with the objective of the Master programme, see 1.1 above.

§ 12 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.
12.2 The master’s project may be executed alone or by groups of 2 students.
12.3 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 in 12 point Times Roman. The project must be furnished with an abstract in English of no more than one A4 page. The abstract must summarize the research question, the methods used, important findings, a discussion if relevant, and a conclusion. The abstract will be included in the overall assessment of the master’s project.
12.4 Assessment will be based on the student’s spelling and writing skills as well as the scientific content of the thesis. The scientific content will carry most weight.
12.5 The master’s project is worth 12-20 ECTS credits. The student decides the credit size of the master’s project.

1 Medicademy is an educational program established by The Danish Association of the Pharmaceutical Industry (LiF).
Part 4 Concluding remarks

§ 13 Independent Elective Study
Students can participate in an independent elective study of 2.5 ECTS or 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.

§ 14 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.

§ 15 Transitional arrangements
The Study Board for Part-time Master’s Programmes will specify transitional arrangements in regards to students enrolled prior to 1 April 2011 who have not yet passed all compulsory courses laid down in the 2007 Curriculum. The students already enrolled under the previous programme will be offered to be transferred to these regulations. The individual implications of the transitional arrangements will be announced to each student in writing.

§ 16 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.

§ 17 Date of commencement
This revised curriculum comes into force on 1 September 2014 and shall apply in relation to students admitted after 1 April 2011.