2018 Curriculum for the Master programme in Medicines Regulatory Affairs at the Faculty of Health and Medical Sciences, University of Copenhagen

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

The Dean approved this new curriculum on 25 April 2024.

This subject-specific curriculum, the course descriptions in the overall University of Copenhagen course database, and the general programme regulations for professional Master's programmes together comprise the curriculum for the Master of Medicines Regulatory Affairs.

Part 1 Objectives and competence profile

§ 1 Objectives
This programme is an international master's programme concerning the registration of medicines including 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, biological, and biotechnological products that will qualify them to specialize in the entire process of medicines approval 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 medicines approval, potentially shortening the length of time it takes for companies to obtain a marketing authorization and managing the medicine on the international market.

The objective of the Master of Medicines Regulatory Affairs (Master i lægemiddelregistrering) is to provide the pharmaceutical industry, preclinical- and clinical research organisations, related enterprises, ministries and boards with academic personnel who have a thorough insight into the area of regulatory affairs and possess a holistic understanding of all aspects of the regulatory aspects of medicines development. The graduates from the master will possess academically based skills enabling them to analyse guidelines, procedures and regulations, and suggest and advise on improvements for existing or formulation of new legislation and guidelines.

1.2 Successful completion of the programme gives the right to use the title Master of Medicines Regulatory Affairs (master i lægemiddelregistrering).
1.3 The degree is worth 60 ECTS.
1.4 The programme belongs under the Study Board for the Professional Master's Programmes.
1.5 The programme belongs under the corps of external examiners for 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 degree. Qualifying degrees are: Master's and/or bachelor's degree in Health & Medical Sciences, Natural Sciences, Applied Sciences, or equivalent qualification from a recognised higher education institution in Denmark or abroad.
- has at least two years of relevant work experience from the pharmaceutical industry, Medicines Agency or other relevant organization or company.
- 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.

2.4The admissions committee may on the basis of an individual assessment admit applicants who do not hold one of the above mentioned degrees if the applicant is deemed by the admissions committee 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.

§ 3 Competence profile

The Master of Medicines Regulatory Affairs programme equips graduates with the following knowledge, skills and competences:

Knowledge:

A graduate from the Master of Medicines Regulatory Affairs will be able to:

- Explain, identify and discuss, based on the best international research, scientific problems that arise in the development of medicines
- Explain, identify and discuss key elements of global (e.g. EMA, FDA) regulatory legislation and regulatory procedures
- Explain and discuss, based on the best international research, key elements of medicines regulatory affairs aspects of quality development, non-clinical development, and clinical development throughout the lifecycle of a medicinal product
- Identify and discuss key elements included in a marketing authorization application (MAA)
- Explain and discuss, based on the best international research, key elements in global regulatory affairs e.g. effectiveness, patient involvement, pharmacovigilance, health technology assessment and their implications for product development and evaluation

Skills:

A graduate from the Master of Medicines Regulatory Affairs will be able to:

- Apply, analyze and consider key scientific elements in regulatory legislation and regulation guidelines
- Analyze and discuss why a regulatory professional should challenge the product information from early development and throughout the entire life cycle of a product
- Evaluate the possibilities for obtaining a marketing authorization (MA) for a given medicinal product
- Apply, analyze and consider key elements in the interface between chemistry, manufacturing and control (CMC), pharmaceutical development, non-clinical as well as clinical data throughout the lifecycle of a medicinal product
- Evaluate the possibilities, benefits and consequences of seeking scientific advise with regulatory authorities
- Apply, analyze and perform ongoing benefit/risk assessment throughout the lifecycle of a medicinal product
- Critically examine and evaluate scientific data and conclusions intended for regulatory review
- Advise on, and formulate effective responses to complex practical regulatory issues.
- Advice on ethical, societal and health economical aspects of patient involvement in medicines development
- Advise and train leaders and employees in regulatory aspects of medicines development, as well as communicate and discuss evidence-based knowledge within that area with researchers (specialists, and non-specialists) or lay-persons within or outside the employing organization.

Competences:

A graduate from the Master of Medicines Regulatory Affairs will be able to:

- Initiate and facilitate interaction between applicants and regulatory authorities based on scientific questions
- Enable application of new methods, technologies and strategies to aid successful medicines development and regulatory review
- Advise on and identify solutions that enable improvement of the regulatory environment by implementing and upholding regulatory compliance and good regulatory practices
- Advise on and develop plans that facilitate a safe, innovative and effective approval of medicines
- Independently initiate and drive the development of a regulatory strategy ensuring a strong, reliable quality based story line for product approvals during the entire product life cycle
- Independently assess and organize their own learning process and assume responsibility for continuous professional development with a view to life-long learning

Part 2 Modules, instruction and maximum duration of study

§ 4 Modules and 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 in Medicines Regulatory Affairs comprises the following courses and exams:

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

Mandatory course	Course title and code	ECTS
	Discovery and Development of Medicines SMIMB1011U/E	5
	Global Pharmaceutical Policy – Rationales and Stakeholders SMRM18001U/E	4
	The EU Regulatory Environment – Procedures and Applications SMRM18002U/E	4
	The US Regulatory Environment SMRM18003U/E	4
	Transparency and Trustworthiness in Drug Development SMRM18004U/E	3
	Clinical Development and Documentation SMRM18005U/E	4
	Drug Regulatory Science SMRM18006U/E	3
	Safety of Medicines - from Non-clinical Development to Pharmacovigilance SMRM18007U/E	4

Mandatory course	Course title and code	ECTS
	Labelling as a Driver for Regulatory Strategy SMRM18008U/E	3

Fixed elective course	Course title and code	ECTS
Students may choose one of two courses	Biopharmaceuticals – Quality Development and Documentation SMRM18009U/E	4
	Quality – Drug Substance and Drug Product SMRM18010U/E	4

Electives	Course title and code	ECTS
Elective courses worth a total of 10 ECTS credits.	List of elective courses	10

Mandatory master's project	Course title and code	ECTS
	Master's project SMRMIFS01U/E	12

§7 Compulsory, constituent subject elements and elective elements
The programme consists of 34 ECTS credits from compulsory study and exam activity and in addition the master's project worth 12 ECTS credits.
7.2 The programme consists of 4 ECTS credits from fixed elective study and exam activity and 10 ECTS credits from elective study and exam activity.
7.3 The programme's constituent subject elements are: All compulsory study and examination activities and the master's project
7.4 The student can plan the sequence and pace of the courses.
7.5 The course descriptions at www.kurser.ku.dk specify learning outcomes, contents, teaching and learning methods, prerequisites for participation, etc.

§ 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 paper 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 paper 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
English is the language of instruction and examination at the Master of Medicines Regulatory Affairs.

§ 10 Elective elements
The Master programme includes a compulsory element of elective courses worth a total of 10 ECTS credits.
10.2 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. In addition the students have access to apply for 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's 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 ECTS points.
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.

§ 12 Independent Elective Study
Students can participate in an independent elective study of 2.5 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.

Part 4 Specific provisions

§ 13 Transitional arrangements

No transitional arrangements are established.

§ 14 Prerequisites for establishing courses

In the event that a course attracts fewer than 10 students, the Faculty of Health and Medical Sciences reserve the right to cancel the course. However, if the course is sought after by students admitted at the Master's 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.

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

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