



Exam schedule for the Master of Medicines Regulatory Affairs (MRA)

Fall semester 2024 / Winter exam 24/25

2016 & 2018 Curriculum Master of Medicines Regulatory Affairs

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General rules for exam registration and deregistration (not master's project)

Course registration automatically registers to ordinary exam.

Deregistration deadline for exam is 14 days before the exam date.

Registration deadline for re-exam is 14 days before the re-exam date.

Email exam registration and deregistration to eksamen@sund.ku.dk.

Master's Project Exam: Rules for registration and deregistration

Registration for the master's project course is done through self-service.

Students register for the master's project exam by submitting a master's project agreement through the online form [\[LINK\]](#) before the specified deadline.

Students can deregister from the master's project exam up to 1 month before the project submission deadline and simultaneously register for a later exam date. Deregistration and registration must be done using this online form [\[LINK\]](#).

The EU Regulatory Environment

Course code: SMRM18002E (18-curr.) SMRMIF010E (16 curr.)

Ordinary exam	25 October, 2024 (10:00-13:00)
Grades, ordinary exam	15 November 2024 at 14:00
Re-exam	5 December 2024 (10:00-13:00)
Grades, re-exam	20 December 2024 at 14:00
Exam form	3-Hour Written Assignment
Exam venue	Digital Exam
External examiner	No
Grading scale	7-point grading scale
Exam responsible	Eva Maiken Holck eva.m.holck@gmail.com / emholck@nykode.com Mette Due Theilade Thomsen mt@pipadviser.com in collab. w/ Atrium

Quality - Drug Substance and Drug Product

Course code: SMRM18010U (16+18-STO)

Ordinary exam	4 November 2024 (10:00-13:00)
Grades, ordinary exam	25 November 2024 at 14:00
Re-exam	7 January 2025 (10:00-13:00)
Grades, re-exam	28 January 2025 at 14:00
Exam form	3-Hour Written Assignment
Exam venue	Digital Exam
External examiner	No
Grading scale	Passed/Not Passed

Ordinary exam	4 November 2024 (10:00-13:00)
Exam responsible	Karen Fich kfi@lundbeck.com Inger Mollerup imo@ingermollerup.com in collab. w/ Atrium

Labelling as a Driver for Regulatory Strategy

Course code: SMRM18008U

Ordinary exam	29 November 2024 at 14.00
Grades, ordinary exam	13 December 2024 at 14:00
Re-exam	15 January 2025 at 14.00
Grades, re-exam	29 January 2025 at 14:00
Exam form	Written Assignment
Exam venue	Digital Exam
External examiner	Yes
Grading scale	7-point grading scale
Exam responsible	Lene Jørgensen lene.jorgensen@sund.ku.dk Jesper Kihl jesper.kihl@sund.ku.dk

Drug Regulatory Science

Course code: SMRM18006E

Ordinary exam	18 December 2024 at 14.00
Grades, ordinary exam	6 January 2025 at 14:00
Re-exam	27 January 2025 at 14.00
Grades, re-exam	10 February 2025 at 14:00
Exam form	Written Assignment
Exam venue	Digital Exam
External examiner	No
Grading scale	7-point grading scale
Exam responsible	Christine Erikstrup Hallgreen christine.hallgreen@sund.ku.dk

Clinical Development and Documentation

Course code: SMRM18005E (16 + 18-curriculum)

Ordinary exam	2 December 2024 (10:00-14:00)
Grades, ordinary exam	9 January 2025 at 14:00
Re-exam	30 January 2025 (10:00-14:00)
Grades, re-exam	27 February 2025 at 14:00
Exam form	4-Hour Written Assignment
Exam venue	Digital Exam
External examiner	No
Grading scale	7-point grading scale
Exam responsible	Christina Rindshøj christina.rindshoej@live.dk / CBRindshoej@zealandpharma.com Jane Møll Pedersen / jamp@novonordisk.com in collab. w/ Atrium

Biopharmaceuticals – Quality Development and Documentation

Course code: SMRM18009E (16 + 18-curriculum)

Ordinary exam	6 January 2025 (10:00-13:00)
Grades, ordinary exam	27 January 2025 at 14:00
Re-exam	25 February 2025 (10:00-13:00)
Grades, re-exam	12 March 2025 at 14:00
Exam form	3-Hour Written Assignment
Exam venue	Digital Exam
External examiner	No
Grading scale	Passed/Not Passed
Exam responsible	Sandra P. Auguste-Bowler SXAP@novonordisk.com Heidi Smed Christensen hsc@genmab.com in collab. w/ Atrium

Master's Project

Course code: SMRMIFS01E

Ordinary exam	Start date: 1 September 2024 Master's project agreement deadline: 30 September 2024 Master's project hand in deadline: Wednesday, 18 December 2024 at 12 noon Oral Exam No later than 29 January 2025
Grades, ordinary exam	No later than 29 January 2025
Re-exam	Master's project hand in: 26 March 2025 at 12 noon Oral Exam No later than 7 May 2025
Grades, re-exam	No later than 7 May 2025
Exam form	Written Assignment (Master's project) with Oral Examination (1.5 hours)
Exam venue	Master's project hand-in: Digital Exam Oral Exam: Arranged and announced by the supervisor
External examiner	Yes
Grading scale	7 point grading scale
Exam responsible	Lene Jørgensen lene.jorgensen@sund.ku.dk

Approved at the Board of Studies for Professional Master Programmes 6 March 2024, with changes approved on 17.06. 2024.

Overview of examination periods for the Master's project

Examination period	Start date	Deadline: Master's project agreement	Deadline: Master's project	Oral Examination
Summer	February 1st	Last weekday in February	Week 22 - Wednesday 12 noon	No later than last weekday in June
Summer re-exam	February 1st	Last weekday in February	Week 39 Wednesday 12 noon	No later than Wednesday week 45
Winter	September 1st	Last weekday in September	Week 51 Wednesday 12 noon	No later than Wednesday week 5
Winter re-exam	September 1st	Last weekday in September	Week 13 Wednesday 12 noon	No later than Wednesday week 19

