



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

Date of publication: 01 May 2024

General rules for exam registration and withdrawal

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.

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
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

Ordinary exam	29 November 2024 at 14.00
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 / jane.moll.pedersen@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

Approved at the Board of Studies for Professional Master Programmes on 06-03-2024