



**Karolinska  
Institutet**

Course syllabus for

# **Regulatory Toxicity Testing, 10 credits**

Regulatorisk toxicitetstestning, 10 hp

This course syllabus is valid from autumn 2023.

Please note that the course syllabus is available in the following versions:

Autumn2019 , Autumn2020 , Autumn2023

Course code	4TX032
Course name	Regulatory Toxicity Testing
Credits	10 credits
Form of Education	Higher Education, study regulation 2007
Main field of study	Toxicology
Level	AV - Second cycle
Grading scale	Pass with distinction, Pass, Fail
Department	Institute of Environmental Medicine
Decided by	Utbildningsnämnden IMM
Decision date	2019-03-07
Revised by	Education committee IMM
Last revision	2023-03-06
Course syllabus valid from	Autumn 2023

## **Specific entry requirements**

At least the grade pass for all courses within the first year and for the course *Global toxicology in a sustainable society* within the second year of the Master's Programme in Toxicology.

## **Objectives**

The course aims at giving the student knowledge and skills in all parts of toxicity testing in vivo and the application of the 3Rs (Reduce, Refine, Replace animal testing).

After the course, the student shall be able to:

Regarding knowledge and understanding

- describe and explain all parts included in toxicity studies in vivo, from handling of laboratory animals, observations and analyses, to compilation and statistical analysis of data, and critical analysis and interpretation of results,
- describe the structure of and explain the importance of protocols (Standard Operating Procedures, SOP) for a toxicity testing in vivo in accordance with harmonized and validated international guidelines and Good Laboratory Practice (GLP).

### Regarding skills and ability

- critically and independently reflect on areas for application of the 3Rs in the area of toxicity testing,
- write a specific part, and contribute to the discussion, conclusion and finalization, of a report of a toxicity study according to standardized structure and style, as well as to international guidelines and GLP,

### Regarding judgement and approach

- reflect on the complexity of toxicology when interpreting results and drawing conclusions in toxicity studies of chemical substances,
- demonstrate a professional and ethical attitude to carrying out toxicity studies in vivo
- based on self-awareness and knowledge on group dynamics to reflect on one's own and others' behaviour and professionalism in group situations.

## Content

The course is divided into the following parts:

### **Toxicity testing, planning, performance and reporting, 6.0 hp**

Grading scale: GU

Planning of a toxicity study in rodents in accordance with Good Laboratory Practise (GLP), international guidelines for standardised testing of chemicals (e g OECD-guideline) and Standard Operating Procedures (SOP). Compilation and evaluation of results. Report writing.

### **Integration of toxicity testing, 4.0 hp**

Grading scale: VU

Integration of planning, performing, analysing and reporting a toxicity study in rodents according to GLP and international guidelines for standardised testing of chemical substances as well as according to present legislation regarding work with experimental animals.

## Teaching methods

Teaching will be in the form of lectures, problem-solving individually or in groups, seminars, group discussions and oral and written presentations.

## Examination

Toxicity testing, planning, performing and reporting (6 credits). The examination consists of written assignments. Graded Pass/Fail.

Integration of toxicity testing (4 credits). The examination consists of a written exam. Graded Pass with distinction/Pass/Fail.

The final grade of the whole course is based on the grade of the part Integration of toxicity testing.

If there are special grounds, or a need for adaptation for a student with a disability, the examiner may decide to deviate from the syllabus's regulations on the examination form, the number of examination opportunities, the possibility of supplementation or exemptions from the compulsory section/s of the course etc. Content and learning outcomes as well as the level of expected skills, knowledge and abilities may not be changed, removed or reduced.

**Compulsory participation**

All practical parts, group exercises including presentations, and some lectures (indicated in the schedule ) are compulsory. The examiner assesses if, and in that case how, absence can be compensated. Before the student has participated in all compulsory parts or compensated absence in accordance with the examiner's instructions, the student's results for respective part will not be registered. Absence from a compulsory activity may result in that the student cannot compensate the absence until the next time the course is given.

**Transitional provisions****Other directives**

The course language is English.

**Literature and other teaching aids****Recommended literature****Handbook of laboratory animal science : essential principles and practices.**

*Hau, Jann; Schapiro, Steven Jay*

Fourth edition : Boca Raton : CRC Press, 2021 - xvii, 994 pages

ISBN:9781138341807 LIBRIS-ID:q4fr6tw6n4jrkkkh

[Library search](#)

**Principles and methods of toxicology**

*Hayes, A. Wallace*

5. ed. : Philadelphia, Pa. : Taylor & Francis, 2008 - xxiii, 2270 s.

ISBN:0-8493-3778-X (ISBN 10) LIBRIS-ID:10593922

[Library search](#)

Hand-outs and reports.