



**Karolinska
Institutet**

Course syllabus for

Regulatory Toxicity Testing, 10 credits

Regulatorisk toxicitetstestning, 10 hp

This course syllabus is valid from autumn 2019.

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	Fail (U), pass (G) or pass with distinction (VG)
Department	Institute of Environmental Medicine
Decided by	Education committee IMM
Decision date	2019-03-07
Course syllabus valid from	Autumn 2019

Specific entry requirements

At least the grade pass on all courses within the first 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 course director 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 course director's instructions, the student's results for respective part will not be registered in LADOK.

Transitional provisions

After each course occasion there will be at least six occasions for the examination within a two-year period from the end of the course.

Other directives

The course language is English.

Course evaluation will be carried out in accordance with the guidelines established by the Board of Higher Education.

Oral evaluation in the form of course council meetings will be carried out during the course.

Literature and other teaching aids

Mandatory literature

Handbook of laboratory animal science. : Essential principles and practices

Hau, Jann; Schapiro, Steven Jay

3. ed. : Boca Raton : CRC Press, cop. 2011 - 723 s.

ISBN:978-1-4200-8455-9 (vol.1) LIBRIS-ID:12096142

[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.