Course syllabus for

Advanced bioanalysis, 7.5 credits

Avancerad bioanalys, 7.5 hp
This course syllabus is valid from spring 2025.
Please note that the course syllabus is available in the following versions:
Spring2024 , Spring2025

Course code	3BL007
Course name	Advanced bioanalysis
Credits	7.5 credits
Form of Education	Higher Education, study regulation 2007
Main field of study	Biomedical Laboratory Science
Level	AV - Second cycle
Grading scale	Pass with distinction, Pass, Fail
Department	Department of Laboratory Medicine
Decided by	Education committee LABMED
Decision date	2023-10-27
Revised by	Education committee LABMED
Last revision	2024-10-07
Course syllabus valid from	Spring 2025

Objectives

Goals

The purpose of the course is for the student to gain in-depth knowledge in the validation process for bioanalytical methods. The student should develop in-depth knowledge to analyze and compile data from validated methods and be able to document results.

Knowledge and understanding

- The student must demonstrate in-depth knowledge of chromatography and mass spectrometry methods and describe/explain the method principles and suggest different possible approaches to analyze biological samples.
- The student must define and explain in detail, the concepts included in bioanalytical validation.

Skills and abilities

- Apply a scientific understanding and be able to advocate the suitability for the choice of a method
- The student independently evaluates data from a method validation and critically interpret and analyze results

- The student can document validation in a professional context

Evaluation ability and approach

- The student must demonstrate the ability to consider "sustainable development goals" in the context of method selection

Content

Content

The course content is based on, and is a deepening of previous knowledge in biochemistry, analytical chemistry, clinical chemistry and pharmacology, learned during the undergraduate education as well as during the first courses on the master program, i.e. Quality assurance and quality development, Scientific methodology and statistics. The course is divided into three parts where the students acquire in-depth knowledge as follows.

- Bioanalytical theory and- method
- Method development with focus on validation and accreditation within bioanalysis
- Sustainable development in relation to method development and validation

Teaching methods

Forms of work

The course takes place remotely with the support of a web-based learning platform. Some scheduled days with seminars, presentations and examinations will be mandatory. The pedagogy will be based on student-centered and student-activated methods, both individually and in groups. Lectures will be given digitally and include interactive education. Interviews with professional laboratory staff will be performed. The students will work in groups with a project work and individually with a reflection log. The course includes reading, discussing, and criticizing course literature, scientific literature, and reports, e.g., guidelines for validation.

Examination

Examination

Method development and validation parts are examined with a written exam in a classroom submission of a written validation report. The report will also be presented orally and examined in a presentation of the project work. Sustainable development aspects are examined with a reflective assignment. VG is required on the written exam in order to get VG as final score of the course. For the other examined parts, G/U is used.

Students who do not pass a regular examination are entitled to re-sit the examination on five more occasions. If the student has failed six examinations/tests, no additional examination is given. Each occasion the student participates in the same test counts as an examination. Submission of a blank exam paper is regarded as an examination. In case a student is registered for an examination but does not attend, this is not regarded as an examination.

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.

The seminars, the presentations 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 course director´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

For a course that has been discontinued, undergone major changes, or where the reading list has been significantly changed, an additional exam (other than the regular exam) of the previous content or literature should be conducted for a period of one year from the date the change took place.

Other directives

The course is given in Swedish and English. Course material is in English. Course evaluation is carried out according to the guidelines established by the Committee for education at first level and advanced level.

Literature and other teaching aids

Recomended literature

Principles and practice of bioanalysis

Venn, Richard F.

2nd ed. : Boca Raton : CRC Press, 2008 - xiii, 326 p.

ISBN:9780849338571 LIBRIS-ID:11156685

Library search

ICH guideline M10 on bioanalytical method validation and study sample analysis

EMA/ICH, 2022

URL: Länk

Bioanalytical Method Validation Guidance for Industry

FDA, 2018

URL: Länk