

Bioanalytics in Drug Development (J000451)

Course size (nominal values; actual values may depend on programme)
 Credits 3.0 Study time 90 h Contact hrs 20.0 h

Course offerings and teaching methods in academic year 2018-2019

Offering	Language	Teaching Method	Hours
A (semester 2)	English	self-reliant study activities	1.25 h
		lecture	10.0 h
		group work	2.5 h
		seminar	1.25 h
		microteaching	2.5 h
		guided self-study	2.5 h

Lecturers in academic year 2018-2019

Stove, Christophe FW03 lecturer-in-charge

Offered in the following programmes in 2018-2019

Programme	crdts	offering
Master of Science in Drug Development	3	A

Teaching languages

English

Keywords

Bioanalysis, sample preparation, chromatography, validation, method development, mass spectrometry

Position of the course

This course thoroughly discusses the different steps that need to be tackled during the development, validation and implementation of bio-analytical methods that are being applied during the drug development process

Contents

This course gives a comparative overview of the currently most applied procedures in a modern bio-analytical laboratory, with discussion of the pros and cons of diverse technologies. The different steps of the method development process will be discussed, with -besides attention for the classical techniques- also discussion of 'alternative sampling and sample preparation strategies', in addition to the discussion of recent developments in chromatography and mass spectrometry. Special attention will go to method validation, with discussion using concrete examples, in the light of current guidelines from FDA or EMA. As a practical exercise, the student will critically discuss a scientific article that refers to these (or other) guidelines.

Initial competences

Having succeeded in education on instrumental analytical techniques, like the courses General Analytical Chemistry and Instrumental Analytical Chemistry, or having acquainted the competences of these courses in another way.

Final competences

- 1 Having knowledge of and insight into bio-analytical method development
- 2 Being able to apply the knowledge and insights on a diverse set of cases
- 3 Being able to critically assess bio-analytical methods, based upon international guidelines
- 4 Being able to point at the potential of newly developed bio-analytical strategies in the context of currently existing, routinely applied strategies
- 5 Being able to point out what the strengths and weaknesses are of different methodologies

Conditions for credit contract

Access to this course unit via a credit contract is determined after successful competences assessment

Conditions for exam contract

This course unit cannot be taken via an exam contract

Teaching methods

Guided self-study, group work, lecture, microteaching, seminar, self-reliant study activities

Extra information on the teaching methods

- Guided self study: the student is expected to critically read a published bioanalytical procedure, in light of what was taught during the courses. This implies both individual work, as group work.
- Microteaching: the student briefly presents to her/his fellow students the strengths/weaknesses of a published bioanalytical procedure that she/he critically read.
- Work college: guided exercises: using concrete examples, pitfalls in bioanalytical method development will be discussed in groups.

Learning materials and price

A course will be provided to the students. This will include the slides shown in the lessons, as well as scientific articles and international guidelines on method validation (all course material is in English).

Price: 6€

References

Course content-related study coaching

Students can ask questions at any time point, during or after the lessons or following appointment. Also via e-mail questions can be asked.

Evaluation methods

end-of-term evaluation and continuous assessment

Examination methods in case of periodic evaluation during the first examination period

Written examination with open questions, written examination with multiple choice questions

Examination methods in case of periodic evaluation during the second examination period

Written examination with open questions, written examination with multiple choice questions

Examination methods in case of permanent evaluation

Participation, peer assessment, report

Possibilities of retake in case of permanent evaluation

not applicable

Extra information on the examination methods

PE: 17

NPE: 3

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Calculation of the examination mark

PE: 85%

NPE: 15%