GHENT UNIVERSITY

Course Specifications

From the academic year 2015-2016 up to and including the

Biotechnology: Biosafety, GMP and Intellectual Property (C002381)

Course size (nominal values; actual values may depend on programme)

Credits 3.0	Study time 80 h	Contact hrs	25.0 h

Course offerings and teaching methods in academic year 2018-2019

A (semester 1)	English	lecture: plenary exercises	10.0 h
		lecture	15.0 h

Lecturers in academic year 2018-2019

Vanhalst, Koen	WE14	lecturer-in-charge
Rudelsheim, Patrick	WE09	co-lecturer

Offered in the following programmes in 2018-2019	crdts	offering
International Master of Science in Agro- and Environmental Nematology	3	A
Master of Science in Biochemistry and Biotechnology	3	A
Exchange programme in Biochemistry and Biotechnology (master's level)	3	A

Teaching languages

English

Keywords

Intellectual property, biosafety, GMP, clinical trials, bio-ethics, European directives

Position of the course

Acquisition of basic knowledge about the regulatory and ethical aspects in biotechnology. At the end of the course, students should be able to manage the basic regulatory and ethical aspects of a biotech project in the field of intellectual property, biosafety, GMP and clinical trials, and they should know where to find additional information.
This course contributes to the following program competencies: MA WE.BB.2.1, MA WE.BB.2.2, MA WE.BB.2.6, MA WE.BB.3.2, MA WE.BB.5.1, MA WE.BB.5.2, MA WE.BB.5.3, MA WE.BB.5.4

Contents

In the field of Intellectual property, intellectual property relevant to biotech is discussed, including patents, plant variety right, copyright, database right and trade- and service marks. A link is made to the relevant European directives. Differences between the European and US patent system are discussed, in view of their practical consequences. The students are thaught where and how to find patent information. In the field of Biosafety, the course starts with the basic principles as laid down in the OECD study, and elaborates on the European directives on contained use, deliberate release, novel foods, labeling, protection of workers at workplace and transport. Special attention is paid to the principles of risk assessment and ethical apsects. Good manufacturing practice starts again from the OECD study, and how it is translated in European directives and US regulations, stressing the practical consequences for the lab organisation. The importance of standard operating procedures in all fields is dicussed.
The basic principles of clinical studies are discussed

Initial competences

Knowledge of the fundamental biotechnological terms and techniques

Final competences

1 Ability to conduct a prior art search and to identify relevant patents in a given

research field.
2 Ability to make a risk assesment and an ethical analysis of a given research field.
3 Ability to determine which European directives are relevant to a given research field.
4 Application of basic knowledge of GMP and clinical trials to set up a GMP facility or to initiate clinical trials.

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

Lecture, lecture: plenary exercises

Learning materials and price

Copies of slides Cost: 15 EUR

References

Web sites: http://www.european-patent-office.org http://biosafety.ihe.be/HomePage.html European directives 98/44/EC (Biotech patenting); 96/9/EC (database protection); EC 2100/94 (PVR); 98/81/EC (contained use); 2001/18/EC (deliberate release); 258/97/EC (Novel foods); EC 50/2000, EC 1829/2003, EC 1830/2003 (labelling); 87/18/EEC, 88/320/EEC (GLP) OECD publication ENV/MC/CHEM(98)17

Course content-related study coaching

Interactive support via Minerva (discussion forum)
Personal guidance by appointment

Evaluation methods

end-of-term evaluation

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

Open book examination, oral examination

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

Open book examination, oral examination

Examination methods in case of permanent evaluation

Possibilities of retake in case of permanent evaluation

not applicable

Extra information on the examination methods

Oral examination with written preparation.

Calculation of the examination mark

Oral examination with written preparation: 100%