GHENT UNIVERSITY

Course Specifications

Valid in the academic year 2024-2025

Regulatory Affairs Life Cycle of Medicines (J000531)

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

Credits 3.0 **Study time 90 h**

Course offerings and teaching methods in academic year 2024-2025

A (semester 1)	English	Gent	seminar
			lecture
			independent work

Lecturers in academic year 2024-2025

Hertleer, Carla	FWO2	staff member
Wynendaele, Evelien	FWO2	lecturer-in-charge
De Spiegeleer, Bart	FWO2	co-lecturer

Offered in the following programmes in 2024-2025	**crdts**	**offering**
International Master of Science in Sustainable Drug Discovery	3	A
Exchange Programme Faculty of Pharmaceutical Sciences	3	A

Teaching languages

English

Keywords

regulatory affairs, life cycle medicines, health product classification, European and international pharmaceutical legislation, marketing authorisation application file, pre- and post-approval activities, discovery and manufacturing of pharmaceuticals

Position of the course

This course provides a broad multi-disciplinary overview of the complete life cycle of different health products, with emphasis on pharmaceuticals. This is important as medicines are generally spearheading other health products such as cosmetics. Moreover, those fields are getting closer to each other, such as companion diagnostics and medicines. Students are introduced into the required activities before as well as after the formal approval of medicines, mainly from an EU viewpoint. Theoretical principles are illustrated by exercises and case studies. Students are also asked to work out a specific contemporary problem concerning regulatory affairs, with emphasis on the role of drug discovery or manufacturing regulations in the life cycle of a medicine.

Contents

1) Life cycle regulatory affairs (RA)
• Importance and place of RA in the pharmaceutical industry
• Approval procedures
• Product classification, incl. ATMP gene/cell/tissue, medical devices, nutrients/functional food, cosmetics and IMP.
2) Content of registration dossier (file) for medicine
• Dossier requirements
• Quality data
• Non-clinical data (toxicology-pharmacology)
• Clinical data
3) Post-approval activities
• Variations
• Price and reimbursement
• Information and pharmaco-vigilance

Initial competences

Basic knowledge of fundamental physical, chemical and biological principles and processes.

Final competences

1 To critically and justifiably classify several health products.
2 To discuss different approval procedures for medicines.
3 To know the content and form requirements of an application file (marketing authorization file).
4 To apply some important regulatory-discovery or manufacturing aspects.
5 To define post-approval activities and responsibilities.
6 To know the specific RA language with its acronyms.
7 To understand the life cycle of a medicine.
8 To write a scientifically justified and critical report on an actual regulatory affairs problem.

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

Seminar, Lecture, Independent work

Study material

Type: Slides

Name: Slides
Indicative price: Free or paid by faculty
Optional: no
Available on Ufora : Yes

References

Is available in course material.

Course content-related study coaching

Guidance of students in working out a RA problem.

Assessment moments

end-of-term and continuous assessment

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

Written assessment

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

Written assessment

Examination methods in case of permanent assessment

Assignment

Possibilities of retake in case of permanent assessment

examination during the second examination period is possible in modified form

Calculation of the examination mark

The report is responsible for 20% of the course score.
The written examination at the end of the semester is responsible for the other 80% of the points.

Students who eschew period aligned and/or non-period aligned activities and evaluations for this course unit may be failed by the examiner.