

## 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	FW02	staff member
Wynendaele, Evelien	FW02	lecturer-in-charge
De Spiegeleer, Bart	FW02	co-lecturer

**Offered in the following programmes in 2024-2025**

	crdts	offering
<a href="#">International Master of Science in Sustainable Drug Discovery</a>	3	A
<a href="#">Exchange Programme Faculty of Pharmaceutical Sciences</a>	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.