GHENT UNIVERSITY

# Course Specifications

Valid as from the academic year 2024-2025

## Regulatory Affairs Health Products (J000445)

**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 (Year) | English | Gent | lecture |
| | | | independent work |
| | | | seminar |

**Lecturers in academic year 2024-2025**

| | | |
|---|---|---|
| Wynendaele, Evelien | FWO2 | lecturer-in-charge |
| De Spiegeleer, Bart | FWO2 | co-lecturer |

| Offered in the following programmes in 2024-2025 | crdts | offering |
|---|---|---|
| Master of Science in Teaching in Health Sciences(main subject Pharmaceutical Sciences) | 3 | A |
| Master of Science in Biomedical Sciences | 3 | A |
| Master of Science in Drug Development | 3 | A |
| Master of Science in Pharmaceutical Engineering | 3 | A |

**Teaching languages**

English

**Keywords**

Authorisations for several health products, regulatory affairs, european pharmaceutical legislation, application file, pre- and post-approval activities

**Position of the course**

This course is an introductory course, aiming to provide the students an overview of the actual requirements and challenges to bring and keep the several classes of health products, with emphasis on medicines, on the market.

**Contents**

This course consists of three major themes:
1) General frame of regulatory affairs (RA)
• Importance and place of RA in the pharmaceutical industry
• European structures and approval procedures
• Product classification, incl. ATMP gen/cell/tissue, medical devices, nutrients and functional foods, biocides and cosmetics
2) Content of registration dossier (file)
• 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 chemistry and biology.

**Final competences**

1 To critically and justifiably classify several health products.

2 To discuss the European approval procedures for medicines.
3 To know the content and form requirements of an application file (marketing authorization dossier).
4 To apply some important regulatory-developmental aspects independently.
5 To define post-approval activities and responsibilities.
6 To know the specific RA language with its acronyms.
7 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

**Extra information on the teaching methods**

During the seminars (guided exercises), problems are being discussed and solved. The individual task encompasses a short report of an actual regulatory affairs problem.

**Study material**

Type: Slides

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

**References**

In the course, reference to several sources is made (e.g. EMA website).

**Course content-related study coaching**

Possibility to ask questions during or after the lectures (oral or email).

**Assessment moments**

end-of-term assessment

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

Written assessment with open-ended questions, Assignment

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

Written assessment with open-ended questions, Assignment

**Examination methods in case of permanent assessment**

**Possibilities of retake in case of permanent assessment**

not applicable

**Calculation of the examination mark**

The individual report counts for 20% of the total points; the written examination for 80%. Submitting the report too late (unjustified) will lead to a total mark of maximum 5/20, irrespective of the score obtained for the written examination.