GHENT UNIVERSITY

Course Specifications

Valid in the academic year 2024-2025

Regulatory Affairs (J000465)

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

Credits 7.0 **Study time 210 h**

Course offerings and teaching methods in academic year 2024-2025

A (Year)	Dutch	Gent	lecture
			group work
			seminar

Lecturers in academic year 2024-2025

Wynendaele, Evelien	FWO2	lecturer-in-charge
De Spiegeleer, Bart	FWO2	co-lecturer
Dierickx, Ann	UA	co-lecturer
Hermans, Nina	UA	co-lecturer
Meeus, Geneviève	UA	co-lecturer
Teuns, Greet	UA	co-lecturer
Van Hemelrijck, An	VUB	co-lecturer

Offered in the following programmes in 2024-2025	**crdts**	**offering**
Master of Science in Industrial Pharmacy	7	A

Teaching languages

Dutch

Keywords

Pharmaceutical legislation, regulatory affairs, application dossier for the registration of medicines, quality assurance.

Position of the course

This course aims to familiarize the pharmacist with the administrative and legal aspects of the tasks of the industrial pharmacist: the relationship pharmaceutical industry-government, the relevant legislation on the matter, content summary of the registration files, quality assurance, ...

Contents

1. Legislation in the pharmaceutical industry (10 hours)
General overview of the pharmaceutical legislation, required to be able to function as a Qualified Person in Belgium.
Thorough reading of and comments on the Royal Decree 06.06.1960 "concerning the manufacture, wholesale distribution and the delivery of medicinal products."
Discussion of two important regulations:
a. information and advertising relating to medicinal products for human use
b. conditions under which physicians samples may be handed over
2. Regulatory affairs: international regulations and guidelines related to the various aspects of the pharmaceutical industry (10 hours)
Four aspects are discussed:
(1) EU product classification and procedures,
(2) CTD with emphasis on innovative regulatory affairs and new/draft guidelines,
(3) post-approval activities,
(4) price and reimbursement.

3. Regulatory affairs: composition of the registration dossier (17.5 hours, partly

under seminar form)
Important aspects and applications such as variations, impurities, non-clinical (preclinical) part of the registration dossier, phytochemical products, in vitro diagnostics, biomarkers and AI/data-science.
4. Management and quality assurance in the pharmaceutical industry (15 hours)
Quality assurance in the pharmaceutical industry

Initial competences

End competences of the Master in Pharmaceutical Care or the Master in Drug Development or the target competences were acquired in a different way.

Final competences

1 Knowledge of the regulations concerning the pharmaceutical industry.
2 Be aware of the administrative processing and compilation of national and European registration files.
3 Specialize in all aspects of quality assurance in the pharmaceutical industry.
4 Formulate a critical and informed opinion regarding a current registration discussion point.

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

Group work, Seminar, Lecture

Extra information on the teaching methods

Lectures where the students have the opportunity to ask questions in class. The teachers themselves involve the students in class when discussing the material (interactive).
Seminars where a specific theme is worked out.

Study material

Type: Slides

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

References

Special material, lecture notes excepted, is not necessary. The course text includes the contents of the courses and is adjusted each year with respect to the ever-changing regulations.

Course content-related study coaching

Opportunities for questions and discussions with the teachers during and after the lessons (individual or in group).

Assessment moments

end-of-term and continuous 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

Assignment

Possibilities of retake in case of permanent assessment

examination during the second examination period is not possible

Extra information on the examination methods

Written exam that assesses the impact on insights (regulatory affairs).
Open book exam (legislation).
Presentation of the group work (quality assurance).

Calculation of the examination mark

A student has passed the course if he/she has obtained at least 10/20. The student must achieve at least 8/20 for all parts to pass the course.
If the student achieves less than 8/20 for one or more parts, the final mark of the course is reduced automatically to the lowest figure obtained for this part.
If the student obtains at least 8/20 for all parts, the final result is calculated taking into account the weights of the different parts:
Legislation in the pharmaceutical industry (a)
Regulatory affairs (b)
Registration file topics (c)
Management and quality control in the pharmaceutical industry (d)
Score = [(a) + (b) + (c) + (d)] / 4