

## 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

FW02

lecturer-in-charge

De Spiegeleer, Bart

FW02

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**

[Master of Science in Industrial Pharmacy](#)

**crdts**

7

**offering**

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