

FARI2MC

2015 - 2016

Advanced Master in Industrial Pharmacy

At Bruxelles Woluwe - 60 credits - 1 year - Day schedule - In frenchDissertation/Graduation Project : **YES** - Internship : **YES**Activities in English: **YES** - Activities in other languages : **NO**Activities on other sites : **NO**Main study domain : **Sciences biomédicales et pharmaceutiques**Organized by: **Faculté de pharmacie et des sciences biomédicales (FASB)**Programme code: **fari2mc** - Francophone Certification Framework: 7**Table of contents**

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FARI2MC - Introduction

Introduction

FARI2MC - Teaching profile

Learning outcomes

The Advanced Master degree in Industrial Pharmacy gives the student all theoretical and practical knowledge to work in the following fields: production, drug quality control and analysis and in the drug approval process, marketing and pharmacovigilance.

This programme comprises theory and practical work in a field chosen by the student (pharmaceutical industry or other bodies or laboratories where the skills of a pharmacist are needed).

The Advanced Master degree in Industrial Pharmacy is the only way to obtain the title of Qualified person (law of the 14th December 2006 regarding drugs used in humans and animals, article 84). For the pharmacist or owners of a degree endowed with equivalent skills, to obtain this title recognized by the Ministry of Health, the Advanced Master degree must be completed by a 6 months experience in one or more pharmaceutical firm(s) owner of an authorization of drug production according to the rules comprised in the Royal decree of the 14th August 1989.

On successful completion of this programme, each student is able to :

1. To master and integrate relevant knowledge in all questions regarding the pharmaceutical industry

- 1.a to tackle, analyze and work with organic, inorganic, natural, biotechnologically produced substances and radiopharmaceuticals.
- 1.b to assess pharmacological data and pharmacokinetics related to biologically active compounds.
- 1.c to engineer a pharmaceutical form with the required physico-chemical characteristics.
- 1.d to collaborate in the realization of a clinical study.
- 1.e to understand intellectual property .
- 1.f to write a drug master file.
- 1.g to insure that rooms devoted to the production are in accordance with the cleanliness standards .
- 1.h to release a batch for the drug market.
- 1.i to solve problems linked to drug production.

2. Scientific approach

- 2.a To integrate and analyze with criticism different scientific approaches to the design, development, production and marketing of the product.
- 2.b To be able to plan scientific experiments, to draw statistically valid conclusions and, if necessary, to modify the plan to get the best results.

3. To communicate professionally and adapt the message to different people

- 3.a to be able to present scientific results.
- 3.b to communicate in English, the main language in scientific communication in the world.
- 3.c to deliver a message or clear and specific guidelines to be implemented within the framework of scientific and administrative work.

4. Sense of responsibility

- 4.a To assume responsibilities in accordance with ethics, laws and best practice.
- 4.b To stay abreast of new rules and laws issued by various national and international bodies in charge of health.
- 4.c To be able to manage and lead a group of people, to assign them tasks in the context of scientific and administrative work and checking if the guidelines or procedures have been properly applied.

5. To evaluate, to assess themselves, to update knowledge and continually improve their practice

5.a by training.

5.b by attending scientific conferences.

Programme structure

The duration of the studies and the training programme is one year, full-time. On the recommendation of the Industrial Pharmacist Management Committee, the study programme can be spread over two academic years, subject to the authorisation of the President of the School of Pharmacy in the case where the student is professionally active elsewhere or if his particular situation is considered to justify this.

The programme comprises **2 parts** :

- the first part is made up of a core syllabus organised by the three universities. This core syllabus is divided into 7 modules (A to G), each including theoretical sessions as well as seminars. The total timetable volume of this core syllabus amounts to 450 hours (45 ECTS), with each university taking in charge one third, or 150 hours of the programme.
- the second part consists of an individual piece of work that the student will prepare during the course of a 12 week training period of work experience carried out in one or several departments, either in one of the universities, or in a pharmaceutical industry proposed by the programme management committee, or yet again in the context of an inter-university SOCRATES/ERASMUS exchange scheme. The total timetable volume of this second part amounts to 150 hours (15 ECTS).

[> Core courses](#) [en-prog-2015-fari2mc-wfari200t.html]

FARI2MC Detailed programme

Programme by subject

CORE COURSES [60.0]

● Mandatory

△ Courses not taught during 2015-2016

⊕ Periodic courses taught during 2015-2016

⊗ Optional

⊙ Periodic courses not taught during 2015-2016

■ Activity with requisites

Click on the course title to see detailed informations (objectives, methods, evaluation...)

o Modules (45 credits)

o Substances actives (50h - 6 crédits) Coord. J. Leclercq - UCL

Ce module est composé des matières suivantes : Substances issues des recherches pharmacochimiques (10h, B. Pirotte ULg - 5h, F. Dufrasne ULB)/ Substances issues des biotechnologies (15h, D. Vermijlen ULB)/ Substances d'origine naturelle (5h, J. Leclercq UCL - 5h, P. Duez ULB)/ Produits radiopharmaceutiques (10h, G. Ghanem ULB). Les étudiants qui suivent ce module s'inscrivent pour cela au cours suivant :

● WFARI2100	Active molecules	Joëlle Leclercq, null SOMEBODY	50h	6 Credits	2q
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o Aspects cliniques (45h - 6 crédits) Coord. R. Denooz - ULg

Ce module est composé des matières suivantes : Métabolisme des médicaments et paramètres pharmacocinétiques (20h, F.-X. Mathy UCL)/ Aspects théoriques et pratiques des études cliniques (y compris les méthodes statistiques appliquées aux études cliniques) (15h, R. Radermecker ULg)/ Information et pharmacovigilance (10h, R. Denooz ULg). Les étudiants qui suivent ce module s'inscrivent pour cela au cours suivant :

● WFARI2101	Aspects cliniques	François-Xavier Mathy, null SOMEBODY	45h	6 Credits	1q
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o Assurance de qualité et management pharmaceutique (65h - 7 crédits) Coord. J. Scouvar - UCL

Ce module est composé des matières suivantes : Principes de management pharmaceutique (10h ULg)/ Assurance de qualité partim a (20h, J. Scouvar UCL)/ Assurance de qualité partim b (7.5h, X. Marcelis UCL)/ Anglais appliqué à l'industrie pharmaceutique (20h, N. Serbest et J. Poupaert UCL)/ Marketing Pharmaceutique (7.5h, V. Bierlaire ULg). Les étudiants qui suivent ce module s'inscrivent pour cela au cours suivant :

WFARI2102	Assurance de qualité et management pharmaceutique	Xavier Marcelis, Thierry Ponce, null SOMEBODY	65h	7 Credits	2q
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o Technologie pharmaceutique (70h - 8 crédits) Coord. J. Goole - ULB

Ce module est composé des matières suivantes : Microbiologie pharmaceutique industrielle (15h, V. Fontaine ULB)/ Préformulation et sélection des formes galéniques (15h, J. Goole ULB)/ Production industrielle des formes galéniques (15h, B. Evrard ULg)/ Production industrielle des biomolécules (15h, R. Vanbever et Ph. Levêque UCL)/ Aspect industriel du développement technologique y compris le conditionnement (10h, L. Denis ULg). Les étudiants qui suivent ce module s'inscrivent au cours:

WFARI2103	Technologie pharmaceutique	null SOMEBODY, Rita Vanbever (coord.)	70h	8 Credits	2q
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o Analyse des médicaments (65h - 7 crédits) Coord. Ph. Hubert - ULg et P. Van Antwerpen - ULB

Pratique des méthodes d'analyse et de contrôle pharma. et biopharma. (partim a 10h, J.-M. Kauffmann et P. Van Antwerpen ULB - partim b 10h, M. Fillet ULg)/ Validation des méthodes d'analyse pharma. et biopharma., qualification de l'appareillage (15h, Ph. Hubert et R. Marini ULg) et prépa. des échantillons pharma. (Process analytical technology 5h, Ph. Hubert et E. Ziemons ULg)/ Méthodes stat. appliquées à l'industrie pharma. (15h, B. Govaerts UCL)/ Planification expéri. (10h, B. Boulanger ULg)

WFARI2104	Analyse des médicaments	Laure Elens, null SOMEBODY	65h	7 Credits	2q
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o Affaires réglementaires et environnement médico-social (80h - 8 crédits) Coord. C. Druet - UCL et F. Dufrasne - ULB

Aspects écon. du développement du médicament (10h, D. Martin ULg)/ Législation pharma. en rapport avec l'industrie (15h, C. Druet UCL - 5h, P. Di Stephano ULB)/ Environnement macro-écon. et pharmaco-économie (10h, A. De Wever ULB)/ Dossier "Common Technical Document" (15h, J. A. De Muylder ULB)/ Réglementations des études précliniques et cliniques (7.5h S. Beken, 5h A. Lenaers, 2.5h D. Basseur ULB)/ Aspects réglementaires particuliers (5h, M. Tits ULg - 5h, F. Vanderbist ULB)

WFARI2105	Affaires réglementaires et environnement médico-social	Catherine Druet, null SOMEBODY	80h	8 Credits	1q
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o Visites et séminaires organisés dans les industries pharmaceutiques (75h - 3 crédits) Coord. F. Dufrasne - R. Vanbever - M. Fillet

Ce module est composé des matières suivantes : Séminaires d'immersion en milieu industriel pharmaceutique (20h UCL - 25h ULB- 30h ULg). Les étudiants qui suivent ce module s'inscrivent pour cela au cours suivant :

WFARI2106	Visites et séminaires organisés dans les industries pharmaceutiques	null SOMEBODY, Rita Vanbever	75h	3 Credits	2q
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o Travail de fin d'études réalisé dans le cadre d'un stage dans l'industrie pharmaceutique - Coord. R. Vanbever - UCL (15 crédits)

WFARI2109	Mémoire (dans le cadre d'un stage de 12 semaines)	N.		15 Credits	
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The programme's courses and learning outcomes

For each UCL training programme, a [reference framework of learning outcomes](#) specifies the competences expected of every graduate on completion of the programme. You can see the contribution of each teaching unit to the programme's reference framework of learning outcomes in the document "In which teaching units are the competences and learning outcomes in the programme's reference framework developed and mastered by the student?"

The document is available by clicking [this link](#) after being authenticated with UCL account.

FARI2MC - Information

Admission

Decree of March 31st 2004 defining higher education, favoring its integration in the European framework of higher education and refinancing universities.

The admission requirements have to be met at the time of enrolment at the university.

All information can be obtained from the [University's Enrolment Office \(Service des inscriptions – SIC\)](#).

The following students, after meeting the conditions set by the academic authorities, have access to the complementary Master's degree with the aim of obtaining the grade that these studies sanction:

- An academic Master's degree within the same field allowing 2nd-cycle studies, including at least 120 credits
- An academic Master's degree, following a decision by the academic authorities, under the complementary conditions that they set and as a result of a motivated decision by the jury
- An academic grade which is similar to those mentioned above, issued by the Flemish Community, the German Community or the Royal Military Academy, under the same conditions
- A foreign academic grade that has been acknowledged as being equivalent to those mentioned above, in application of this decree, a European-level directive or an international convention, under the same conditions
- Under the same conditions, one or several titles or academic grade issued by the Flemish Community, the German Community or the Royal Military Academy, sanctioning 2nd-cycle studies and valued at least 300 credits by the jury, or sanctioning 2nd-cycle studies and valued at least 240 credits completed of 60 credits, the all that must be valued by the jury according to the decree of March 31st, 2004 (art 54, 5 °)

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In the event of the divergence between the different linguistic versions of the present conditions, the French version shall prevail

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Specific Admission Requirements

This programme is accessible to pharmacists holding a diploma from the French-speaking Community in Belgium or a recognised equivalent.

Admission procedure

Enrolments are made at the university chosen by the student who pays the corresponding fee in the institution of his choice. The degree is awarded by this same institution. Applications for admission should be addressed to the secretary's office of the School of Pharmacy, by means of a special form issued by the latter. Applications are examined by the Admission Committee for complementary masters (3rd cycle) and then by the Programme Management Committee. Notice of refusal is given to the applicant by the academic secretary.

Teaching method

The lessons are divided into modules.

The methods used are both theoretical and practical.

Students will attend lectures given by teachers from the partner universities as well as professionals from the pharmaceutical industry or the Federal Public Service of Public Health. Mandatory related activities are organized: visits to companies or laboratories and exercises.

Students will complete an internship in a company, laboratory or a public body whose activities are related to drugs and legislation. It will prepare a report on the activities carried out during the course. This report will be presented to a jury composed of three scientists from each of the partner universities.

Evaluation

The evaluation methods comply with the [regulations concerning studies and exams](#). More detailed explanation of the modalities specific to each learning unit are available on their description sheets under the heading "Learning outcomes evaluation method".

Student evaluation on the inter-university programme content will consist of a single oral session of exams per module (from A to F, described above).

An oral defence of the individual piece of work will also be organised and evaluated by an inter-university jury. In order to obtain official recognition by the Ministry of Public Health for the title "person responsible for the conformity of medication products by a pharmaceutical firm", the pharmacist who has obtained his inter-university degree as an industrial pharmacist is obliged to do a 6 months complementary apprenticeship in a pharmaceutical firm in accordance with the procedures laid down by the Royal Decree of 14 August, 1989.

Contacts

Curriculum Management

Entite de la structure FASB

Acronyme	FASB
Dénomination	Faculté de pharmacie et des sciences biomédicales
Adresse	Avenue Mounier 73 bte B1.73.02 1200 Woluwe-Saint-Lambert
Secteur	Secteur des sciences de la santé (SSS)
Faculté	Faculté de pharmacie et des sciences biomédicales (FASB)
Mandats	Joëlle Leclercq Doyen
Commissions de programme	Ecole de pharmacie (FARM) Ecole des sciences biomédicales (SBIM)

Responsable académique UCL : [Guillaume Arnould](#)

Responsable académique UCL : [Joëlle Leclercq](#)

Jury:

Secrétaire de jury d'examen : [François Dufasne](#) (Tel: 02/650.52.35)

Président de jury d'examen : [Jean-Michel Kauffman](#) (Tel: 02/650.52.15)

Usefull Contacts

