

FARI2MC

2014 - 2015

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**Organized by: **Faculté de pharmacie et des sciences biomédicales (FASB)**Programme code: **fari2mc** - European Qualifications Framework (EQF): 7**Table of contents**

Introduction	2
Teaching profile	3
- Learning outcomes	3
- Programme structure	3
- Detailed programme	3
- Programme by subject	3
Information	5
- Admission	5
- Evaluation	6
- Contacts	6

FARI2MC - Introduction

Introduction

FARI2MC - Teaching profile

Learning outcomes

The training programme in Industrial Pharmacy prepares the students in the practice of responsibilities linked to the production, control and analysis of medicaments, as well as in the registration, marketing and the pharmacovigilance of these same medicaments.

This programme offers the possibility for the student to complete the theoretical sessions with practical experience in a sector of the student's choice. The complementary master's in Industrial Pharmacy is the direction chosen by those who wish to acquire the qualified status of a pharmacist (pharmacist responsible for the conformity of the medicaments produced by a pharmaceutical firm - Royal Decree of 06 June, 1960) by completing a university training programme. In order to obtain this official recognition by the Ministry of Public Health, the degree course must be completed by a period of practical experience of 6 months in one or several pharmaceutical firms granted official authorisation for the industrial fabrication of medicaments in accordance with the directives laid down by the Royal Decree of 14th August, 1989.

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-2014-fari2mc-wfari200t.html]

FARI2MC Detailed programme

Programme by subject

CORE COURSES [60.0]

● Mandatory

△ Courses not taught during 2014-2015

⊕ Periodic courses taught during 2014-2015

⊗ Optional

⊙ Periodic courses not taught during 2014-2015

‡ Two years course

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

● Modules (45 credits)

● 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
-------------	------------------	-----------------------------------	-----	-----------	----

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
-----------	-------------------	---	-----	-----------	----

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, Jacques Poupaert, Jean Scouvar (coord.), Nevin Serbest, null SOMEBODY	65h	7 Credits	2q
-----------	---	--	-----	-----------	----

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
-----------	----------------------------	--	-----	-----------	----

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	Bernadette Govaerts, Pierre Lebrun, null SOMEBODY	65h	7 Credits	2q
-----------	-------------------------	---	-----	-----------	----

o Affaires réglementaires et environnement médico-social (80h - 8 crédits) Coord. C. Druetz - UCL et F. Dufrasne - ULB

Aspects écon. du développement du médicament (10h, D. Martin ULg)/ Législation pharma. en rapport avec l'industrie (15h, C. Druetz 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. Brasseur ULB)/ Aspects réglementaires particuliers (5h, M. Tits ULg - 5h, F. Vanderbist ULB)

WFARI2105	Affaires réglementaires et environnement médico-social	Catherine Druetz, null SOMEBODY	80h	8 Credits	1q
-----------	--	------------------------------------	-----	-----------	----

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
-----------	---	---------------------------------	-----	-----------	----

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	
-----------	---	----	--	------------	--

FARI2MC - Information

Admission

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

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.

The mentioned information may of modification for 2014-2015

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 °)

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

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.

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	Emmanuel Hermans Doyen
Commissions de programme	Ecole de pharmacie (FARM) Ecole des sciences biomédicales (SBIM)

Responsable académique UCL : **Rita Vanbever**

Jury

Secrétaire du jury d'examens : **François Dufrasne**

Président de jury : #mailto:Jean-Michel (ULB) Kauffmann:jmkauf@ulb.ac.be# (Tel: 0032 2 650 5215)

Secrétaire du jury : #mailto:François (ULB) Dufrasne:dufrasne@ulb.ac.be# (Tel: 0032 2 650 52 35)

Usefull Contacts

Secrétariat du programme : **Murielle Callier**

