Information

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Presentation

The complementary Masters in Industrial Pharmacy is the route taken by those wishing to acquire the status of a qualified person (A.R. 14 December 2006 relating to Drugs for Human and Veterinary Use, article 84). To obtain this official recognition from the Minister for Public Health, the degree must be completed, for those holding a pharmacy degree or a degree with equivalent competences (See. Particular conditions), with 6 months of practical experience in one or more pharmaceutical companies which hold authorisation for the industrial manufacture of drugs according to the conditions set out in A.R. of 14 August 1989.
The complementary Masters in Industrial Pharmacy prepares students for standard tasks in drug manufacture and analysis. The programme also integrates courses in contemporary areas such as biotechnology, regulations, quality assurance, economic aspects of drugs, and clinical trials.
An inter-university programme involving the ULB, UCL and ULg was created to this end in 1997.

Particular requierements

A qualified person is someone who is legally responsible for the pharmaceutical activities of a permit holder; they must be registered on an up-to-date list. Request for registration on this list, accompanied by the required supporting documentation, must be addressed to the Minister.
Only those holding the legal degree of Industrial Pharmacist or the complementary Masters in Industrial Pharmacy, obtained in line with the legislation on the awarding of academic grades and the University exam programme, or those who are legally exempt, can be registered as qualified persons (without additional requirements).
Holders of a degree in pharmacy, medicine, veterinary medicine, chemistry, biology or biomedical sciences may also be approved as qualified persons, provided they demonstrate having a theoretical and practical academic level for at least the following basic subjects :

* Experimental physics ;
* General and inorganic chemistry ;
* Organic chemistry ;
* Analytical chemistry ;
* Pharmaceutical chemistry, including drug analysis ;
* General and applied biochemistry (medical) ;
* Physiology ;
* Microbiology ;
* Pharmacology ;
* Pharmaceutical technology ;
* Toxicology ;
* Pharmacognosy

For further information about the basic contents, see the programme of the Bachelor in Pharmaceutical sciences : http://progcours.ulg.ac.be/cocoon/programmes/MBPHAR01.html and the Master in Pharmaceutical sciences : http://progcours.ulg.ac.be/cocoon/programmes/TUR_MMPHARMA.html.
In addition, these persons have to proove that they are qualified and that they have taken theoretical and practical courses of an academic level about the following subjects :

* In-depth knowledge in anlysis of quality control,
* In-depth knowledge in pharmaceutical biotechnology,
* In-depth knowledge in pharmaceutical technology, including validation and GMP standards,
* Specific knowledge in legislation applicable to pharmaceutical industry,
* In-depth knowledge of the grant conditions of the Regulation of therapeutic goods.

These courses are taught in the Advanced Master in Industrial Pharmacy.

Official recognition by the Department of Public Health in Belgium

* Citizens of another State of the European Union who hold an equivalent degree may also be recognized on the same criteria.

* The applicant of approval has to prove that he/she has acquired a practical experience of at least two years full time in one or several companies located in Belgium who are holders of an authorization to manufacture drugs. The experience acquired in a company established in another Member State may also be taken into account.
* This experience must focus on the qualitative analysis of drugs, the quantitative analysis of active substances, the manufacturing of controls "in process". Its duration can be reduced by one year when the university course lasts for at least five years and by one year and a half when the training cycle lasts at least six years, that is to say, after the Advanced Master in Industry Pharmacy.
* The practice experience mus be certified by the person responsible for the placement.

Duration

* One year of study, with the possibility of spreading the programme over two years after a recommendation supplied by the Jury of the host university.

Collegiality

Coordinator : Philippe HUBERT
For the 'ULg : Vincent BIERLAIRE, Bruno BOULANGER, Raphaël DENOOZ, Dominique MARTIN, Laurence DENIS, Brigitte EVRARD, Marianne FILLET, Bernard PIROTTE, Eric ROZET, André SCHEEN, Monique TITS, Jean-Michel VANDERHOFSTADT, Eric ZIEMONS.
Pour l'ULB : Karim AMIGHI, Sonja BEKEN, Daniel BRASSEUR, Jean-Paul DEHAYE, Jean-Antoine DE MUYLDER, Patrick DI STEFANO, Pierre DUEZ, François DUFRASNES, Véronique FONTAINE, Ghanem GHANEM, Bernadette GOVAERTS, Jean-Michel KAUFFMAN, A. LENAERS, Pierre VAN ANTWERPEN, Francis VANDERBIST.
For the UCL : Catherine DRUEZ, Jean GILLARD, Didier LAMBERT, Xavier MARCELIS, Joëlle QUETIN-LECLERCQ, Nevin SERBEST, Jean SCOUVART, Roger VERBEECK, N...

A single year

Compulsory courses

PHIN2004-1	*Active substances*				**6**
	- *Substances issues de recherches pharmacochimiques, part a* - Bernard PIROTTE	10	-	-	
	- *Substances issues de recherches pharmacochimiques, part b* - Françoise DUFRASNE	5	-	-	
	- *Substances issues des biotechnologies* - JeanPaul DEHAYE	15	-	-	
	- *Substances d'origine naturelle, part a* - Joëlle QUETINLECLERCQ	5	-	-	
	- *Substances d'origine naturelle, part b* - Pierre DUEZ	5	-	-	
	- *Produits radiopharmaceutiques* - Ghanem GHANEM	10	-	-	
PHIN2008-2	*Clinical viewpoints*				**6**
	- *Métabolisme des médicaments et paramètres pharmacocinétiques* - Roger VERBEEK	20	-	-	
	- *Aspects théoriques et pratiques des études cliniques (y compris les méthodes statistiques appliquées aux études cliniques)* - André SCHEEN	15	-	-	
	- *Information et pharmacovigilance* - Raphaël DENOOZ	10	-	-	
PHIN2013-2	*Quality assurance and pharmaceutical management*				**7**
	- *Principles of pharmaceutical management* - JeanMichel VAN DER HOFSTADT	10	-	-	
	- *Quality assurance, part a : basic concepts and quality assurance organisation* - Jean SCOUVART	20	-	-	
	- *Quality assurance, part b : Analytical technology of procedures and risk analysis* - Xavier MARCELIS	7,5	-	-	
	- *English applied to the pharmaceutical industry* - Didier LAMBERT, Nevin SERBEST	20	-	-	
	- *Pharmaceutical marketing* - Vincent BIERLAIRE	7,5	-	-	
PHIN2022-1	*Industrial pharmaceutical technology*				**8**
	- *Microbiologie pharmaceutique industrielle* - Véronique FONTAINE	15	-	-	
	- *Préformulation et sélection des formes galéniques* - Karim AMIGHI	15	-	-	
	- *Production industrielle des formes galéniques* - Brigitte EVRARD	15	-	-	
	- *Génie pharmaceutique* - Jean GILLARD	15	-	-	
	- *Aspects industriels du développement technologique y compris le conditionnement* - Laurence DENIS	10	-	-	
PHIN2023-1	*Drug analysis*				**7**
	- *Analytical methods and pharmaceutical and biopharmaceutical control, part a* - JeanMichel KAUFFMAN, Pierre VAN ANTWERPEN	10	-	-	
	- *Analytical methods and pharmaceutical and biopharmaceutical control, part b* - Marianne FILLET	10	-	-	
	- *Methods in pharmaceutical and biopharmaceutical analysis, part a : Validation and*	15	-	-	

	qualification of equipment - Philippe HUBERT, Eric ROZET				
	- Methods in pharmaceutical and biopharmaceutical analysis, part b : Process analytical technology - Philippe HUBERT, Eric ZIEMONS	5	-	-	
	- Statistical methods applied to the pharmaceutical industry - Bernadette GOVAERTS	15	-	-	
	- Experimental planning and "quality by design" - Bruno BOULANGER	10	-	-	
PHIN2029-2	*Regulation and the medical-social environment*				**8**
	- Economic aspects of drug development - Dominique MARTIN	10	-	-	
	- Legislation and procedures applied to pharmaceutical industry, part a : legislation - Catherine DRUEZ	10	5	-	
	- Legislation and procedures applied to pharmaceutical industry, part b : patents and protection - Patrick DI STEFANO	5	-	-	
	- Macroeconomic environment and pharmaco-economics - Pierre DUEZ	10	-	-	
	- CTD File (Common Technical Document) - JeanAntoine DE MUYLDER	15	-	-	
	- Regulations of preclinical and clinical studies, part a : pharmaceutical toxicological files - Sonia BEKEN	15	-	-	
	- Regulations of preclinical and clinical studies, part b : clinical studies - A LENAERS	5	-	-	
	- Regulations of preclinical and clinical studies, part c : pediatric studies - Daniel BRASSEUR	2,5	-	-	
	- Specific regulatory issues, part a : medicine and herbal dietary supplement - Monique TITS	5	-	-	
	- Specific regulatory issues, part b : Preformulation and galenical development documentation - Francis VANDERBIST	5	-	-	
PHIN2032-1	*Visits and seminars organised in the pharmaceutical industry* - COLLÉGIALITÉ - [77,5h Vis.]	-	-	[+]	**3**
MTFE2000-1	*Final work* - COLLÉGIALITÉ	-	-	-	**15**