UCLouvain

wfarm2104

2020

GOOD MANUFACTURING AND QUALITY

Due to the COVID-19 crisis, the information below is subject to change, in particular that concerning the teaching mode (presential, distance or in a comodal or hybrid format).

3 credits	30.0 h + 15.0 h	Q2

Teacher(s)	Leclercq Joëlle (coordinator) ;Pronce Thierry ;Préat Véronique ;
Language :	French
Place of the course	Bruxelles Woluwe
Main themes	The course will cover the basic principles of Pharmaceutical Quality Assurance as well as the standards and legislation applicable to laboratory work in the pharmaceutical industry (R&D, clinical development and quality control).
Aims	1. Understand the different standards applicable to laboratory activities in the pharmaceutical industry 2. Understand and apply the essential elements (staff training, documentation, life cycle of an analytical method, equipment management, reference standards and critical reagents and sampling) 1 3. Organize your work in a quality assurance system 4. Write the necessary procedures for its maintenance. 5. Know how to establish the specifications of a drug 6. Know how to establish and interpret a control chart - - - - *The contribution of this Teaching Unit to the development and command of the skills and learning outcomes of the programme(s) can be accessed at the end of this sheet, in the section entitled "Programmes/courses offering this Teaching Unit".*
Evaluation methods	**Due to the COVID-19 crisis, the information in this section is particularly likely to change.** Students will be evaluated on their ability to Understand the philosophy of Good Laboratory Practice and Pharmaceutical Quality Assurance, write one or more simple procedures (personal work) know how to establish the specification of a drug be able to evaluate the performance criteria of an analytical method Establish and interpret a control chart The exam will be written (face-to-face or distance).
Teaching methods	**Due to the COVID-19 crisis, the information in this section is particularly likely to change.** theoretical courses (if sanitary measures allow it), exercices and practical applications, visit of laboratories/ industries
Content	Students will receive theoretical training - on good laboratory practices and the implementation of a pharmaceutical quality assurance system. They will visit pharmaceutical industries. - on good laboratory practices and the implementation of a quality assurance system. They will visit laboratories (research and pharmaceutical industry) working in quality assurance and will receive practical training in the form of discussions and seminars.
Other infos	Prequisite : pharmaceutical technology, analytical chemistry and instrumental Evaluation will be done on their aptitude to understand philosophy of GMP, GLP and quality assurance and to write simple procedure(s).
Faculty or entity in charge	FARM

Programmes containing this learning unit (UE)

Program title	Acronym	Credits	Prerequisite	Aims
Master [120] in Biomedicine	SBIM2M	3		
Master [60] in Biomedicine	SBIM2M1	3		
Master [120] in Pharmacy	FARM2M	3		