



3.00 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).
Learning outcomes	<p>At the end of this learning unit, the student is able to :</p> <p>1 Students should have the knowledge to organise their work in a quality assurance system and write procedures in relation with it.</p>
Evaluation methods	<p>Students will be evaluated on their ability to</p> <p>Understand the philosophy of Good Laboratory Practice and Pharmaceutical Quality Assurance,</p> <p>write one or more simple procedures (personal work)</p> <p>know how to establish the specification of a drug</p> <p>be able to evaluate the performance criteria of an analytical method</p> <p>Establish and interpret a control chart</p> <p>The exam will be written (face-to-face or distance).</p>
Teaching methods	theoretical courses (if sanitary measures allow it), exercices and practical applications, visit of laboratories/ industries
Content	<p>Students will receive theoretical training</p> <ul style="list-style-type: none"> - 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. <p>They will visit laboratories (research and pharmaceutical industry) working in quality assurance and will receive practical training in the form of discussions and seminars.</p>
Other infos	Prerequisite : 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	Learning outcomes
Master [60] in Biomedicine	SBIM2M1	3		
Master [120] in Pharmacy	FARM2M	3		
Master [120] in Biomedicine	SBIM2M	3		