


This learning unit is not open to incoming exchange students!

Teacher(s)	. SOMEBODY ;Marcelis Xavier (coordinator) ;Pronce Thierry ;
Language :	French
Place of the course	Bruxelles Woluwe
Prerequisites	The student will have learned some fundamentals supporting the activities of the pharmaceutical industry and how it is regulated by imposed requirements.
Main themes	<p>Quality and Quality Assurance requirements are defined for each and every level they appear in pharmaceutical industry, i.e. for rooms and environment classification, equipment and machines, products (intermediate raw materials and finished products), documentation (including procedures, methods, processes descriptions, raw data) and working staff (organisation, responsibilities, job description). There are many situational and practical examples available to illustrate the content.</p> <p>Thèmes abordés :</p> <p>Principes de management pharmaceutique VANDERHOFSTADT Jean-Michel (10h)</p> <p>Assurance qualité, partim a: Concepts de base et organisation de l'assurance qualité PRONCE Thierry (20h)</p> <p>Assurance qualité, partim b : Approche de Qualification et de Validation and Analyse de risques MARCELIS Xavier (7.5 h)</p> <p>Anglais appliqué à l'industrie pharmaceutique -POUPAERT Jacques, SERBEST Nevin (20h)</p> <p>Marketing pharmaceutique BIERLAIRE Vincent (7.5h)</p>
Learning outcomes	<p>At the end of this learning unit, the student is able to :</p> <ul style="list-style-type: none"> · Define fundamentals of Quality, total Quality Management, Good Manufacturing Practices · Introduce the student to the goals and concept behind Quality Assurance and Quality Control in the pharmaceutical industry. <p>1</p> <ul style="list-style-type: none"> · Define the scope of Quality Assurance and establish the « compliance » criteria according to the regulatory requirements. · To introduce the student to the concepts of plant and equipment qualification, process validation and risk analysis used in the pharmaceutical industry.
Evaluation methods	<p>The module examination could be placed outside the official June session.</p> <p>The examination will be conducted orally within the module to which the course is attached.</p> <p>The possibility of a written examination may also be considered. Students will be informed in due course.</p>
Teaching methods	Teaching is based on PowerPoint slides covering the points covered, as well as practical exercises. A copy of these documents is available free of charge on the Moodle platform (not compulsory), and certain documents can be given to the student.
Content	<p>Part A</p> <p>Introduction to Quality systems in general terms and their specific application into the pharmaceutical field.</p> <p>Quality Assurance - Quality Control definitions.</p> <p>Quality Assurance organisation.</p> <p>Quality Assurance philosophy.</p> <p>Quality Assurance pillars with their implication to different levels.</p> <ul style="list-style-type: none"> -personnel -material -equipment -processes -documentation <p>Internal ' External audit preparation.</p> <p>Suitable behaviour during an audit.</p> <p>Part B</p> <p>Presentation of the approaches to qualification of installations and equipment and validation of processes.</p>

	Presentation of the concept of "Risk Management" with practical examples.
Faculty or entity in charge	FARM

Programmes containing this learning unit (UE)				
Program title	Acronym	Credits	Prerequisite	Learning outcomes
Advanced Master in Industrial Pharmacy	FARI2MC	7		