UCLouvain

wfari2102

2022

Assurance de qualité et management pharmaceutique

7.00 credits	65.5 h	Q1 and Q2

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	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. Thèmes abordés : Principes de management pharmaceutique VANDERHOFSTADT Jean-MicheI (10h) Assurance qualité, partim a: Concepts de base et organisation de l'assurance qualité PRONCE Thierry (20h) Assurance qualité, partim b : Approche de Qualification et de Validation and Analyse de risques MARCELIS Xavier (7.5 h) Anglais appliqué à l'industrie pharmaceutique -POUPAERT Jacques, SERBEST Nevin (20h) Marketing pharmaceutique BIERLAIRE Vincent (7.5h)
Learning outcomes	**At the end of this learning unit, the student is able to :** 1 · 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. · 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	The examination will be orally conducted within the course module
Teaching methods	The learning will be provided through slides (PowerPoint) and practical exercises. A copy of those documents will be delivered to the student.
Content	Part A Introduction to Quality systems in general terms and their specific application into the pharmaceutical field. Quality Assurance - Quality Control definitions. Quality Assurance organisation. Quality Assurance philosophy. Quality Assurance pillars with their implication to different levels. -personnel -material -equipment -processes -documentation Internal ' External audit preparation. Suitable behaviour during an audit. Part B Presentation of the approaches to qualification of installations and equipment and validation of processes. Presentation of the concept of "Risk Management" with practical examples.

Other infos	The learning will be provided through slides (PowerPoint) and pratical exercices. A copy of those documents wil be delivered to the student.
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		