WFARI2102

2013-2014

Assurance de qualité et management pharmaceutique

8.0 credits	72.5 h

Teacher(s) :	Marcelis Xavier ; Scouvart Jean (coordinator) ;
Language :	Français
Place of the course	Bruxelles Woluwe
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.
Aims :	· 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. · Introduce the notions of "Process Analytical Technology" (PAT) and "Risk Management" in the frame of the FDA initiative called "Pharmaceutical CGMP's for the 21st Century". *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 :	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 Installations and equipment qualification. Internal ' External audit preparation. Suitable behaviour during an audit. Part B Process validation. Presentation of the 'Process Analytical Technology' (PAT) concept and of the 'Risk Management' approach with practical examples
Other infos :	The student will have learned some fundamentals supporting the activities of the pharmaceutical industry and how it is regulated by imposed requirements.
Cycle and year of study :	> Advanced Master in Industrial Pharmacy
Faculty or entity in charge:	FARM