

In view of the health context linked to the spread of the coronavirus, the methods of organisation and evaluation of the learning units could be adapted in different situations; these possible new methods have been - or will be - communicated by the teachers to the students.

7 credits	65.0 h	Q2
-----------	--------	----

Teacher(s)	Marcelis Xavier ;Pronce Thierry (coordinator) ;SOMEBODY ;
Language :	French
Place of the course	Bruxelles Woluwe
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 et 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>
Aims	<ul style="list-style-type: none"> <li>· Define fundamentals of Quality, total Quality Management, Good Manufacturing Practices</li> <li>· Introduce the student to the goals and concept behind Quality Assurance and Quality Control in the pharmaceutical industry.</li> </ul> <p>1</p> <ul style="list-style-type: none"> <li>· Define the scope of Quality Assurance and establish the « compliance » criteria according to the regulatory requirements.</li> <li>· 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".</li> </ul> <p>-----</p> <p><i>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".</i></p>
Evaluation methods	<p><b>Due to the COVID-19 crisis, the information in this section is particularly likely to change.</b></p> <p>The examination will be orally conducted within the course module</p>
Teaching methods	<p><b>Due to the COVID-19 crisis, the information in this section is particularly likely to change.</b></p> <p>The learning will be provided through slides (PowerPoint) and practical exercises. A copy of those documents will be delivered to the student.</p>
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"> <li>-personnel</li> <li>-material</li> <li>-equipment</li> <li>-processes</li> <li>-documentation</li> </ul> <p>Installations and equipment qualification.</p> <p>Internal ' External audit preparation.</p> <p>Suitable behaviour during an audit.</p> <p>Part B</p> <p>Process validation.</p>

	Presentation of the "Process Analytical Technology" (PAT) concept and of the "Risk Management" approach with practical examples
Other infos	The learning will be provided through slides (PowerPoint) and practical exercises. A copy of those documents will be delivered to the student.
Faculty or entity in charge	FARM

<b>Programmes containing this learning unit (UE)</b>				
Program title	Acronym	Credits	Prerequisite	Aims
Advanced Master in Industrial Pharmacy	FARI2MC	7		