UCLouvain

wfarm2104

## GOOD MANUFACTURING AND QUALITY

2023

| 3.00 credits 30.0 h + 15.0 h Q2 | 3.00 credits | 30.0 h + 15.0 h | Q2 |
|---------------------------------|--------------|-----------------|----|
|---------------------------------|--------------|-----------------|----|

| Teacher(s)                  | Leclercq Joëlle (coordinator) ;Pronce Thierry ;   |  |  |  |  |  |
|-----------------------------|---|--|--|--|--|--|
| Language :                  | French > English-friendly   |  |  |  |  |  |
| Place of the course         | Bruxelles Woluwe  |  |  |  |  |  |
| Main themes                 | Teaching will deal with good manufacturing procedures in pharmacies and in industry and good laboratory procedures in laboratories as well as legislation and norms related to quality assurance, advantages to work in a quality system and organisation that it implies.  |  |  |  |  |  |
| Learning outcomes           | At the end of this learning unit, the student is able to:  Students should have the knowledge to organise their work in a quality assurance system and write procedures in relation with it.  |  |  |  |  |  |
| Evaluation methods          | Students will be evaluated on their ability to Understand the philosophy of Good Laboratory Practice and Pharmaceutical Quality Assurance, write one or more simple procedures (personal work) know how to establish the specification of a drug be able to evaluate the performance criteria of an analytical method Establish and interpret a control chart The exam will be written (face-to-face or distance) except in particular cases.                   |  |  |  |  |  |
| Teaching methods            | theoretical courses (if sanitary measures allow it), exercices and practical applications, visit of laboratories/industries   |  |  |  |  |  |
| Content                     | Students will receive theoretical training  - 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.  They will visit laboratories (research and pharmaceutical industry) working in quality assurance and will receive practical training in the form of discussions and seminars. |  |  |  |  |  |
| Other infos                 | 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 [120] in Biomedicine                   | SBIM2M  | 3       |              | ٩                 |  |  |
| Master [60] in Biomedicine                    | SBIM2M1 | 3       |              | ٩                 |  |  |
| Master [120] in Pharmacy                      | FARM2M  | 3       |              | ٩                 |  |  |