



Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-622	Master Thesis	20
Prerequisites	Department	Semester
None	Health Sciences	Fall
Type of Course	Field	Language of Instruction
Compulsory	Pharmacy	English
Level of Course	Lecturer(s)	Year of Study
2 nd Cycle	Member of Faculty	2 nd
Mode of Delivery	Work Placement	Corequisites
e-learning	--	PHAR-621

Course Objectives:

During the final project, students will have the opportunity to apply the knowledge they gain during the program to actual cases or deepen their knowledge through in-depth research. Each student will select a topic on their area of interest within Regulatory Affairs based on their current employment and / or future career aims and will receive guidance by a faculty advisor based on the advisors' area of expertise. Students will prior be exposed to research methodology and are expected to use this while researching the topic. Upon completion of the project the student must demonstrate competency by writing a comprehensive thesis on the selected topic.

Learning Outcomes:

After completion of the course students are expected to be able to:

- Development of a detailed regulatory project with defined goals and objectives.
- Strategy development for supporting the selected project.
- Application of knowledge to real – life situations.
- Investigation of case studies similar or related to the selected regulatory topic.
- Research, evaluation and presentation of legally justifiable position on a case study based on scientific evidence.
- Oral and written defense of selected regulatory topic, with an independent and novel insight.

Course Content:

The final project can be either a hypothetical real – life case study or a regulatory research study.

Examples of final project topics include:

Risk assessment of a toxic substance

Premarket approval application for a pharmaceutical product or a medical device

Post-marketing surveillance of drug adverse effect

Policy statements on an ethical consideration in human subject research

- Other as appropriate

Learning Activities and Teaching Methods:

Periodical meetings and discussion between the student and the faculty advisor for the project's progress.

Assessment Methods:

Submission of thesis to faculty advisor one month prior to final defense, for review, evaluation and approval.

Oral defense of thesis before a thesis committee.