



## Course Syllabus

<b>Course Code</b>	<b>Course Title</b>	<b>ECTS Credits</b>
PHAR-614	Post Graduate Assignment	15
<b>Prerequisites</b>	<b>Department</b>	<b>Semester</b>
Completion of all previous courses	Life and Health Sciences	3 <sup>rd</sup>
<b>Type of Course</b>	<b>Field</b>	<b>Language of Instruction</b>
Required	Pharmacy	English
<b>Level of Course</b>	<b>Lecturer(s)</b>	<b>Year of Study</b>
2 <sup>nd</sup> Cycle	Depending on Topic	2 <sup>nd</sup>
<b>Mode of Delivery</b>	<b>Work Placement</b>	<b>Co-requisites</b>
Distance Learning	NA	NA

### 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. 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:

1. Development of a detailed regulatory project with defined goals and objectives.
2. Strategy development for supporting the selected project.
3. Application of knowledge to real – life situations.
4. Investigation of case studies similar or related to the selected regulatory topic.
5. Research, evaluation and presentation of legally justifiable position on a case study based on scientific evidence.
6. 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 effects
- Policy statements on an ethical consideration in human subject research

**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.

**Required Textbooks / Readings:**

(Will depend on topic)