UNIVERSITY of NICOSIA

# Course Syllabus

| Course Code | Course Title | ECTS Credits |
|---|---|---|
| PHAR-607 | International Regulations (ICH & FDA) | 7.5 |
| **Prerequisites** | **Department** | **Semester** |
| None | Life and Health Sciences | 2nd |
| **Type of Course** | **Field** | **Language of Instruction** |
| Required | Pharmacy | English |
| **Level of Course** | **Lecturer(s)** | **Year of Study** |
| 2nd Cycle | George Aislaitner | 1st |
| **Mode of Delivery** | **Work Placement** | **Corequisites** |
| Distance Learning | NA | NA |

**Course Objectives:**

The expansion of global markets has resulted in increasing regulatory demands for the pharmaceutical industry. More and more pharmaceutical companies are expanding their activities and are trying to establish their presence in many regions and countries. As a result they are facing the challenge of having to cope with diverse regulatory requirements and operating standards.

The aim of the course is to provide an overview of the different regulatory agencies and regulations applied in major international markets for pharmaceutical products and medical devices, such as the United States of America, Canada, Japan and BRIC countries. The differences between these countries and the European Union in terms of pharmaceutical legislation will be discussed. Moreover, international harmonization efforts and global collaboration are going to be explored and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines are going to be examined.

By the end of this course, students will be able to apply knowledge of international regulations in order to plan a global regulatory strategy for product development for international markets.

**Learning Outcomes:**

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

1. Interpret the role of both national agencies and international bodies in the regulation of pharmaceutical products and medical devices.

2. Comprehend the role of International Conference on Harmonisation (ICH) in medicines regulation.
3. Understand the pharmaceutical product and medical device regulations implemented to international markets.
4. Apply practical guidelines in order to comply with the above-mentioned regulations.
5. Distinguish the principles applied in the European Union compared to provisions implemented in other countries.
6. Develop product registration strategies in international markets.
7. Define documentation required for application and approval as well as labeling requirements in international markets.
8. Describe the co-operation developed between regulatory stakeholders.
9. Critically reflect upon global medicines legislation and guidelines.

**Course Content:**

- Historical overview of the development of pharmaceutical laws and regulations worldwide (EU, US and Japan).
- International Conference of Harmonization (ICH): role, structure procedures, and Common Technical Document (CTD) requirements.
- Role of World Health Organization (WHO) in the international harmonization process.
- Regulatory framework in the US, Canada, Japan and BRIC countries.
- Overview of pre-market and dossier documentation requirements in international markets.
- FDA Drug Approval, Regulation and Compliance procedures.
- Overview of GxPs in the US.
- Regulation of Advertising, Promotion and Labeling in the US.
- Differences between US and EU requirements for the manufacture and control of pharmaceutical products and medical devices.
- Annual reporting requirements, changes to approved marketing applications, post-marketing adverse reaction reporting, GMP inspections, product recalls, and risk management.

**Learning Activities and Teaching Methods:**

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and e-books), access to additional videos and commercials related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies and other formative and summative assessments.

**Assessment Methods:**

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| Continuous Assessment (assignments), Final Exam |

**Required Textbooks / Readings:**

| Title | Author(s) | Publisher | Year | ISBN |
|---|---|---|---|---|
| *Nonclinical Safety Assessment, A Guide to International Pharmaceutical Regulations*. John. | Brock, W. J., Hastings, K. L., McGown, K. M. | Wiley & Sons, Ltd | 2013 | |
| *International Pharmaceutical Product Registration*. | Cartwright, A. C., Matthews, B, R. | CRC Press. | 2016 | |
| *The Textbook of Pharmaceutical Medicine 7th edition.* | Griffin, J. P., Posner, J., Barker, G. R. | John Wiley & Sons, Ltd. | 2013 | |