UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-618	Quality Assurance and compliance	10
Prerequisites	**Department**	**Semester**
None	Health Sciences	Spring
Type of Course	**Field**	**Language of Instruction**
Compulsory	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Dr Mourelatou, Dr Hapeshi, Savsek M	1st
Mode of Delivery	**Work Placement**	**Corequisites**
e-learning	--	None

Course Objectives:

Quality assurance (QA) is fundamental for the drug manufacturing process, since it ensures the production of medications that meet specific quality, safety and stability standards, hence are safe and effective. Furthermore, through QA a pharmaceutical company is able to comply with the current pharmaceutical legislation, thus avoiding penalties from compliance-related violations, and maintain its reputation, by avoiding incidents that can produce negative publicity.

QA in the pharmaceutical industry covers all aspects that can influence the quality of a drug product, e.g., development, production, quality control, inspections, distribution etc. From the initial steps of raw material supply throughout the manufacturing process, to storage and distribution, all processes are being monitored and controlled in order to consistently produce pharmaceutical products of high quality and comply with the regulations.

For accomplishing the above-mentioned objectives of QA, several components are necessary such as the development and continuous amelioration of quality management systems, development of standard operation procedures (SOPs), continuous training of employees, deviations management, documentation, audits (internal and external), quality risk management, compliance with good manufacturing practices (GMPs) and good distribution practices (GDP), corrective and preventive management system (CAPA), management review etc.

This course will explain the importance of Quality Assurance in the pharmaceutical industry, and will provide an overview of all its vital components and how their implementation leads to the production of high-quality pharmaceutical products and regulatory compliance.

Learning Outcomes:

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

- Analyze the importance and responsibilities of quality assurance and quality management systems in the pharmaceutical industry
- Relate quality assurance, quality control, quality management and good manufacturing practices
- Compare and contrast each Quality System Element of QA, such as training, calibration, change control etc.
- Assess the significance of Quality by design (QbD)
- Illustrate how to prepare and conduct an inspection
- Outline the techniques and tools used for implementing Corrective and preventive action (CAPA)
- Describe and assess all the steps and documentation of process validation

Course Content:

- **Principles of Quality Assurance** (components of quality assurance, Good Manufacturing Practice (GMP), Good Distribution Practices (GDP), concept of total quality management (TQM), traditional quality management and Total quality management, quality control, ICH Guidelines, ISO 9000 & ISO14000, etc.)
- **Benefits of quality assurance** (Identifying Opportunities for Organizational Continuous Improvement, benefits to the customer, to the employee and to organization)
- **Quality Improvement** (e.g., lean manufacturing, quality by design)
- **Personnel** (Qualification, Experience, training, responsibilities of personnel, legal aspects)
- **Facilities and Equipment** (design, construction, maintenance, equipment identification etc.)
- **Quality Control**
- **Materials management** (raw and packing materials, purchasing, rejected materials, recalled materials, waste materials, reference standard etc.)
- **Documentation** and **Complaints**
- **Manufacturing control and operation** (e.g., process deviations, time limitations on production, expiration date for pharmaceuticals, production record review, technology transfer)
- **Validation and Qualification**
- **Corrective and preventive action**
- **Inspection and auditing**
- **Safety and environmental protection**

Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and ebooks), access to additional videos related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies, wikis, and major assignments.

Assessment Methods:

Continuous Assessment (major assignments and weekly activities), Final Exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Quality 2nd Edition,	K. McCormick, J. Sanders	Elsevier	2022	eBook ISBN: 9780323994606, Paperback ISBN: 9780323908153
Quality Assurance Compliance: Procedures for Pharmaceutical and Biotechnology Manufacturers, 1994,	Ira C. Peine	Taylor & Francis,	1994	ISBN:0935184511, 9780935184518
Quality Assurance of Pharmaceuticals 2018: WHO guidelines, related guidance and GXP training materials, February 2019, ISBN:		World Health Organization (WHO),	2019	9789241550314