Course Unit Descriptor

Study Programme: Pharmaceutical engineering

Course Unit Title: Quality and safety menagment in the pharmaceutical industry

Course Unit Code: FI404

Name of Lecturer(s): Assoc. Prof. Dragoljub Cvetković, PhD; Ass. Prof. Aleksandra Ranitović, PhD

Type and Level of Studies: Undergraduate academic studies

Course Status (compulsory/elective): Elective

Semester (winter/summer): Winter

Language of instruction: English

Mode of course unit delivery (face-to-face/distance learning): Face-to-face

Number of ECTS Allocated: 7

Prerequisites: -

Course Aims:

The aim of the course is to acquire knowledge about modern approach and the concept of safety management and quality in the pharmaceutical industry, the biological, chemical and physical contaminants, pre-requisite programs for safety and product quality (good production, hygiene and laboratory practice), integrated system safety management and quality, the current domestic and international rules on safety and quality.

Learning Outcomes:

Students are trained to understand theoretical and practical principles of implementation of consistent, efficient and effective management system, as well as systematic improvement of performance of modern management system of safety and quality in pharmaceutical industry.

Syllabus:

Theory

Preliminary considerations relating to the concept of quality, quality factors, traditional and modern approach to quality and safety of products. The criteria of quality and products safety, the main contaminants of products, Good manufacturing, laboratory and hygienic practices, requirements of ISO 9000: 2001, ISO 22000, ISO 17025, GMP, GHP and DLP, EC directives, theoretical basis of the HACCP system, implementation of HACCP system, organization and accreditation of laboratories according to ISO 17025.

Practice

Practical knowledge of the standards ISO 9000, ISO 22000, ISO 17025, International Codex and regulations. Prerequisite programs, documentation, implementation of HACCP (appointment HACCP team, product description, flow chart, verification of the flow chart, the hazard analysis, definition of critical control points (CCPs) and critical limits, the definition of monitoring, corrective action, verification and documentation of the HACCP system).

Required Reading:

1. Denyer S.P., Hodges N.A., Gorman S.P.: Pharmaceutical Microbiology, Blackwell, 2004.
2. Lightfoot N.F., Maier E.A.: Microbiological Analyses of Food and Water, Guidelines for Quality Assurance, 2012, Elsevier, The Netherlands.
3. Watson, David G.: Pharmaceutical Analysis, Edinburgh: Elsevier, 2005.

Weekly Contact Hours: 6	**Lectures:** 3	**Practical work:** 3

Teaching Methods:

Lectures and students group work			
Knowledge Assessment (maximum of 100 points):			
Pre-exam obligations	points	**Final exam**	points
Active class participation	5	written exam	-
Practical work	15	oral exam	30
Preliminary exam(s)	40	…….	
Seminar(s)	10		
The methods of knowledge assessment may differ; the table presents only some of the options: written exam, oral exam, project presentation, seminars, etc.			