UNIVERSITY OF NOVI SAD
FACULTY OF MEDICINE

Study program: Doctoral Academic Studies in Biomedical Sciences

Course title: QUALITY SYSTEM IN PHARMACY

Teacher: Mladena N. Lalić-Popović, Veljko S. Krstonošić, Nataša B. Milić, Nataša P. Milošević, Milica T. Atanacković Krstonošić, Jelena Helen M. Cvejić, Mira P. Mikulić, Neda S. Gavarić

Course status: elective

ECTS Credits: 15

Condition: -

Course aim

Introducing the student to the concept of good practice, its structure and application in various fields of medicine development, quality control and use.

Expected outcome of the course:

The student acquires knowledge of all major good practices used in the active pharmaceutical ingredient design, manufacturing, quality control, testing, administration, distribution, registration and post-marketing monitoring of medicines. They also make acquaintance in detail the concept of good pharmacy practice that covers all segments of the pharmaceutical healthcare.

Course description

Theoretical education

1. The concept of good practice. Principles and structure. Application and types
2. Good Regulatory Practice
3. Model Informed Drug Discovery and Development
4. Good agricultural and collection practices for medicinal plants
5. Good Pharmacy Practice
6. Good Manufacturing Practice
7. Good Practices for Pharmaceutical Quality Control Laboratories
8. Good Clinical Laboratory Practice
9. Good Distribution Practice
10. Good Clinical Practice
11. Good Pharmacovigilance Practice

Practical education

Detailed introduction to good practice in the area of interest of the candidate. Writing a seminar paper in this area.

Literature

Compulsory

1. Fip reference guide on good pharmacy practice in community and hospital settings. 1st edition. 2009.
2. WHO guidelines on good agricultural and collection practices for medicinal plants
3. Model Informed Drug Discovery and Development (MID3). 2015
4. EudraLex. Good Manufacturing Practice (GMP) guidelines
5. WHO. Good practices for pharmaceutical quality control laboratories. 2009.
6. WHO. Good clinical laboratory practice (GCLP). 2009.
7. European Commission. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use. 2013.
8. EMA. Guideline for good clinical practice. 2016.
9. WHO. Good regulatory practices: guidelines for national regulatory authorities for medical products. 2016.
10. EMA. Guideline on good pharmacovigilance practices. 2017.
11. ICH Q7 Good manufacturing practice for active pharmaceutical ingredients. 2000.
12. ICH guideline Q9 on quality risk management. 2015.
13. ICH guideline Q10 on pharmaceutical quality system. 2015.

Number of active classes	**Theory:** 60	**Practices**: 45

Teaching methods: oral lectures, interactive classes, practical classes, laboratory work

Student activity assessment (maximally 100 points)

lectures: 30

written exam: 70