



Study program: Integrated academic studies in Medicine
Name of the subject: Professionally Orientated Education of Health Workers in Pharmaceutical Industry
Teachers: Nebojša Kladar, Aleksandra Nikolić, Branislava Srđenović Čonić, Veljko Krstonošić, Dejan Ćirin, Milica Atanacković Krstonošić, Mira Mikulić, Nina Brkić Jovanović, Nebojša Stilinović, Nebojša Pavlović
Status of the subject: elective
Number of ECTS credits: 3
Conditions: /
<p>Subject goal</p> <p>Students will be introduced to different aspects of work in pharmaceutical industry. They will gain the knowledge required for understanding of basics of new pharmaceutical formulations development, as well as for their placement on the market. Also, they will be trained for individual implementation of quality control in pharmaceutical industry (regulatory framework, validation of analytical methods, the assessment of results, certification of processes), as well as for performing pharmacoeconomic analysis. They will gain the knowledge related to communication skills required for successful marketing and sales of pharmaceutical products.</p>
<p>Outcome of the subject</p> <p>By enrollment in this course the students will gain the fundamental knowledge required for understanding business processes in pharmaceutical industry. Furthermore, the proposed mode of education will enable them to apply for large spectra of job positions available in pharmaceutical industry.</p>
<p>Subject content</p> <p><i>Theory</i></p> <ol style="list-style-type: none"> 1. Development of new pharmaceutical formulations – from initial formulation and registration to placement on market 2. Quality control in production of drugs, medical devices, dietary supplements and cosmetics 3. Pharmaceutical legislative 4. Pharmacoeconomics 5. BSCI Code of Conduct 6. Quality assurance of production process (ISO, HCCP, GMP, GLP) 7. Health industry and environmental protection 8. Business communication – the approach to health workers, the approach to patient 9. Basic terms in pharmaceutical marketing <p><i>Practical learning</i></p> <ol style="list-style-type: none"> 1. Development and validation of analytical method for determination analyte of interest 2. Pharmacoeconomic analysis of data 3. Steps in career development (from job offer to skilled professional) 4. Practical in-company training
<p>Literature</p> <ol style="list-style-type: none"> 1. Amfori BSCI Code of Conduct v.2021 2. Vogenberg F.R. Introduction to Applied Pharmacoeconomics. New York: Mc. Grow-Hill; 2001. 3. Current regulations of Republic of Serbia related to the health sector and pharmacy 4. European Commission. Directive 2004/10/EC of the European Parliament and of the Council on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances 5. European Commission. Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use. 6. Mark Gibson, Pharmaceutical Pre-formulation and Formulation, 2nd Ed., Informa Healthcare, 2009.

7. ICH guidances www.ich.org			
8. Scripts for internal use			
Number of active teaching classes		Theoretical teaching: 15	Practical teaching: 30
Method of carrying out the teaching			
1. Theoretical lectures			
2. Practical trainings (laboratory training, seminars, in-company training)			
Evaluation of knowledge (maximum number of points 100)			
Pre-exam obligations	Points	Final exam	Points
Activity during lectures	5	Written exam	30
Practical teaching	15	Oral exam	
Colloquium			
Seminar(s)	50		