



Study program: Doctoral Academic Studies in Biomedical Sciences		
Name of the subject: PRINCIPLES OF GOOD LABORATORY PRACTICE		
Teacher(s): Velibor S. Čabarkapa Isidora N. Samojlik, Stojan M. Petković, Saša N. Vukmirović, Nebojša P. Stilinović, Vesna M. Mijatović Jovin, Branislava P. Ilinčić, Dragana M. Zgonjanin Bosić, Stanislava V. Nikolić		
Status of the subject: elective		
Number of ECTS points: 15		
Condition: -		
Goal of the subject To enable the student to organize or participate to work in the laboratory according to the principles of Good Laboratory Practice (GLP).		
Outcome of the subject <i>Knowledge:</i> Getting to know the Good Laboratory Practice Guide. <i>Skills:</i> Students will be able to work in the laboratory according to the principles of good laboratory practice so that they can organize and ensure the quality of work, prepare documentation for individual segments of work in the laboratory and perform the necessary actions.		
Content of the subject <i>Theoretical lectures</i> <ul style="list-style-type: none"> - Good Laboratory Practice (GLP): field of application, definitions and terms, organization of laboratory, work and staff. - Quality Assurance (QA) and Quality Control (QC) systems: devices, materials, reagents, test substances, test systems, laboratory accreditation. - GLP documentation: standard operating proceeding and procedure (SOP), records and notes, plans and final reports, archiving and storage of data. - Application of GLP in biomedical research (experiments on laboratory animals). - Application of GLP in the analytical laboratory (analytical testing of drugs and poisons). - Application of GLP in clinical-biochemical laboratories. - Application of GLP in a microbiology laboratory (<i>in vitro</i> microbiological testing). - The importance and application of GLP principles in forensic practice (chain of custody in forensic practice, with references to histopathological and forensic laboratories). - Application of GLP in forensic DNA laboratory. - Application of GLP in nuclear medical testing: organization of laboratories, basic principles of radiopharmaceutical application <i>in vitro</i>. - The importance and application of GLP principles in Good Clinical Practice. <i>Practical lectures</i> Introducing students to the quality assurance and quality control system and documentation in the GLP laboratory. Preparation of one segment of documentation (standard operating procedures, instructions, research plan, reports) after practical work and stay in the laboratory working according to GLP principles.		
Recommended literature <i>Compulsory</i> 1. OECD Principles Of Good Laboratory Practice And Compliance Monitoring (http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm) <i>Additional</i> 1. Handbook: Good Laboratory Practice (GLP): Quality practices for regulated non-clinical research and development 2nd ed. TDR, World Health Organization, Geneva, Switzerland 2009.		
Number of active classes	Theory: 60	Practice: 45
Methods of delivering lectures: Interactive lectures and practices; Consultations; Essays		
Evaluation of knowledge (maximum number of points 100) lectures: 20 practices: 20		

essay: 30

oral exam: 30