

ZNAČAJ DOBRE LABORATORIJSKE PRAKSE U LABORATORIJAMA VISOKE MEDICINSKE ŠKOLE PRIJEDOR

Mira Obradović¹, Radoslav Grujić¹, Brankica Kaurin – Šarac²

¹Visoka medicinska škola Prijedor, Nikole Pašića 4A, Prijedor,
Republika Srpska, Bosna i Hercegovina

²JZU Dom zdravlja Prijedor, Vožda Karađorđa 2, Prijedor,
Bosna i Hercegovina

Sažetak: Kao dio službenih propisa, Dobra laboratorijska praksa (GLP) predstavlja standardizovani program za osiguranje kvaliteta i integritet podataka o nekliničkim ispitivanjima, koji se dostavljaju regulatornim nacionalnim ili međunarodnim tijelima. GLP propisi pokrivaju mnoge aspekte nekliničkih istraživanja. Zbog važnosti nekliničkih laboratorijskih ispitivanja zahtijeva da se ona provode u skladu sa naučno utemeljenim protokolima, sa posebnom pažnjom usmjerenom na kvalitet. Na osnovu OECD Principa dobre laboratorijske prakse, većina država u svijetu je usvojila vlastite Principe DLP. Prema nacionalnim propisima u većini država provode se redovni inspekciji nadzor i provjera podataka radi praćenja usklađenosti laboratorija sa zahtjevima GLP-a. Visoka medicinska škola u Prijedoru nabavila je i instalirala modernu opremu u tri laboratorije: hemijska laboratorija, biohemijska laboratorija i mikrobiološka laboratorija. Cilj ovog rada je analiza dokumentacije koju je neophodno razviti i usvojiti, kako bi laboratorija ispunila formalne uslove za obavljanje aktivnosti vezanih za neklinička ispitivanja. Osim obuke studenata, rukovodstvo Visoke medicinske škole želi da se laboratorijama vrše određena neklinička istraživanja, te da se osim principa Dobre laboratorijske prakse (GLP), u radu laboratorija stvore pretpostavke za prihvatanje principa Dobre kliničke laboratorijske prakse (GLCP). U radu se analiziraju zahtjevi OECD Principa dobre laboratorijske prakse, zahtjevi standarda ISO 15189 i zahtjevi Dobre kliničke laboratorijske prakse. Nakon tabelarnog pregleda i poređenja zahtjeva iz navedenih dokumenata, pojedinačno se analiziraju zahtjevi i prikazuju smjernice za ispunjenje zahtjeva u laboratorijama Visoke medicinske škole. Provedena analiza obuhvata detalje u vezi sa organizacijom i osobljem laboratorije, ciljevima programa osiguranja kvaliteta, sistemom ispitivanja (analiza, testiranja), odlaganjem otpada, opremom i mjernim instrumentima, reagensima i drugim potrošnim materijalima, prijemom i rukovanjem uzorcima, opisom i čuvanjem testnih i referentnih materijala, izradom standardnih operativnih procedura, izvođenjem ispitivanja, izvještavanjem o rezultatima ispitivanja, te o postupcima skladištenja i čuvanja zapisa. Provedeno istraživanje je rukovodstvu i osoblju laboratorija dalo smjernice u vezi narednih koraka ka ispunjenju zahtjeva Dobre laboratorijske prakse.

Ključne riječi: Dobra laboratorijska praksa, GLP, Medicinska laboratorija za obuku studenata

APPLICATION OF THE PRINCIPLES OF GOOD LABORATORY PRACTICE IN THE LABORATORIES OF THE COLLEGE OF HEALTH SCIENCE PRIJEDOR

Mira Obradović¹, Radoslav Grujić¹, Brankica Kaurin – Šarac²

¹College of Health Science Prijedor, Nikole Pašića 4A, Prijedor, Republic of Srpska, Bosnia and Herzegovina

²Health centre Prijedor, Vožda Karađorđa 2, Prijedor, Bosnia and Herzegovina

Abstract: As part of official regulations, Good Laboratory Practice (GLP) is a standardized program for ensuring the quality and integrity of data on non-clinical trials, which are submitted to regulatory national or international bodies. GLP regulations cover many aspects of non-clinical research. The importance of non-clinical laboratory tests requires that they are conducted in accordance with scientifically based protocols, with special attention focused on quality. Based on the OECD Principles of Good Laboratory Practice, most countries in the world have adopted their own GLP Principles. According to national regulations, regular inspections, supervision and data verification are carried out in most countries to monitor laboratory compliance with GLP requirements. The medical college in Prijedor has installed modern equipment in three laboratories: a chemical laboratory, a biochemical laboratory and a microbiological laboratory. In addition to training students, the management of the College of Health Sciences Prijedor wants the laboratories to carry out certain non-clinical research and, in addition to the principles of Good Laboratory Practice (GLP), create prerequisites for the acceptance of the principles of Good Clinical Laboratory Practice (GLCP) in the work of the laboratory. The paper analyzes the requirements of the OECD Principles of Good Laboratory Practice, the requirements of the ISO 15189 standard and the requirements of Good Clinical Laboratory Practice. After tabular review and comparison of the requirements from the mentioned documents, the requirements are analyzed individually and guidelines for fulfilling the requirements in the laboratories of the College of Medicine are presented. The analysis carried out includes details related to the organization and personnel of the laboratory, the objectives of the quality assurance program, the examination system (analysis, testing), waste disposal, equipment and measuring instruments, reagents and other consumables, receiving and handling of samples, description and storage of examination and reference materials, creating standard operating procedures, performing tests, reporting test results, and storage and record keeping procedures. The conducted research gave guidelines to the management and staff of the laboratory regarding the next steps towards fulfilling the requirements of Good Laboratory Practice.

Keywords: Good laboratory practice, GLP, Medical laboratory for student training