doi: 10.7251/ZSAN2302413O **Review paper**

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

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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 College of Health Science 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 Science 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 Health Science 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, Medical laboratory for student trainin*

Introduction

During scientific and non-clinical research, it is necessary to apply control over the conduct of research activities. This control contributes to the provision of reliable, consistent and reproducible results [1]. The OECD document defines the principles of GLP as: "Good laboratory practice (GLP) deals with the organizational process and conditions under which research in laboratories is planned, performed, monitored, recorded and reported" [2]. GLP is accepted in most countries in the world, because it has a great contribution to ensuring safety, increasing work efficiency and accuracy of laboratory test results [3, 4].

Good Laboratory Practice (GLP) and Standard Operating Procedures (SOP) provide guidelines for the proper use of research and other equipment in the laboratory, for the maintenance and sanitation of facilities and equipment, and for the reporting of test results. GLP is the non-clinical counterpart of Good Manufacturing Practice (GMP) used in industrial settings [1] and Good Clinical Laboratory Practice (GCLP) used during testing of human materials for the purpose of diagnosing disease.

The OECD Principles of Good Laboratory Practice are routinely used in large academic and research institutions. However, researchers at smaller colleges, where staff and resources are limited, often neglect or omit the application of GLPs and SOPs. It is considered unthinkable for a higher education institution, staff and/or students at an academic institution to falsify data or not follow ethical principles during research. However, in some situations it is possible for laboratories to receive and display substandard and/or incorrect products results. There are many such examples, which may arise as a result of equipment failure, poor sanitary conditions in facilities, errors in the processing of results, and the like. The reasons for such occurrences can be different, and the most common are the lack of proper training of the department and supervision of activities in the laboratory [1].

The aim of this work is to provide information on GLP and analysis documentation that is necessary to develop and adopt in a chemical laboratory at a higher education institution that trains students to test chemical materials for human health and the environment, and samples of human origin during the diagnostic process. From the presentation in this paper, students should understand the importance of applying GLP, and the laboratory itself should meet the formal requirements for performing activities related to non-clinical tests.

Material and methods

During the research in this paper, a review of several OECD Principles of Good Laboratory Practice was carried out. The requirements from this document were compared with the Good Clinical Laboratory Practice and the ISO 15189 standard. On this occasion, areas were identified in the course of which students can participate in their interpretation and practical application. Several standard operating procedures

and work instructions were developed, through the application of which the students contributed to the improvement of the quality of the test results in the laboratory.

Results and discussion

OECD Principles of Good Laboratory Practice (GLP)

As part of the Chemicals Control Program of the Organization for Economic Co*operation and Development (*OECD), the document **Principles of Good Laboratory Practice (GLP)** was adopted. It was developed based on the FDA regulations for non-clinical laboratory tests, which were published by the FDA in 1976. OECD DLP principles ensure data reliability and reproducibility of safety testing. In 1981, the OECD Council officially proposed the use of the Principles of Good Laboratory Practice. Subsequently, many countries adopted their own GLP regulations [5] The OECD adopted a revised GLP Principles document, which replaced the original principles, and published guidance for the work of control bodies regarding the introduction of procedures necessary to monitor industry compliance with these principles, and guidelines for compliance with the principles during the implementation of the necessary control activities (inspection in laboratories and test verification) [2].

Good Laboratory Practice (GLP) principles promote the quality and validity of test data used to determine the safety of chemicals and chemical products. It is a management concept that covers the organizational process and conditions under which laboratory tests are planned, performed, monitored, recorded and the process of reporting on conducted laboratory tests. The GLP principles must be followed by examination institutions that submit the results of their examinations to the national authorities. Based on the data from the test laboratory reports, the competent state authorities assess the safety of the use of chemicals and their impact on human health and the environment. GLP regulations are accepted as international standards for non-clinical laboratory testing of health and environmental safety, which are required by regulations for the purpose of registration or licensing of chemical products of various types [6].

The question of the quality of data obtained during measurements is important at the international level. The purpose of the Principles of Good Laboratory Practice is to improve the development of the quality of test data. The possibility of comparing the quality of test results is the basis for mutual acceptance of laboratory analysis data between countries. If national regulatory authorities can rely on data from overseas tests, retesting can be avoided and costs to industry and government reduced. Moreover, common principles for GLP facilitate the exchange of information and prevent the emergence of technical barriers to trade, while contributing to the protection of human health and the environment [2].

In the European Union (EU), GLP principles and procedures are included in the corresponding directives. The principles of GLP are included in regulations related to chemicals, human medical products, veterinary products, detergents, food

additives, additives used in animal feed, genetically modified food for humans and animals, pesticides, biocides and cosmetics [7] and in regulations on medical devices. Where applicable, compliance with the provisions of Directive 2004/10/EC must be demonstrated. The US Food and Drug Administration (FDA) requires the use of GLP during safety testing of medical devices. The principles of GLP are applied in the Republic of Srpska and neighboring countries [8, 9, 10] .

Definition of GLP

The OECD guidelines provide definitions of many terms related to Good Laboratory Practice. National regulations (for example, EU, USA, SR, Serbia, Croatia) adopted those definitions with minimal adaptation to the local situation and other national regulations [11]. The definitions refer to several groups of terms (terms): good laboratory practice (1 term), terms related to the organization of the testing laboratory (10 terms), terms related to non-clinical safety testing for human health and the environment (12 terms)) and terms related to the substance being tested (4 terms).

In the OECD document [2], the following definition of Good Laboratory Practice is given: " Good Laboratory Practice is a quality system that refers to organizational processes and conditions in which non-clinical tests that are safe for health and the environment (hereinafter: non-clinical tests)". That definition is adopted in national regulations in this area [8, 9, 10].

Purpose of GLP

During all phases of laboratory measurement, errors often occur. In order to reduce or completely eliminate these errors, Good Laboratory Practice (GLP) is applied in practice. The use of GLP principles is good whenever the testing laboratory is not specifically required to follow the relevant standards. Jean Cobb [12] lists three simple rules to follow during laboratory testing:

1. Say what you are doing (write standard operating procedures),
2. Do what you say (follow written procedures),
3. Be able to prove it (keep good records).

The principles of good laboratory practice (GLP) support the development of quality and validity of results obtained during testing (measurement), which are used in determining the safety of chemicals and chemical products [13]. GLP protects the integrity and quality of the data obtained in the laboratory, which are used to confirm the degree of conformity of the product. The GLP describes good practices for non-clinical laboratory tests that support trials or marketing authorizations for products governed by national regulations.

GLP aims to reduce errors or confusion through specific labeling requirements for chemical products. Experience in the application of GLP is important for employers in certain cases. If they have practical experience in working on tests according to the

principles of GLP, the employer will design their activities more precisely. Good planning is more than half the effort on the track to achieve success. By using a well-designed and defined test procedure, analysts can more easily evaluate the test outcome. GLP relies heavily on creating and following a pre-defined test plan. Good laboratory practice can be used to detect errors during testing, but also to protect analysts from unfounded accusations. In this way, institutions and laboratories benefit from the application of the basic rules of GLP.

Scope of GLP

The principles of GLP are applied to non-clinical tests of the safety of chemicals on human health and the environment, and for the purpose of harmonizing test procedures at the international level. The OECD principles of Good Laboratory Practice should be applied to all non-clinical safety tests of substances that are part of pharmaceutical products, pesticides, cosmetic products, veterinary drugs, food additives, animal feed additives and industrial chemicals . The entities analyzed can be of different origin: synthetic chemicals, substances of natural or biological origin and, in some cases, they can be living organisms. The purpose of examination (testing) of the mentioned materials is to obtain data on their characteristics and/or their safety in terms of human health and/or environmental protection.

The principles of GLP, except in cases for which there are different legal solutions, apply to all non-clinical tests on environmental health and safety, which are required by regulations for the purpose of registration or licensing of pharmaceutical products, pesticides, food and feed additives, cosmetic products , veterinary drugs and similar products, as well as for the regulation of industrial chemicals.

A comparative view of the requirements of GLP, GCLP and ISO 15189

In chemical laboratories at a higher education institution where students are trained, it is desirable to apply the rules of GLP, GCLP and the corresponding standards (ISO 15189 and ISO 17025). The requirements of these documents overlap to a large extent (Figure 1), which makes the application of two or more documents easier. Before the implementation of regulations and standards, it is necessary to carry out their comparative analysis and to determine the same or similar requirements, to design the documents (SOPs) of the laboratory in this way.

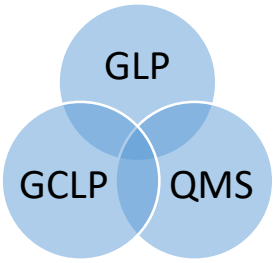

Figure 1. Comparative view of GLP, GCLP and QMS requirements

Table 1 shows a comparative analysis of the GLP, GCLP and ISO 15189:2018 standards. GLP refers to the following areas and activities: Test Facility Management, Quality Assurance Program, Meeting Test Facility Requirements, Equipment, Receiving, Handling, Sampling and Storage, Standard Operating Procedures, Conducting the Study, Reporting Study Results, Storage and Retention of Records and materials [14]. Susan M. Bornstein-Forst [1] considers that the application of the following components of GLP is desirable for laboratories at small higher education institutions: Organization and personnel, Facilities, Equipment, reagents and materials (physical, chemical and biological), Reporting of results and Archiving and preservation.

Table 1. Comparative analysis of the requirements of the GLP, GCLP and ISO 15189:2018 documents

OECD principles Good laboratory practices	**Good clinical laboratory practice[2]**	**Standard ISO 15189:2018**
Test Facility Organisation and Personnel (1) Test Facility Management's Responsibilities (1.1) Study Director's Responsibilities (1.2) Principal Investigator's Responsibilities (1.3) Study Personnel's Responsibilities (1.4)	Organization and personnel (5) Trial Facility Management Responsibilities (5.1) Analytical Project Manager Responsibilities (5.2) Trial Staff Responsibilities (5.3)	**Requirements for structure and requirements management (5)** Legal entity (5.1) Laboratory director (5.2) Laboratory activities (5.3) Structure and authority (5.4) Objectives and policies (5.5) Risk management (5.6)
Quality Assurance Programme (2) General (2.1) Responsibilities of the Quality Assurance Personnel (2.2)	Quality audit (15)	**Management system requirements (8)** General requirements (8.1) Management system documentation (8.2) Control of management system documents (8.3) Control of records (8.4) Actions to address risks and opportunities (8.5) Improvement (8.6) Nonconformities and corrective actions (8.7) Evaluations (8.8) Management reviews (8.9)

[2] WHO. 2009. Good clinical laboratory practice (GCLP). ISBN 978 92 4 159785 2

OECD principles Good laboratory practices	Good clinical laboratory practice[2]	Standard ISO 15189:2018
Facilities (3) General (3.1) Test System Facilities (3.2) Facilities for Handling Test and Reference Items (3.3) Archive Facilities (3.4) Waste Disposal (3.5)	Facilities (6) Trial Facilities (6.1) Archive Facilities (6.2) Waste Disposal (6.3)	**Resource requirements (6)** General (6.1) Personnel (6.2) Facilities and environmental conditions (6.3) Equipment (6.4) Equipment calibration and metrological traceability (6.5)
Apparatus, Material, and Reagents (4)	Equipment , materials and reagents (7) Equipment (7.1) Material (7.2) Reagents (7.3)	
Test systems (5) Physical / Chemical (5.1) Biological (5.2)	Trial materials (11) Receipt (11.1) Chain of Custody (11.2) Logistics (11.3)	
Test and Reference Items (6) Receipt, Handling, Sampling and Storage (6.1) Characterisation (6.2)		
Standard Operating Procedures (7)	Standard operating procedures (SOPS) (8) General (8.1) Application (8.2)	
Performance of the Study (8) Study plan (8.1) Content of the Study Plan (8.2) Conduct of the Study (8.3)	Planning of work (9) Analytical Plan (9.1) Content of the Analytical Plan (9.2) Conduct of work (12) General (12.1) Computer system (12.2) Method Validation (12.3) Processing trial material (12.4) Sub-contracting (10)	**Requirements process (7)** General (7.1) Pre-exam processes (7.2) Processes tests (7.3) Processes after tests (7.4) Mismatched Operation (7.5) Control management data and information (7.6) Complaints (7.7) Planning continuity and readiness for extraordinary situations (7.8)

OECD principles Good laboratory practices	Good clinical laboratory practice[2]	Standard ISO 15189:2018
Reporting of Study Results (9) General (9.1) Content final report (9,2)	Reporting results (13) General (13.1) Analytical Report (13.2) Content of the Analytical report (13.3) Analytical results (13.4)	
Storage and Retention of Records and Materials (10)	Storage and retention of records (16)	
GLP PRINCIPLES AND COMPLIANCE MONITORING Decision on mutual acceptance data in the assessment chemical Decision on compliance with DLP principles		
	Confidentiality (17)	**General requests (4)** Impartiality (4.1) Confidentiality (4.2) Requirements which relate _ on patients (4.3)
		Appendix A Supplementary requirements for Point-of-Care Testing (POCT) General (A.1) Management (A.2) Insurance program quality (A.3) Training program (A.4)

Components of Good Laboratory Practice (GLP)

Laboratory management should be aware of the fact that the laboratory may be subject to inspection by the state body for monitoring compliance with GLP, which is why it must insist on the application and comprehensive implementation of GLP requirements.

Place of inquiry

The term "test facility" means a place where one or more phases of a test study are conducted. This term includes: buildings, test rooms and other premises, and the people who work there and/or are responsible for conducting the study. The test

facility should be built in a suitable location, should have the necessary rooms and should be of suitable size. In addition, the Principles of Good Laboratory Practice require the provision of conditions for the accommodation of equipment, samples and data and for their maintenance and use, as well as conditions for the accommodation and archiving of supporting documentation. Orderliness in the use and maintenance of documentation contributes to confidence in the quality of the work performed and facilitates the performance of daily activities in accordance with quality standards. GLP requirements for personnel include the need to implement procedures that describe sanitary conditions, health measures, personnel clothing and dress, test protocol, test methods, data analysis, report generation, quality assurance function, and more. Approved Standard Operating Procedures (SOPs) should be used during testing. Laboratories within smaller higher education institutions should clearly define work duties and the way of reporting on the execution of work tasks. If the way of maintenance and supervision of equipment and operations in the laboratory are not clearly and comprehensibly defined, many activities will not be performed or will not be performed correctly, especially by individuals who do not have expertise. All user groups, from students to professors, must follow SOPs and sanitary SOPs (SSOPs). The staff should clearly understand the functions they will perform, if necessary they should be provided with the necessary training.

During the application of the Principles of Good Laboratory Practice and/or Quality Assurance, Laboratories within smaller higher education institutions face certain problems [1]. The most frequently encountered problems are: lack of resources, lack of funds and insufficiently competent staff. Clear definition of duties and alignment of employees' expertise with work duties contribute to efficiency in performance work assignments. In this context, most academic institutions see the solution in the improvement and application of the verification system. The method of using equipment, calibration, verification and repair of equipment, and sanitation procedures, must be provided through SOP, SSOP and GLP policies. In the absence of defined guidelines, laboratory staff may have wrong assumptions about (for example) who cleans and maintains equipment, who reports equipment failure, how often and how maintenance is required, how toxic waste is disposed of, etc.

Maintenance and sanitation require established prerequisite practices including SOPs and SSOPs. Supervision over the performance of work in the laboratory is difficult to implement, when the policies are not clear and/or available.

Quality assurance program

The testing laboratory should have a documented quality assurance program, which guarantees that tests are conducted in accordance with the Principles of Good Laboratory Practice. The management of the testing laboratory must be designated by a person responsible for quality assurance in the laboratory. This person should ensure a complete and honest flow of information within the testing laboratory. Quality Assurance personnel are responsible for maintaining copies of all approved test plans and Standard Operating Procedures used in the testing laboratory. They

should check that the test plan contains the information required for compliance with the Principles of Good Laboratory Practice. In addition, these persons should determine the existence of procedures by which checks are carried out in order to determine whether the tests were carried out in accordance with the Principles of Good Laboratory Practice.

Bornstein-Forst (2022) [1] lists several examples of quality controls in a testing laboratory. Quality control includes the process, procedures, and authorizations used to accept or reject all components, drug containers, process materials, packaging materials, labeling, and medical products, and authorization to review records from the manufacturing process. This is how it is checked whether errors have occurred, whether they have been fully investigated. In the final reports, it is necessary to confirm that the methods, procedures and observations are accurately and completely described, and that the results are accurate and fully reflect the raw data of the research.

Fulfilling the requirements of the testing institution

Handling and disposal of waste should be done in a way that does not risk the integrity of the test. This implies the need to provide appropriate facilities for the collection, storage and disposal of waste, as well as procedures for decontamination and transport of waste.

The laboratory should ensure that only reagents specified in the appropriate SOP are used during testing. The SOP should define the way of labeling the reagents. All reagents and solutions must be adequately labeled. Spoiled reagents or expired reagents and solutions must not be used during testing. The date of opening of the original package for each reagent should be recorded and care should be taken of the storage temperature and expiration date [5].

Samples should be clearly identified, to allow full traceability. Each test and all parts of the test should have a unique identification. All observations during the examination should be clearly and legibly recorded. A note should be entered at the time of observation. The note should be permanent. The corrections entered must not hide the original entry. Reasons must be given for all corrections. All entries and corrections to them should be dated and initialed. At the end of the test, all raw data should be compiled, cataloged and archived. During the archiving of raw data and samples, and other documents (study plan and study report, etc.), secure storage should be ensured [16].

Equipment

The equipment and materials used in the testing laboratory must not negatively affect the testing [2]. Equipment, including validated computerized systems, should be located in a manner that meets the principles of GLP. In addition, the equipment should be designed appropriately and should have the necessary capacity for the

scope of testing carried out in the laboratory. Equipment should be properly recorded. Records should contain: name of the equipment and manufacturer, model or type, serial number, date of receipt of the equipment in the laboratory, a copy of the manufacturer's instructions for use. Equipment used in the laboratory should be periodically inspected, cleaned, maintained and calibrated in accordance with Standard Operating Procedures. The manufacturer's manuals provide useful information and suggestions for the frequency of cleaning and maintenance of measuring instruments in the laboratory. Equipment calibration should be carried out according to national or international measurement standards. Instrument validation is a necessary process for any analytical chemistry laboratory. The frequency of calibration, revalidation and testing depends on the instrument and the extent of its use in the laboratory. A key point in considering the frequency of maintenance and calibration is the necessary assurance of data validity [1]. In some cases, it would be necessary to ensure the traceability of performed calibrations according to "national or international measurement standards".

Chemicals, reagents, and solutions should be labeled to indicate identity, expiration date, and special storage instructions. Information on source, date of preparation and stability should be available. The validity period can be extended based on a documented assessment or analysis.

Computerized systems are used during most laboratory testing activities: planning, execution and reporting of results, and direct or indirect data collection from automated instruments, recording, processing, reporting, management and storage of data, etc. All computerized systems used to generate, measure or evaluate data intended for use should be developed, validated, operated and maintained in a manner consistent with GLP principles.

The procedure for the procurement of equipment, reagents and other materials must be clear and must be carried out in each specific case. In addition, the academic institution should define policies and responsibilities in connection with the joint use of equipment. SOPs applicable to the use of equipment should provide guidance on who may use the equipment, how the equipment is used, records of use and equipment breakdowns.

All persons residing and working in the laboratory, including students, must understand how the equipment and reagents are used (proper SOP). In addition, they must be familiar with laboratory safety measures, how to report equipment failure and accident reporting, and the implementation of sanitary standard operating procedures (SSOP) and other related activities.

Receiving, handling, sampling and storage

A well-designed logistics concept is needed for the reception, storage, handling and disposal of test items, together with provisions for adequate documentation of all procedures related to the handling of test items. The reception, handling, sampling

and storage of samples, reagents and control materials should be prepared in an appropriate manner. It is necessary to establish and maintain a record of the characteristics of the test and reference material, the date of receipt, the date of expiration of the term of use, the quantities received and used during the test. The procedures used for these purposes should maintain a link between the analytical data and the samples from which the data were obtained.

Sample receiving and storage areas must be separate from other sample or reference material storage areas. In order to prevent sample contamination, in the analytical laboratory it is necessary to clearly separate the rooms used for sample preparation, measurement, preparation of reagent solutions, preparation of the reference standard, and rooms for washing glassware. For the storage of samples, reagents and control materials, it is necessary to provide rooms with different temperatures (rooms at room temperature, rooms at the temperature of the refrigerator or at the temperature of the freezer). In some cases, it is necessary to provide conditions that provide protection from light, moisture or oxygen.

All samples and reference materials should be properly identified. For each test, it is necessary to know the identity of the reference material, including the batch number, purity, composition, concentration and other characteristics. Analysts should be familiar with the stability of test and reference materials under storage and testing conditions.

Standard Operating Procedures (SOP)

Standard Operating Procedures (SOPs) are written procedures for conducting activities in a testing laboratory. The SOP should allow qualified personnel to perform the procedure. After becoming familiar with the SOP, the staff needs to be trained in its application. The goal of standard operating procedures is to ensure the quality and integrity of data generated in the testing laboratory. SOPs are usually presented in chronological order of the steps of the activity to which they relate. In test laboratories, SOPs are most often used for performing routine checks, cleaning, maintenance, testing and calibration, analytical methods, definition of raw data, record keeping, reporting, storage, mixing and recovery of data, and description of actions to be taken to eliminate the malfunction equipment [1]. Any deviation from the Standard Operating Procedures should be documented and should be confirmed by the laboratory director and the principal investigator.

The laboratory should use the same form for writing standard operating procedures. It is essential that each SOP contains the following information: purpose, scope, policy, definitions, roles and responsibilities, procedures, references, annexes, and appropriate information in the footnotes. The version and author of the SOP should be indicated in the footnote. Here you can enter data on the date of approval of the document and the person who approved it. In the appendix to the SOP, the following can be attached: technical and safety information, laboratory contacts, references and supporting documentation. Every part of the SOP must be precise. After the change,

it is necessary to indicate the change itself, as well as the date, author and reason for the change to the SOP.

Test execution

From the beginning of the test to the sending of the final report, it is necessary to follow the requirements given by GLP. Before starting the test, a written plan should be made for each test [16]. The test plan should contain the following information: Test identification, test samples and reference materials, sponsor and test facility information, dates, test methods, questions (where applicable), and records [2]. The Laboratory Director should approve the Test Plan. In addition, thay should verify that the plan complies with GLP.

Reporting of test results

During the test, raw data is generated, which represents the original (so-called raw) data collected during the test procedure. After the examination, a final report should be prepared. It contains the following information: descriptive title, identification of the test unit by code or name, characterization of the test unit including purity, stability and homogeneity. Information about the sponsor and the trial facility should include the following information: name and address of the sponsor, the trial director, the principal investigator(s) and phase(s) of the trial, the investigators who contributed to the reports for the final report, the start and end dates of the experiment [1]. GLP requires the security and integrity of data, regardless of whether they are recorded electronically or manually, and that it is possible to reconstruct the way in which the final results and conclusions were obtained [16].

Disposal and preservation of records and materials

Storage and preservation of records and materials should be prepared in an appropriate manner. Test plan, raw (original) data, samples of test and reference materials and final report, and records of all checks performed according to the quality assurance plan, as well as data on qualification, training, experience and job description of personnel. It is necessary to keep records and reports on the maintenance and calibration of the apparatus. Validation documentation for computer systems should be kept in the archive for a period determined by the competent authority. Records must be kept for a long period of time in which they must not be lost or damaged. The storage of all materials and documents should be secure. The facilities and environmental conditions in these facilities should protect archival materials from deterioration.

The success of GLP and related procedures depends on full compliance by participants at all levels, with strong administrative support for all laboratory processes.

A well-established and functional quality management system is an integral part of every diagnostic laboratory [17]. The development and implementation of a

comprehensive quality system in the laboratory is based on good laboratory practice (GLP), quality management (QM), quality assurance (QA) and quality control (QC) [18]. Quality management in the current context can be considered a modern version of the concept of "Good Laboratory Practice" (GLP) used so far [11, 19].

The basic principles of GLP can and should be applied in all operations in the faculty laboratory. All employees in the laboratory and the faculty as a whole, and students should accept and apply GLP and SOPs during their work. For preclinical laboratories that manufacture or test food, cosmetics, and drugs, GLP components focus on quality assurance (QA) and quality control (QC), as well as product safety and/or tests that confirm their reliability [1] . However, academic institutions have a different mandate, that is, the education and training of students, that is, their preparation for a future career. Therefore, the goal of implementing GLP in the faculty's laboratories is to provide uniform training for all students through structured processes.

"Quality" in the teaching laboratory appears as a continuous record of excellence in training [1]. Adopting SOPs across an academic institution facilitates training and provides a means to track inventory and shared equipment while ensuring user safety. Immediate performance results are measured in a manner similar to proactive quality assurance (QA). For example, if the syllabus for a laboratory course in Analytical Chemistry states as a learning objective “preparation of solutions for analysis”, then the methodology for preparing solutions can be written in detail as an SOP. On the other hand, the summative evaluation of students at the end of the semester (for example, the final exam of students) is analogous to reactive quality control (QC) procedures in industrial settings. However, through the adoption of a common SOP, the faculty can assess whether students, laboratory technicians, teaching assistants and professors, and the administration at the faculty consistently perform the operations for which they are in charge [1].

Conclusion

In the coming years, laboratories at higher education institutions will strive to simultaneously apply the quality management system and the principles of good laboratory practice.
In the long term, the application of GLP will greatly affect the improvement of work efficiency and safety in the laboratory.
The practical application of GLP provides students with pre-professional training and strengthens collegial respect.

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ZNAČAJ DOBRE LABORATORIJSKE PRAKSE U LABORATORIJAMA VISOKE MEDICINSKE ŠKOLE PRIJEDOR

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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 instalisala 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, Medicinska laboratorija za obuku studenata*