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Research Article

Implementation of good laboratory practices in the cellular biotechnology laboratory of the biological sciences faculty, Ricardo Palma University

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Abstract

This study aimed to evaluate the impact of implementing Good Laboratory Practices (GLP) in the Cellular Biotechnology Laboratory of Ricardo Palma University. A quasi-experimental pre–post design was applied, including the development of standard operating procedures (SOPs), a structured training programme and a compliance self-inspection. Fourteen participants were evaluated before and after training. The mean knowledge score increased from 10.63 ± 0.93 to 14.93 ± 0.73, representing a 40% improvement. Additionally, compliance with GLP increased across all evaluated categories, with notable improvements in biosafety, SOP implementation, and waste management. These findings suggest that a structured GLP implementation can significantly enhance both knowledge and operational performance in academic laboratories. Future studies should incorporate external audits and objective quality indicators to strengthen validation.

Keywords: Good Laboratory Practices, cellular biotechnology, research quality, laboratory safety, biosafety.

1. Introduction

Biotechnology laboratories play a key role in biomedical research and academic training, especially in areas such as cell culture, bioengineering and biomedicine. In this context, the implementation of Good Laboratory Practices (GLP) is essential to ensure the integrity, reproducibility and reliability of experimental results [1]. GLP, originally developed by the Organization for Economic Co-operation and Development (OECD) and adopted internationally, establishes a set of normative principles that regulate the design, execution, monitoring, documentation and auditing of laboratory studies.

Compliance with these standards not only improves the quality of the data generated but also guarantees the traceability of procedures and reinforces safety in the handling of biological and chemical materials. In academic environments, the adoption of these principles is even more critical, as it allows consolidating a scientific training based on standardized methodologies and framed in international regulations, preparing students for highly regulated professional contexts [2].

In response to this need, the Cellular Biotechnology Laboratory of Ricardo Palma University has undergone an optimization process oriented to the adoption of GLP. The remodelling of the laboratory included the redesign of its facilities under the cleanroom concept, ensuring a controlled environment through the implementation of positive pressure filtered air systems, a key factor in reducing the risk of microbiological contamination in cell cultures [3]. Likewise, a segregated infrastructure with differentiated airlocks for personnel and materials was established to mitigate cross-contamination and improve operational biosafety.

At the same time, a quality management system was developed based on the standardization of operating procedures through the preparation of Standard Operating Procedures (SOP). These documents detail specific protocols for the preparation of reagents, the use and maintenance of critical equipment such as CO_2 incubators and biosafety cabinets, the cleaning and disinfection of work areas, as well as the storage and handling of inputs under traceability and biosafety criteria [4].

To ensure the correct implementation of these procedures, a training plan structured in four phases was established: competency diagnosis, program design, implementation and evaluation of the impact on laboratory operations.

In addition, a system of document control and activity registration was incorporated to monitor environmental conditions, input management and the execution of experimental activities in real time, ensuring compliance with international standards of traceability and auditing of scientific data [5]. These mechanisms not only optimize laboratory management but also guarantee the reproducibility and reliability of experimental studies, facilitating their validation in academic accreditation and institutional certification processes.

This study describes the GLP implementation process in the Cellular Biotechnology Laboratory, describing the structural and methodological changes applied, the evaluation of their impact on the

laboratory's operation and the implications for academic training and research. It is expected that this initiative will contribute to consolidate a quality management model in academic laboratories, aligned with regulatory requirements and international best practices in biotechnology. Therefore, this study aimed to evaluate the impact of implementing Good Laboratory Practices (GLP) on knowledge acquisition and operational compliance in an academic biotechnology laboratory.

2. Methods

2.1 Study design

This study corresponds to a quasi-experimental quality improvement study with a pre–post design without a control group, aimed at evaluating the impact of the implementation of Good Laboratory Practices (GLP) in the Cellular Biotechnology Laboratory of Ricardo Palma University.

2.2 Implementation period

The implementation was carried out during the 2025 academic period, following the remodelling of the laboratory under the cleanroom concept, incorporating positive pressure systems and filtered airflow.

The implementation included five components: structural redesign, development and implementation of standard operating procedures (SOPs), implementation of a document control system, training programme, and compliance self-inspection.

2.3 Laboratory team training programme

The training programme was developed in four stages: diagnosis, programme design, implementation, and evaluation, taking into account the specific needs of the laboratory personnel.

The diagnostic phase included an initial assessment using semi-structured interviews and in situ observation, allowing identification of the knowledge and skills of laboratory personnel in relation to GLP.

Based on this diagnosis, a programme combining theoretical and practical sessions was structured. The content covered key topics such as GLP principles, safe equipment handling, biosafety, process traceability, and record documentation.

The theoretical sessions consisted of workshops explaining the fundamentals of GLP and their application in a university setting. Practical training included demonstrations and supervised exercises related to critical procedures, such as preparation of culture media, use of biosafety cabinets, and cleaning of work areas.

To evaluate the impact of the training, pre- and post-training assessments were conducted to measure progress in knowledge and acquired skills.

A total of 14 participants took part in the training programme, all of whom were involved in academic and research activities in the laboratory during the implementation period (3 professors, 4 thesis students, and 7 undergraduate students).

Inclusion criteria were: active participation in practical sessions or research projects, full attendance in the training programme, and voluntary consent to participate in the evaluations.

2.4 Design and implementation of standard operating procedures (SOPs)

Standard operating procedures were developed for the main laboratory activities, including preparation of reagents and cell culture media, biosafety procedures, cleaning and disinfection of the cleanroom, and routine laboratory procedures, among others. These procedures were accompanied by data recording templates.

In addition, specific SOPs were developed for the use of critical laboratory equipment, including CO_2 incubators, automatic pipettes, and biosafety cabinets, with the aim of ensuring proper handling, operational safety, traceability, and optimal maintenance.

For the development of these procedures, manufacturer manuals, technical specifications, and applicable regulations for each piece of equipment were reviewed and analysed. This allowed identification of best practices for operation and maintenance, ensuring compliance with GLP requirements.

Each SOP included: objective, scope, responsibilities, detailed procedure, associated records, code, version, and effective date.

2.5 Evaluation of the impact of GLP implementation

The impact of GLP implementation was evaluated using two complementary approaches: assessment of knowledge acquired during training and verification of operational compliance through structured self-inspection.

To assess the impact of the training programme, a structured instrument was applied before and after the programme to measure changes in knowledge related to GLP principles. Scores were expressed on a scale from 0 to 20 points, where higher values indicate greater conceptual mastery of GLP.

Results were analysed using descriptive statistics, calculating the mean and standard deviation of pre- and post-training scores.

Additionally, a structured self-inspection was conducted before and after GLP implementation to assess the level of compliance with operational procedures and implemented recording systems.

The self-inspection was carried out using a checklist developed based on GLP principles and good cell culture practice guidelines. The checklist included categories such as:

a) Infrastructure and facilities
b) Standard operating procedures
c) Biosafety
d) Laboratory equipment
e) Materials and reagents
f) Cleaning and disinfection
g) Biological waste management

Each item was classified as "compliant" or "non-compliant", and overall compliance was expressed as the percentage of compliant criteria relative to the total number of evaluated items.

2.6 Document control

Procedures were established to develop, control, and review all documents aimed at ensuring the quality, integrity, and reliability of generated data. A master list was also created to indicate the current status and version of all documents.

2.7 Ethical considerations

This study was conducted within institutional quality improvement activities and did not involve experimental research on humans or animals. The institutional ethics approval was not required for the study. Participation in the evaluations was voluntary and anonymous, and the data were used exclusively for academic and institutional improvement purposes.

3. Results

3.1 Implementation of Good Laboratory Practices

The implementation of Good Laboratory Practices (GLP) in the Cellular Biotechnology Laboratory enabled the establishment of a structured operational and quality management system.

A total of 22 Standard Operating Procedures (SOPs) were developed and implemented, covering critical laboratory processes including infrastructure and environmental control, biosafety, laboratory equipment management, materials and reagents handling, cleaning and disinfection, biological waste management, personnel organization, and staff training. Each SOP was standardized with defined objectives, responsibilities, procedures, and associated records, ensuring traceability and reproducibility of laboratory activities (Table 1)

Table 1: Standard Operating Procedures (SOP) implemented

Code	Category	Description	Implementation Date	Version
FCB-01	Infrastructure and Environmental Conditions	Control of Access and Personnel Flow	15/01/2025	V 1.0
FCB-02	Infrastructure and Environmental Conditions	Monitoring of Environmental Conditions	15/01/2025	V 1.0
FCB-03	Infrastructure and Environmental Conditions	Laboratory Infrastructure Maintenance	15/01/2025	V 1.0
FCB-04	Biosafety	Use and Maintenance of Personal Protective Equipment (PPE)	15/01/2025	V 1.0
FCB-05	Biosafety	Action in Case of Chemical Spills	15/01/2025	V 1.0
FCB-06	Biosafety	Hand Washing	15/01/2025	V 1.0
FCB-07	Laboratory Equipment	Verification and Calibration of Laboratory Equipment	15/01/2025	V 1.0
FCB-08	Laboratory Equipment	Preventive and Corrective Maintenance of Laboratory Equipment	15/01/2025	V 1.0
FCB-09	Materials and Reagents	Reception and Storage of Supplies	15/01/2025	V 1.0
FCB-10	Materials and Reagents	Labeling and Preparation of Reagents	15/01/2025	V 1.0
FCB-11	Cleaning and Disinfection	Cleaning and Disinfection of Critical Areas	15/01/2025	V 1.0
FCB-12	Cleaning and Disinfection	Washing of Laboratory Material	15/01/2025	V 1.0
FCB-13	Biological Waste Management	Management of Biological Waste	15/01/2025	V 1.0
FCB-14	Biological Waste Management	Management of Contaminated Disposable Material	15/01/2025	V 1.0
FCB-15	Biological Waste Management	Management of Sharps Waste	15/01/2025	V 1.0
FCB-16	Personnel organization	Functions Manual	15/01/2025	V 1.0

FCB-17	Personnel organization	Organizational Chart Update Procedure	15/01/2025	V 1.0
FCB-18	Operating Procedures	Standard Operating Procedure for Document Preparation	15/01/2025	V 1.0
FCB-19	Staff Training	Induction Procedure	15/01/2025	V 1.0
FCB-20	Staff Training	Cleaning and Disinfection of Critical Areas	15/01/2025	V 1.0
FCB-21	Staff Training	Washing of Laboratory Material	15/01/2025	V 1.0
FCB-22	Staff Training	Management of Biological Waste	15/01/2025	V 1.0

The implementation of these SOPs contributed to the formalization of laboratory processes and the establishment of a document control system that supports compliance with GLP principles.

3.2 Results of the training programme

A total of 14 participants completed both the pre- and post-training evaluations. The results showed a clear increase in knowledge related to Good Laboratory Practices following the intervention. The mean score increased from 10.63 ± 0.93 in the pre-training evaluation to 14.93 ± 0.73 in the post-training evaluation, representing an approximate 40% improvement in the level of knowledge acquired (Table 2).

Table 2: Comparison of pre- and post-training scores in Good Laboratory Practices (n = 14)

Evaluation	Mean ± SD	Minimum	Maximum
Pre-training	10.63 ± 0.93	9	12
Post-training	14.93 ± 0.73	14	17

Values are expressed as mean ± standard deviation (SD).

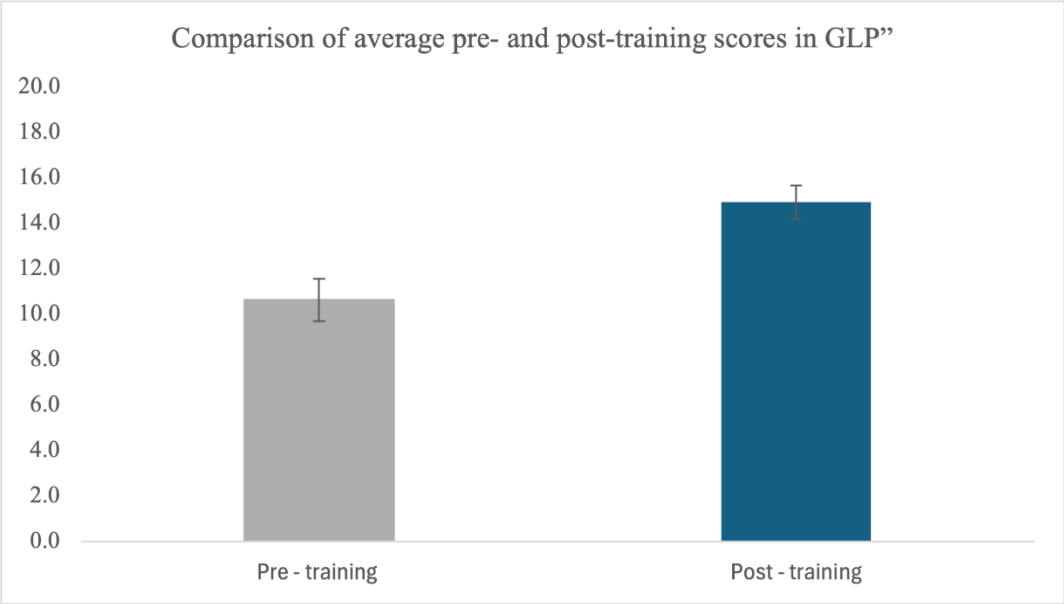

Figure 1. Comparison of pre- and post-training scores in Good Laboratory Practices (GLP) (n = 14)

Additionally, the minimum score increased from 9 to 14, while the maximum score increased from 12 to 17, indicating an overall upward shift in performance across all participants. The variability of the scores decreased after the intervention, as reflected by the reduction in standard deviation. As shown in Figure 1, a consistent increase in scores was observed after the implementation of the training programme.

3.3 Results of the structured self-inspection.

The structured self-inspection enabled the evaluation of compliance with Good Laboratory Practices (GLP) before and after the implementation across nine operational categories, based on a checklist comprising a total of 90 evaluated items (10 items per category) (Table 3).

Table 3: Number of checklist items evaluated in the GLP self-inspection

Category	**Total items evaluated**
Infrastructure and facilities	10
Standard operating procedures (SOPs)	10
Biosafety	10
Personnel training	10
Laboratory equipment	10
Personnel organization	10
Cleaning and disinfection	10
Materials and reagents	10
Biological waste management	10
Total	**90**

As shown in Table 4, compliance levels prior to the implementation of GLP were generally low, ranging from 0% to 30% across most evaluated categories. Following the implementation, a substantial improvement in compliance was observed, with values increasing to between 60% and 100%, depending on the category.

Notably, the most pronounced improvements were observed in categories directly related to standardization and biosafety. Specifically, compliance in Standard Operating Procedures (SOPs) increased from 0% to 80%, while biosafety and biological waste management reached full compliance (100%), representing increases of 80 percentage points. Similarly, cleaning and disinfection improved from 30% to 100%, corresponding to a 70-percentage point increase.

In addition, moderate improvements were observed in personnel organization (from 30% to 90%), as well as in infrastructure and facilities, laboratory equipment, and materials and reagents, each increasing from approximately 30% to 80%.

Although all categories showed improvement, the lowest increase was observed in personnel training, which rose from 20% to 60%. Despite this, the improvement remains relevant within the context of progressive implementation of GLP.

Overall, these findings indicate that the implementation of GLP resulted in a substantial and consistent increase in compliance across all evaluated operational areas, particularly in those associated with process standardization, biosafety, and contamination control. As illustrated in Figure 2, compliance increased across all evaluated categories after GLP implementation.

Table 4. Compliance with Good Laboratory Practices (GLP) by category before and after implementation

GLP category	**Compliance before implementation (%)**	**Compliance after implementation (%)**	**Improvement (pp)**
Infrastructure and facilities	30	80	50
Standard operating procedures (SOPs)	0	80	80
Biosafety	20	100	80
Personnel training	20	60	40
Laboratory equipment	30	80	50

Personnel organization	30	90	60
Cleaning and disinfection	30	100	70
Materials and reagents	30	80	50
Biological waste management	20	100	80

pp: percentage points

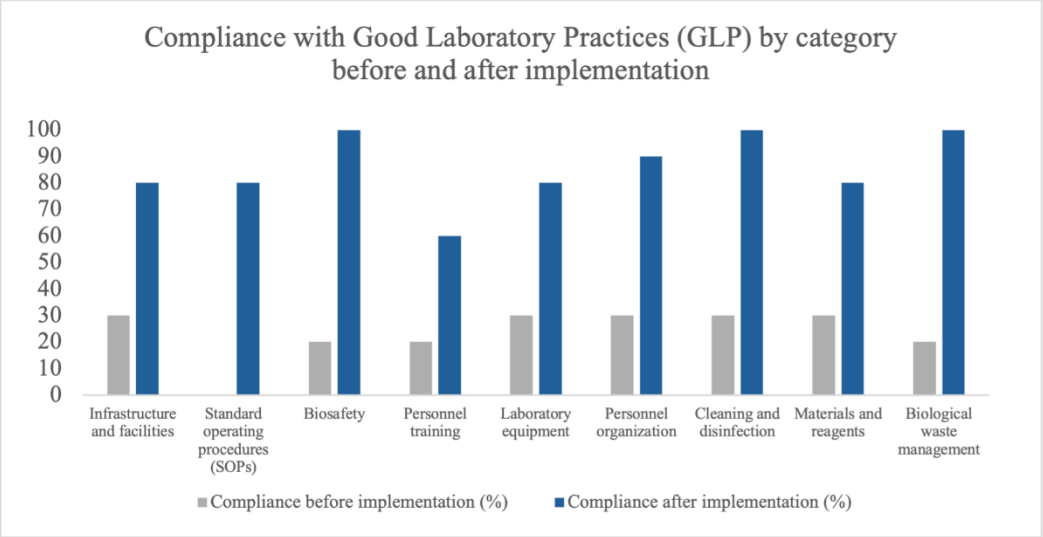

Figure 2. Compliance with Good Laboratory Practices (GLP) by category before and after implementation

Discussion

The implementation of Good Laboratory Practices (GLP) in the Cellular Biotechnology Laboratory resulted in measurable improvements in both knowledge acquisition and operational compliance. The observed increase in training scores (from 10.63 ± 0.93 to 14.93 ± 0.73) indicates that a structured training programme can effectively strengthen understanding of GLP principles in academic settings. This finding is consistent with previous reports highlighting the importance of systematic training in improving laboratory quality and safety awareness [6].

In addition to educational outcomes, the structured self-inspection revealed substantial improvements in compliance across all evaluated categories, particularly in biosafety, standard operating procedures, and biological waste management. These results are in line with the principles described in the Good Cell Culture Practice guidelines, which emphasize standardization, documentation, and contamination control as critical elements for ensuring data reliability and laboratory safety (5,3).

The significant increase in compliance related to SOPs (from 0% to 80%) underscores the central role of standardized procedures in laboratory quality systems. Previous studies have demonstrated that the implementation of SOPs contributes to reproducibility, traceability, and consistency in experimental workflows [4]. Similarly, improvements observed in cleaning and disinfection and biosafety practices reflect the effectiveness of integrating procedural standardization with practical training.

Despite these advances, the relatively lower improvement observed in personnel training compliance (20% to 60%) suggests that behavioral and organizational changes may require longer implementation periods. This aligns with quality management literature, which indicates that the consolidation of a quality culture is a gradual process that depends on continuous training and monitoring [2].

This study contributes to the limited body of evidence on the implementation of GLP in academic laboratories, demonstrating that structured interventions combining infrastructure improvements, SOP development, training, and internal evaluation can significantly enhance laboratory performance. However, some limitations should be acknowledged. The study was conducted in a single laboratory with a limited sample size (n = 14), and the evaluation relied on internal self-inspection rather than external auditing. Additionally, microbiological or contamination indicators were not included.

Future studies should incorporate larger sample sizes, external validation mechanisms, and objective performance indicators, such as contamination rates or non-conformity records, to further strengthen the evidence base.

Conclusion

The implementation of Good Laboratory Practices (GLP) in the Cellular Biotechnology Laboratory led to measurable improvements in both knowledge acquisition and operational compliance. The structured training programme significantly increased participants' understanding of GLP principles, as evidenced by the improvement in evaluation scores.

Furthermore, the implementation of standard operating procedures (SOPs), together with a document control system and structured self-inspection, contributed to a substantial increase in compliance across all evaluated categories. The most notable improvements were observed in biosafety, cleaning and disinfection, and biological waste management, highlighting the effectiveness of standardized procedures in strengthening laboratory practices.

These findings suggest that the integration of infrastructure improvements, procedural standardization, and targeted training constitutes an effective strategy for enhancing quality and safety in academic laboratories.

However, the study was limited by its small sample size and the use of internal self-inspection. Therefore, future research should incorporate external evaluation mechanisms and objective performance indicators to further validate the impact of GLP implementation.

Overall, this study provides practical evidence supporting the feasibility and benefits of implementing GLP in academic laboratory settings, with potential applicability to similar institutions seeking to strengthen their quality management systems.

Authors Contributions

J.N conceptualized the study. J.M, H.G and E.C have all contributed to the manuscript's writing, reviewing, and editing. E.C designed the figures.

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Not applicable.

Conflicts of Interest

All the authors declare that they do not have conflicts of interest.

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