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REGULATIONS AND STANDARDS IN GOOD LABORATORY PRACTICES FOR CELL CULTURES: A REVIEW

NORMATIVAS Y ESTÁNDARES EN BUENAS PRÁCTICAS DE LABORATORIO PARA CULTIVOS CELULARES: UNA REVISIÓN

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REVIEW ARTICLES

ABSTRACT

Introduction: Good Laboratory Practices (GLP) in cell culture are essential to ensure the quality and reproducibility of results in scientific and biomedical research. This review aimed to comprehensively analyze the regulations and standards related to GLP in the management of cell cultures, emphasizing their importance for the quality and reliability of scientific findings. A literature review was conducted, encompassing 33 articles published between 1994 and 2023 in academically relevant databases such as Scopus, ProQuest, ResearchGate, ScienceDirect, Springer, among others. Search terms included "Good Laboratory Practices," "GLP," "regulations," and "cell cultures," with specific selection criteria applied. Extracted data covered regulatory frameworks, governing bodies, and areas of application. The findings highlight that guidelines issued by organizations such as the Organisation for Economic Co-operation and Development (OECD), the U.S. Food and Drug Administration (FDA), and the European Medicines Agency (EMA) are essential for the proper implementation of GLP in laboratories working with cell cultures. Furthermore, critical aspects such as precise documentation of procedures, continuous staff training, and implementation of quality and sterility control measures are addressed. The review concludes that the rigorous application of GLP is crucial for ensuring reproducibility, quality, and safety of results, as well as for compliance with regulatory standards—thereby strengthening scientific integrity and fostering advances in biotechnology and biomedicine.

Keywords: Laboratories, Pharmaceutical preparations, Regulations, Reference standards, Cells, Cultured. (Source: MESH-NLM)

RESUMEN

Introducción: Las buenas prácticas de laboratorio (BPL) en cultivos celulares son fundamentales para garantizar la calidad y reproducibilidad de los resultados en la investigación científica y biomédica. El objetivo de esta revisión fue analizar de manera integral las normativas y estándares relacionados con las BPL en el manejo de cultivos celulares, destacando su relevancia en la calidad y reproducibilidad de los resultados científicos. Se llevó a cabo una revisión bibliográfica, abarcando un total de 33 artículos publicados en bases de datos de relevancia académica como Scopus, ProQuest, ResearchGate, Sciencedirect, Springer, entre otras, entre 1994 y 2023. Se utilizaron términos como "buenas prácticas de laboratorio", "BPL", "normativas", "cultivos celulares", aplicando criterios de selección. Los datos extraídos incluyen normativas, organismos reguladores y áreas de aplicación. Los resultados destacan que las directrices emitidas por organismos como la Organización para la Cooperación y el Desarrollo Económicos, la Administración de Alimentos y Medicamentos de los Estados Unidos y la Agencia Europea de Medicamentos son fundamentales para la correcta implementación de las BPL en laboratorios que trabajan con cultivos celulares. Además, se abordan aspectos críticos como la documentación precisa de procedimientos, la capacitación continua del personal y la implementación de medidas de control de calidad y esterilidad. Se concluye que la aplicación rigurosa de las BPL es crucial para la reproducibilidad, calidad y seguridad de los resultados, así como para el cumplimiento de normativas regulatorias, fortaleciendo la integridad científica y promoviendo el desarrollo de la biotecnología y la biomedicina.

Palabras clave: Laboratorios; Preparaciones farmacéuticas; Reglamentación; Estándares; Células cultivadas (Fuente: DeCS- BIREME)

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INTRODUCTION

In the field of scientific and biomedical research, the rigorous implementation of Good Laboratory Practices (GLP) is essential to ensure the quality and reproducibility of results in studies involving cell cultures [1]. These practices consist of a set of rules and standards that must be precisely followed by researchers and laboratory technicians[2]. In the context of cell cultures, international regulations and standards provide a detailed framework for the proper handling of cells, from their collection, storage, and manipulation to their disposal. In this regard, the Organisation for Economic Co-operation and Development (OECD) has developed specific guidelines addressing the design and maintenance of facilities, staff training, and data management [3,4].

The application of GLP is subject to oversight by regulatory agencies, with the aim of ensuring the reliability and reproducibility of the results obtained [5]. In the United States, the Food and Drug Administration (FDA) and the Environmental Protection Agency supervise the application of GLP in laboratories working with cell cultures. These agencies establish strict requirements for documenting procedures, validating equipment and methods, and training personnel involved in cell culture studies, ensuring that the generated data is reliable and useful in evaluating pharmaceutical and chemical products [6,7]. In turn, the European Union implements a comprehensive approach that combines Good Manufacturing Practices (GMP) with GLP to ensure that products derived from cell cultures meet the required quality and safety standards for use in clinical trials and therapeutic applications [8]. This approach covers aspects such as continuous monitoring of culture conditions, contaminant control, and traceability of materials used [9].

Together, these regulatory frameworks provide a global framework that enables laboratories to operate with high levels of precision and accuracy, generating reliable data that contribute to the advancement of research [10].

GLP is essential not only for the protection of human health and the environment but also for fostering scientific collaboration, ensuring regulatory compliance, and promoting the development of new technologies [11]. Adherence to these norms and standards increases confidence in research results, especially in the field of cell cultures, where the reproducibility and validity of data are crucial for scientific progress and technological innovation [12]. In this context, the objective of this review article is to analyze in detail the current regulations and standards related to Good Laboratory Practices in the handling of cell cultures.

METHODS

General design

A scope review study was conducted with a descriptive approach, aimed at identifying, analyzing, and synthesizing the regulations and standards related to GLP in cell cultures. The study considered scientific literature published between 1998 and 2023.

Study search

A comprehensive search was conducted in recognized academic databases, including Scopus, ProQuest, ResearchGate, ScienceDirect, and Springer. Combinations of terms such as "Good Laboratory Practices," "GLP," "regulations," and "cell cultures" were used. Additionally, institutional repositories from international organizations such as the Organisation for Economic Cooperation and Development (OECD), the Food and Drug Administration (FDA), and the European Medicines Agency (EMA) were manually consulted.

Selection criteria

Studies, technical documents, and regulatory guidelines explicitly addressing GLP in the context of cell cultures were included. Opinion articles, non-peer-reviewed studies, and those not directly related to the topic were excluded. Duplicates identified across the different databases were also removed to avoid redundancies in the analysis.

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Variables

The variables of interest were: issuing organization of the regulation, type of document (guideline, standard, or regulation), country of origin, year of publication, and scope of application (regulatory, technical, or training). Aspects related to the content of GLP, such as procedure documentation, quality control, staff training, and traceability, were also considered.

Instruments and procedures for data collection

A structured template in Microsoft Excel 2016 was designed to organize the collected information. Each record was individually examined, and if the primary source did not contain all necessary data, the information was supplemented with documents available in official institutional portals. The matrix allowed for the systematic organization of relevant elements for analysis.

Analysis plan

The analysis was qualitative, focusing on a narrative synthesis. The data were categorized according to predefined thematic axes, such as international standards, quality control, biosafety, and professional training. No inferential statistical tests were applied due to the descriptive focus of the review.

Ethical aspects

Since the study only used publicly accessible secondary sources without sensitive or identifiable information, approval from a research ethics committee was not required. Scientific rigor and academic integrity were ensured through the proper citation of all sources used.

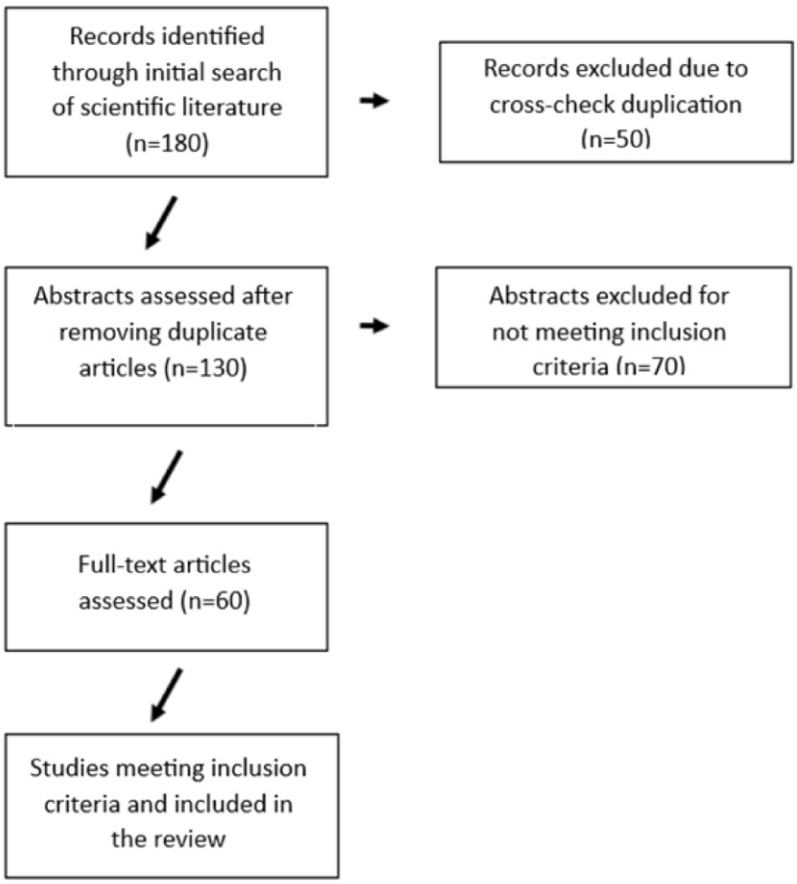

Figure 1. Flowchart of the process of identification, selection, and inclusion of studies in the review, based on records obtained from scientific databases and international regulatory repositories.

reproducibility, leading to duplicated efforts, resource waste, and contradictory results. Detailed documentation and strict adherence to SOPs ensure that other scientific teams can replicate the experiments accurately, thereby strengthening the credibility and robustness of the findings[1].

In the industrial setting, standardized SOPs are essential to comply with regulatory requirements and ensure the quality of biological products. The production of vaccines, cell therapies, and other products derived from cell cultures requires highly controlled and documented cultivation conditions, essential to meet international standards of safety and efficacy [18]. The standardization of pre-culture SOPs is an indispensable practice for achieving controlled experimental environments, protecting the authenticity of cell lines, preventing contamination, and ensuring scientific reproducibility. Furthermore, these procedures become key tools in regulatory compliance and the development of safe, effective, and scientifically robust biotechnologies.

Guaranteeing the quality of materials and methods

The quality of the materials and methods used in cell cultures is essential for obtaining consistent, reliable, and reproducible results. The rigorous implementation of regulations and standards ensures that each stage of the process meets the necessary quality criteria to validate the results obtained. Maintaining consistency in the materials used is crucial, as any variability in their components can significantly influence experimental results, compromising the integrity of in vitro studies [19]. Reagents and culture media must be of high purity and certified by accredited suppliers, who must provide quality documentation such as certificates of analysis (CoA) to guarantee safety, efficacy, and compliance with product standards. This documentation ensures the absence of contaminants that could alter cell growth or interfere with experimental results.

Furthermore, validation tests between batches must be conducted to minimize differences that may affect cell behavior [1]. Materials that come into direct contact with cells or tissues require special attention due to their ability to modify the properties of the culture. Therefore, it is essential that the equipment used is suitable for its specific purpose and subjected to rigorous quality assurance procedures, which should cover everything from acquisition and installation to calibration, performance monitoring, and periodic maintenance[4].

Continuous analysis and monitoring of quality control data not only allows for verifying that parameters remain within acceptable limits, but also enables the early detection of abnormal trends. Even when data remain within established ranges, a gradual variation pattern, such as a sustained increase, can indicate underlying problems that require corrective attention. This proactive approach to monitoring facilitates the timely identification and resolution of deviations before they become significant failures in the cellular systems [4].

An efficient Quality Management (QM) system must incorporate multiple essential components to ensure the accuracy and reliability of processes and results. These components include verifying that all materials — including cells, tissues, and equipment — are appropriate for their intended use and meet established quality standards; implementing proper storage practices, considering parameters such as temperature, humidity, and exposure to light; and rigorously monitoring specific batches of critical materials to detect any variation that could affect their performance. This is particularly relevant in the case of sensitive reagents, such as serum, which may require validation tests before use [20].

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RESULTS

Good Laboratory Practices

GLP constitute a set of principles, procedures, and standards designed to ensure the quality, reproducibility, and reliability of the results generated in scientific studies [11]. Their origin dates back to the 1960s, following various incidents in the pharmaceutical industry in the United States, which led to the creation of Good Manufacturing Practices (GMP) as a mechanism to ensure the identity, safety, and efficacy of drugs [13]. In this context, GLP emerged, focused on ensuring quality in laboratory testing, including the standardization of methods and the assurance of controlled experimental conditions.

GLP has become an essential standard in the pharmaceutical and biotechnology industries, particularly in the field of cell cultures. These practices are critical for the production of vaccines, biologic drugs, cell therapies, enzymes, antibodies, and recombinant proteins. Their implementation spans from preclinical research to large-scale production, allowing for thorough quality control and ensuring the validity and reproducibility of the data obtained[14,15].

The systematic application of GLP promotes not only the quality of products and processes but also the competitiveness in the biotechnology sector, fostering a culture of quality and continuous improvement within institutions. Additionally, it promotes the development of new skills in work teams, facilitating the adoption of demanding methodological standards at all stages of scientific and industrial processes.

Establishment of operational procedures prior to culturing

The standardization of pre-culture operational procedures (SOPs) is crucial to guarantee reproducibility, quality, and safety in scientific research and biotechnological applications. Cell cultures are essential tools in biomedicine and biotechnology, with applications ranging from the study of cellular physiology to the large-scale production of artificial tissues and biological products [1]. However, the inherent variability of cultivation methods and conditions can compromise the reliability of results, making the standardization of procedures indispensable. One of the primary benefits of SOPs in cell cultures is the acquisition of consistent and reproducible results. To achieve this, it is essential to maintain a homogeneous and controlled culture environment, taking into account parameters such as temperature, pH, nutrient and gas concentrations, as well as sterility conditions. The combined adoption of GLP and Good Cell Culture Practices (GCCP) provides a structured framework for the development, implementation, and monitoring of SOPs, favoring scientific integrity and the safety of procedures[16].

Standardization also plays a key role in the handling of cell lines, as these can undergo genetic and phenotypic alterations that modify their behavior and compromise the validity of experiments. Implementing rigorous SOPs for the manipulation and maintenance of cell lines—including protocols for cryopreservation, thawing, subculturing, and monitoring—helps preserve their authenticity and functionality [1]. This is especially important in collaborative studies, where consistency between samples is crucial for the joint interpretation of results.

Additionally, cross-contamination and cell authenticity are two critical aspects addressed through standardization. Contamination by bacteria, fungi, or mycoplasma can alter results and compromise biosafety. SOPs include strict sterilization practices, microbiological monitoring, and procedure validation to prevent these issues [4]. Moreover, the authenticity of cell lines is verified through genetic characterization techniques (such as STR) and phenotypic assessments, ensuring that the cells used correspond to the declared line and have not been replaced or inadvertently mixed [17]. Another essential aspect is reproducibility. This is a fundamental principle in science, as it allows experiments to be replicated by other researchers. The absence of standardized SOPs compromises

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On the other hand, authentication and verification of cell lines are crucial to prevent cross-contamination and the use of misidentified cells. Previous studies have shown that a significant percentage of cell lines used in research do not correspond to the identity they are attributed to, which can lead to experimental errors and compromise reproducibility. To address this issue, it is recommended to perform authentication through Short Tandem Repeat (STR) tests, a key strategy to confirm cellular identity. Furthermore, it is essential to follow standardized and rigorous procedures in the preparation and maintenance of cell cultures. These procedures should include everything from disinfecting the work area to the aseptic handling of all materials, with the aim of minimizing the risk of cross-contamination.

The quality of cell culture also depends on the storage and shelf life of the culture media. These should be stored at the recommended temperature — generally between 2 °C and 8 °C — and protected from direct light to prevent degradation and preserve their functionality during the experiment [20]. Sterility is another critical aspect in cell culture handling. The strict application of decontamination protocols, the use of properly sterilized equipment, and staff training in aseptic techniques are essential to prevent bacterial, fungal, or viral contamination, and to ensure the integrity of the culture.

In addition, detailed documentation of all materials and methods used is crucial to ensure traceability and experimental reproducibility. In this regard, Electronic Laboratory Notebooks (ELN) are recommended tools to improve the accuracy, accessibility, and organization of information. These systems allow for documenting every phase of the experimental process, facilitating the verification and review of the generated data [21]. The traceability of materials, including documentation of sources and the inclusion of CoA for each reagent batch, is key to accurately assessing their impact on experimental results and ensuring the quality of the inputs used [4].

The technical competence of personnel is another determining factor in the successful application of GLP. Continuous training in cell culture techniques, quality control, and biosafety regulations is necessary to ensure that personnel stay updated with scientific and technological advancements. Frequent staff rotation or lack of proper training can introduce significant variability into results and negatively affect the quality of the generated data [17].

Continuous evaluation and improvement of processes are fundamental principles within GLP. The implementation of internal and external audits allows for detecting opportunities for improvement and updating protocols in line with the most recent evidence and international standards. Regulations such as the guidelines from the International Organization for Standardization (ISO) and the Food and Drug Administration (FDA) provide robust frameworks for implementing quality management systems [4].

Documentation of information

The reproducibility of experiments in cell culture, one of the fundamental pillars of scientific research, largely depends on the quality, accuracy, and completeness of the documentation. The lack of detailed information on methods, materials, and experimental conditions has been identified as one of the main causes of reproducibility issues in preclinical studies [22]. Even small variations in protocols can lead to significantly different results [23], making it imperative that researchers document clearly and completely all aspects of their experiments. This includes the cell line used and its genetic characteristics, culture media, supplements, equipment, incubation conditions, and applied procedures. Documentary traceability refers to the ability to track all elements and steps of an experiment from its origin to the final results. This requires maintaining detailed records of all reagents, equipment, and procedures, in order to identify and correct possible errors or deviations. This traceability is achieved by systematically recording the culture media, added supplements, and specific incubation

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conditions.

The exact composition of the medium, serum concentration, antibiotics, growth factors, and other substances[24] should be documented, as well as parameters like temperature, CO_2 level, and humidity. Any variation in these parameters during the course of the experiment must be properly recorded [25]. Documentation should also include the methods used for cell passage and subculturing, specifying the reagents used (e.g., trypsin), incubation times[26] , as well as the description and calibration of the equipment used [27]. It is essential to record these data in real-time and not retrospectively, to avoid omissions or errors[23]. The use of standardized work sheet formats and validated protocols helps ensure consistency in the record-keeping [25]. Additionally, internal quality controls are necessary to authenticate the integrity and accuracy of the documentation before results are disseminated[22].

Accurate and complete documentation of materials and methods not only ensures traceability and reproducibility but also strengthens the credibility of the findings. Researchers who adhere to these good practices are better positioned to replicate their own studies and contribute to the advancement of scientific knowledge in their community.

Biosafety management in cell cultures

Biosafety in cell cultures is regulated by national and international guidelines based on ethical standards and principles of scientific responsibility [28]. The effective implementation of biosafety measures is essential to protect the integrity of experimental work, the health of personnel, public health, and the environment[29]. Given that the use of cell cultures presents various biosafety challenges, it is essential to conduct thorough biological risk assessments before initiating any procedure. These assessments help identify potential risks, estimate their likelihood of occurrence, and evaluate their possible consequences [29]. Both the intrinsic characteristics of the cell culture and any subsequently acquired properties should be considered, as well as the possibility of deliberate contamination with pathogenic agents[30].

Managing these risks involves identifying them, implementing mitigation measures, and reevaluating the residual risk to ensure it has been reduced to an acceptable level. The risk assessment plan should consider physical, chemical, and biological risks, extending beyond the laboratory to include the entire facility and its environment[1].

While the assignment of biosafety containment levels may vary depending on the context, it is recognized that most containment protocols aim to prevent inadvertent contamination of cell cultures and reduce hazards to personnel. In particular, activities involving human or primate cell cultures should be carried out under containment level 2 conditions, using class II biosafety cabinets and adhering to Good Laboratory Practices[29].

Ethics and laws

Research involving biological materials must adhere to fundamental ethical principles such as human dignity, scientific honesty, equity, and social responsibility. These principles guide scientific practice towards responsible, respectful, and transparent development [31]. In the context of cell and tissue culture, there is a legal and ethical obligation to ensure the welfare, responsibility, and compliance with regulations, regardless of the cellular origin. Before starting any experimental activity, a thorough review of applicable legal, ethical, and regulatory provisions is essential [32]. In Peru, the regulatory framework related to the use of biological material in cell cultures includes several instruments. Supreme Decree No. 017-2006-SA regulates clinical trials, establishing procedures and requirements to protect participants' rights and safety, as well as the integrity of the data obtained [33]. In addition, Law No. 22/2006-PE promotes the safe and responsible use of modern biotechnology, ensuring that research meets international biosafety and ethical standards[34].

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Comprehensive training of personnel

Training laboratory personnel is a key element for the compliance with GLP [14]. A comprehensive training program should include solid initial training, continuous skill development, and periodic performance evaluation. Keeping up-to-date with new methodologies and technologies, as well as providing systematic feedback, helps maintain a high level of professional competence.

Key areas of training include: laboratory procedures, cell and tissue handling, quality control, documentation, safety, legislation, and ethical research principles [1]. All personnel should be familiar with applicable regulations, guidelines, and laws at the institutional, national, and international levels [35]. This training not only ensures regulatory compliance but also contributes to operational efficiency, laboratory safety, and the generation of reliable and high-quality scientific results[35].

CONCLUSION

The rigorous implementation of Good Laboratory Practices (GLP) in cell cultures is essential to ensure the quality, reproducibility, and reliability of results in scientific and biomedical research. The standardization of procedures, cell line authentication, precise documentation, and continuous staff training are essential pillars for ensuring the integrity of studies. Moreover, compliance with ethical and legal regulatory frameworks strengthens scientific credibility and promotes responsible development in biotechnology and biomedicine. In light of the advancement of new technologies, such as organoids and 3D bio-printing, it is necessary to adapt and harmonize existing standards to facilitate collaborative, high-impact research.

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REFERENCES

1.Pamies D, Leist M, Coecke S, Bowe G, Allen DG, Gstraunthaler G, et al. Guidance document on Good Cell and Tissue Culture Practice 2.0 (GCCP 2.0). ALTEX - Altern Anim Exp. 2022;39(1):30–70.doi:10.14573/altex.2111011

2. Salgar JB, Bais SK, Teli AS. Review on Good Laboratory Practices. Int J Adv Res Sci Commun Technol. 2023;3(1):338–49.doi:10.48175/IJARSCT-8307

3. OECD. The Role and Responsibility of the Sponsor in the Application of the Principles of GLP [Internet]. 1998 [citado el 3 de marzo de 2025]. Disponible en: https://www.oecd.org/en/publications/the-role-and-responsibility-of-the-sponsor-in-the-application-of-the-principles-of-glp_9789264078734-en.html.

4. OECD. Guidance Document on Good In Vitro Method Practices (GIVIMP) [Internet]. 2018 [citado el 3 de marzo de 2025]. Disponible en: https://www.oecd.org/en/publications/guidance-document-on-good-in-vitro-method-practices-givimp_9789264304796-en.html

5. Nguyen L, Leach A, Piwowar-Manning E, Marzinke M, Levesque A, Gregorio C, et al. Strengthening the Application of the DAIDS GCLP Guidelines: The Implementation of an Integrated Laboratory Oversight Framework. AIDS Res Hum Retroviruses. 2024;40(11):622–30.doi:10.1089/aid.2024.0042

6. Chen Z. Good Laboratory Practice (GLP) 101 – Regulations and Basic Studies. Disponible en: https://www.fda.gov/media/165993/download.

7. US EPA O. Good Laboratory Practices Standards Compliance Monitoring Program [Internet]. 2013 [citado el 3 de marzo de 2025]. Disponible en: https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program.

8. Cuende N, Ciccocioppo R, Forte M, Galipeau J, Ikonomou L, Levine BL, et al. Patient access to and ethical considerations of the application of the European Union hospital exemption rule for advanced therapy medicinal products. Cytotherapy. 2022;24(7):686–90.doi:10.1016/j.jcyt.2022.03.007

9. Good manufacturing practice - European Medicines Agency (EMA) [Internet]. 2022 [citado el 3 de marzo de 2025]. Disponible en: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice.

10. Doneski L. Good Laboratory Practice (GLP): An Overview for the Analytical Chemist. LCGC International. 2023;41(9):381–5.doi:10.56530/lcgc.na.un1878g5

11. Cervantes Peralta M, Gutiérrez Rico LM, Reynoso Zárate AF, Canihua Rojas J, López Galán EE, Munarriz Aedo JS, et al. MANUAL DE BUENAS PRÁCTICAS DE LABORATORIO [Internet]. Instituto Nacional de Innovación Agraria; 2021 [citado el 3 de marzo de 2025]. Disponible en: https://hdl.handle.net/20.500.12955/1375.

12. Ludwig TE, Andrews PW, Barbaric I, Benvenisty N, Bhattacharyya A, Crook JM, et al. ISSCR standards for the use of human stem cells in basic research. Stem Cell Rep. 2023;18(9):1744–52.doi:10.1016/j.stemcr.2023.08.003

13. Red PARF G de T en BP de L. Buenas prácticas de la OMS para laboratorios de control de calidad de productos farmacéuticos [Internet]. Organización Mundial de la Salud (OMS); 2010 [citado el 3 de marzo de 2025]. Disponible en: https://www3.paho.org/hq/dmdocuments/2011/Espanol-control-calidad-laboratorios-farmaceuticos.pdf.

14. World Health Organization. Laboratory Quality Management System Handbook [Internet]. 2011 [citado el 3 de marzo de 2025]. Disponible en: https://iris.who.int/bitstream/handle/10665/44665/9789241548274_eng.pdf?sequence=1.

15. Dos Santos ER, Rodrigues ECC, Granjeiro JM. The principles of good laboratory practices in biotechnology: multicriteria decision aid (MCDA) as an innovative model for transferring knowledge. Accreditation Qual Assur. 2023;28(5):197–208. doi:10.1007/s00769-023-01546-x

16. Gstraunthaler G. Standardisation in cell and tissue culture: the need for specific GLP guidelines in the cell culture laboratory (Good Cell Culture Practice – GCCP). ALTEX. 2005;22(Spec Issue 2):230–3.

17. Pamies D, Bal-Price A, Simeonov A, Tagle D, Allen D, Gerhold D, et al. Good Cell Culture Practice for stem cells and stem-cell-derived models. ALTEX. 2017;34(1):95–132.doi:10.14573/altex.1607121

18. Dwarshuis NJ, Parratt K, Santiago-Miranda A, Roy K. Cells as advanced therapeutics: State-of-the-art, challenges, and opportunities in large scale biomanufacturing of high-quality cells for adoptive immunotherapies. Adv Drug Deliv Rev. 2017;114:222–39. doi:10.1016/j.addr.2017.06.005

19. Amanda Capes-Davis, R. Ian Freshney. Freshney's Culture of Animal Cells: A Manual of Basic Technique and Specialized Applications, 8th Edition | Wiley [Internet]. 2016 [citado el 3 de marzo de 2025]. Disponible en: https://www.wiley.com/en-us/Freshney's+Culture+of+Animal+Cells%3A+A+Manual+of+Basic+Technique+and+Specialized+Applications%2C+8th+Edition-p-9781119513049.

20. Krebs A, Waldmann T, Wilks MF, Van Vugt-Lussenburg BMA, Van der Burg B, Terron A, et al. Template for the description of cell-based toxicological test methods to allow evaluation and regulatory use of the data. ALTEX. 2019;36(4):682–99. doi:10.14573/altex.1909271

21. Babic Z, Capes-Davis A, Martone ME, Bairoch A, Ozyurt IB, Gillespie TH, et al. Incidences of problematic cell lines are lower in papers that use RRIDs to identify cell lines. eLife. 2019;8:e41676.doi:10.7554/eLife.41676

22. Begley CG, Ellis LM. Drug development: Raise standards for preclinical cancer research. Nature. 2012;483(7391):531–3.doi:10.1038/483531a

23. Peat J, Barton B, Elliott E. Correlation and Regression. En: Statistics Workbook for Evidence-Based Health Care [Internet]. John Wiley & Sons, Ltd; 2008 [citado el 3 de marzo de 2025]. p. 93–109.doi:10.1002/9781444300499.ch7

24. Wilson & Hunt. Wilson & Hunt Molecular Biology Of The Cell The Problems Book 6th Edition C 2015 [Internet]. 2015 [citado el 3 de marzo de 2025]. Disponible en: http://archive.org/details/WilsonHuntMolecularBiologyOfTheCellTheProblemsBook6thEditionC2015.

25. Martínez Carpio PA, Navarro Moreno MA. El cultivo celular en la investigación básica del cáncer de mama. Rev Oncol Publ Of Fed Soc Esp Oncol Inst Nac Cancerol México. 2003;5(4):184–91.doi:10.1007/BF02712400

26. Phelan MC. Basic techniques in mammalian cell tissue culture. Curr Protoc Cell Biol. 2007;Chapter 1:Unit 1.1.doi:10.1002/0471143030.cb0101s36

27. Bonavida B. Methods in Molecular Biology Series [Internet]. New York: Springer; 2015 [citado el 3 de marzo de 2025]. (Methods in Molecular Biology; vol. Cancer Cell Culture). Disponible en: https://www.springer.com/series/7651.

28. Idowu B, Di Silvio L. Principles of good laboratory practice (GLP) for in vitro cell culture applications. En: Salih V, editor. Standardisation in Cell and Tissue Engineering [Internet]. Woodhead Publishing; 2013 [citado el 3 de marzo de 2025]. p. 127–47. (Woodhead Publishing Series in Biomaterials). doi:10.1533/9780857098726.2.127

29. Herman P, Pauwels K. Biosafety Recommendations on the Handling of Animal Cell Cultures. En: Al-Rubeai M, editor. Animal Cell Culture [Internet]. Cham: Springer International Publishing; 2015 [citado el 3 de marzo de 2025]. p. 689–716. doi:10.1007/978-3-319-10320-4_22

30. Pauwels K, Herman P, Van sVaerenbergh B, Dai Do Thi C, Berghmans L, Waeterloos G, et al. Animal Cell Cultures: Risk Assessment and Biosafety Recommendations. Appl Biosaf. 2007;12(1):26–38. doi:10.1177/153567600701200105

31. Cardozo-de Martínez CA, D. Sorokin P, Sotomayor MA. Bioética y derecho a decidir sobreel propio cuerpo, sus extensiones, productos y derivados: el discutible caso de las células HeLa. Med Lab. 2015;21(11–12):565–78.doi:10.36384/01232576.150

32. Vargas B, Elsy N. Técnicas de cultivos celulares e ingeniería de tejidos. 2016 [citado el 3 de marzo de 2025]; Disponible en: http://ilitia.cua.uam.mx:8080/jspui/handle/123456789/143.

33. Roque-Henriquez JC, Minaya-Martínez GE, Fuentes-Delgado DJ. Reglamento de Ensayos Clínicos en el Perú y Declaración de Helsinki. Acta Médica Peru. 2014;31(3):188–188. Disponible en: http://www.scielo.org.pe/scielo.php?script=sci_arttext&pid=S1728-59172014000300009.

34. Comisión de Educación, Ciencia, Tecnología, Cultura, Patrimonio Cultural, Juventud y Deporte. Dictamen recaído en las observaciones del Poder Ejecutivo a la autógrafa de la Ley General de Desarrollo de la Biotecnología Moderna en el Perú, Proyecto de Ley No 22/2006-PE [Internet]. Congreso de la República del Perú; 2006 [citado el 3 de marzo de 2025]. Disponible en: https://www2.congreso.gob.pe/Sicr/ApoyComisiones/dictamen20062011.nsf/01aa16afd5c617f8052572590070b7f0/$file/biotecnolog%C3%8Da_educacion_22.pdf.

35. Coecke S, Balls M, Bowe G, Davis J, Gstraunthaler G, Hartung T, et al. Guidance on good cell culture practice. a report of the second ECVAM task force on good cell culture practice. Altern Lab Anim ATLA. 2005;33(3):261–87. doi:10.1177/026119290503300313