

Market Analysis for Implementing Good Laboratory Practices at the SENAI Institute of Innovation in Advanced Health Systems (ISI-SAS) of SENAI CIMATEC

Gabrielle Novais Manzoli^{1*}, Maria Conceição Moares Lima¹, Leticia de Alencar Pereira Rodrigues¹, Afrânio Ferreira Evangelista¹, Bruna Aparecida Souza Machado¹

¹SENAI CIMATEC University Center; Salvador, Bahia, Brazil

Good Laboratory Practices (GLP) comprise a quality system encompassing organizational processes and conditions under which non-clinical safety studies for human health and the environment are planned, developed, monitored, recorded, archived, and reported. The objective of this work was to analyze the market to guide decision-making regarding the implementation of GLP at CIMATEC's ISI-SAS, following NIT-Dicla-035, with a focus on achieving Conformity with the Principles of Good Laboratory Practices recognized by Cgcre of Inmetro. This study showed that the prevalence of Test Facilities in Brazil's South and Southeast regions became evident. Most companies that responded to the questionnaire expressed interest in GLP studies, particularly cytotoxicity. By comparing the requirements of NIT-Dilca-035 with the structure of ISI-SAS, it was determined that implementing GLP in this sector is feasible, leading to the initiation of Good Laboratory Practices implementation in this area.

Keywords: Good Laboratory Practices. Quality. Health. Environment.

The Principles of Good Laboratory Practice (GLP) constitute a quality system encompassing the organizational processes and conditions under which non-clinical studies on human health and environmental safety are planned, developed, monitored, recorded, archived, and reported. Tests conducted by these principles are typically mandated by regulatory bodies for evaluating and registering products such as pharmaceuticals, cosmetics, and genetically modified organisms, among others. GLP principles also benefit research endeavors by ensuring quality, credibility, and relevance in health research, enhancing result reliability, and promoting result efficiency and reproducibility.

In Brazil, the National Institute of Metrology, Quality, and Technology – INMETRO, under the General Accreditation Coordination (Cgcre), is the official entity responsible for overseeing compliance with Good Laboratory Practice Principles (GLP) [1]. Implementing GLP is a crucial strategy to guarantee the quality, reliability, and integrity of data generated in studies or tests. Brazil's

comprehensive adherence through Inmetro's Cgcre to the Organization for Economic Co-operation and Development (OECD) Acts related to Mutual Acceptance of Data (MAD) by GLP Principles encompasses various test item categories, including pharmaceuticals and cosmetics. These categories align with the profile of products developed and tested at the SENAI Institute of Advanced Health Systems (ISI-SAS/SENAI CIMATEC).

ISI-SAS serves as a research, development, and innovation center with a mission to become a leader in developing new health technologies to directly contribute to the technological and scientific advancement of the national industry. Alongside its goal of providing excellent services, combined with the scarcity of recognized laboratories offering services in compliance with GLP standards in Brazil's north and northeast regions, achieving GLP recognition is a priority in ISI-SAS's quest to deliver quality and excellence in its analyses. Therefore, this study aimed to survey service demands requiring GLP recognition and define which tests should be prioritized for initial implementation within ISI-SAS facilities.

Materials and Methods

The method employed for this study consisted of three main phases:

Received on 10 February 2024; revised 12 May 2024.

Address for correspondence: Gabrielle Novais Manzoli. Av. Orlando Gomes, 1845, Piatã, Salvador, Bahia, Brazil. Zipcode: 41650-010 E-mail: gabrielle.manzoli@fbter.org.br.

J Bioeng. Tech. Health 2024;7(2):178-181
© 2024 by SENAI CIMATEC. All rights reserved.

Survey of Recognized Testing Institutions for GLP in Brazil

The survey of test installations was conducted using data from the Inmetro website [2]. Quantitative data were gathered, including percentages by status (Active or Inactive), region, and state in Brazil.

Analysis of Inmetro Standards Associated with GLP

The standards analysis was performed directly on the Inmetro website. Base documents for implementing Good Laboratory Practices (GLP) [1] and documents focusing on the Study Specialty Area designated for implementation were scrutinized. In total, 33 documents were analyzed to define the necessary documents and action plan for GLP implementation.

Market Research for Feasibility Assessment

Market research was carried out through a questionnaire titled "Research on Priority Areas for Recognition in Good Laboratory Practices (GLP)," generated in Forms. The questionnaire was distributed to customers to identify demands for GLP-recognized testing, aimed at boosting production and commercialization of products within the local industry, particularly in sectors such as Pharmaceuticals, Cosmetics, Personal Care Products, Medical Devices, and Biotechnology. Sindusfarma provided publicity support. The

results were categorized by area of study specialty: Toxicological Studies, Cytotoxicity Studies, Studies with GMOs, and Others. Each group was further subclassified based on the type of study, and these data were presented descriptively, reporting quantity and percentage.

Results and Discussion

As of March 2024, Brazil boasts 51 recognized test facilities for Good Laboratory Practices (GLP), with 47 of them (92.2%) currently holding active recognition [2]. Geographically, there is a notable concentration of GLP-recognized Test Facilities in the Southeast region of Brazil, accounting for 35 facilities (68.6%) (Figure 1). Specifically, the State of São Paulo stands out within this region with 31 recognized facilities (60.8%) (Figure 2).

Regarding the Specialty Area, it is evident that a significant portion of recognized companies in Brazil (59%) are focused on Waste Studies related to "Pesticides, their components, and similar substances" (Figure 3). This highlights a specific emphasis within the GLP framework on environmental and toxicological studies, particularly in pesticide-related research.

The concentration of GLP-recognized Test Facilities in the Southeast, particularly in São Paulo, aligns with the region's prominence in scientific research and industrial development. It also reflects the strategic positioning of these facilities to cater to the demand for GLP-compliant testing services, especially in areas related to environmental and public health concerns.

Figure 1. Test facilities recognized for GLP by the Brazilian Region.

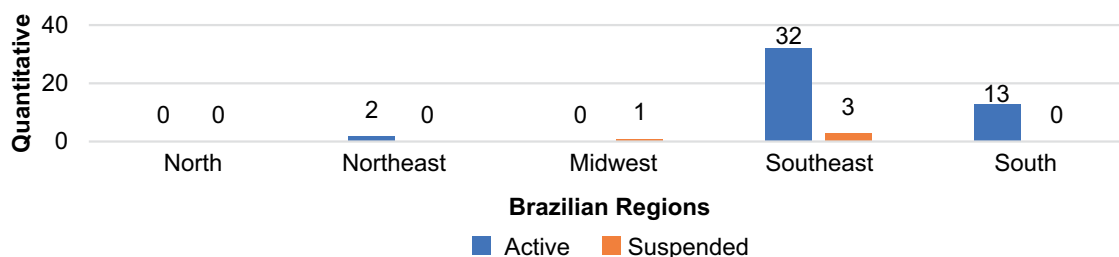


Figure 2. Test facilities are recognized for GLP by the Brazilian state.

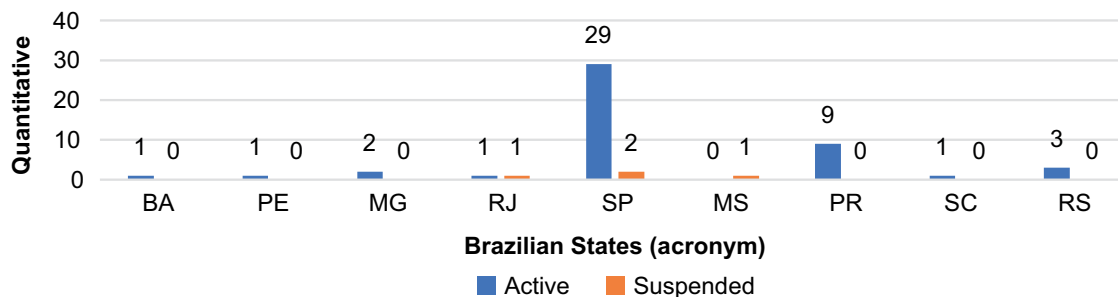
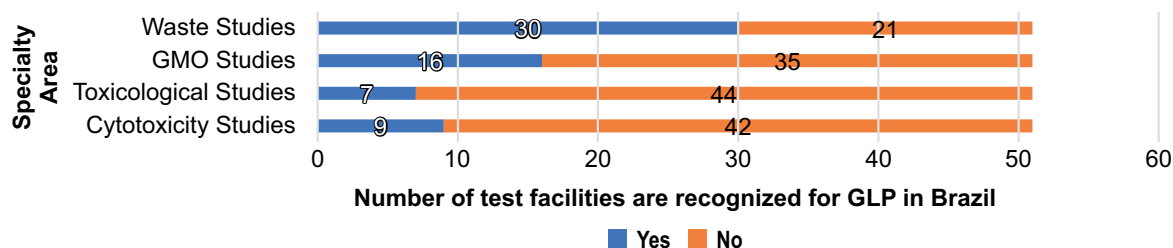


Figure 3. Test facilities are recognized for GLP by the specialty area.

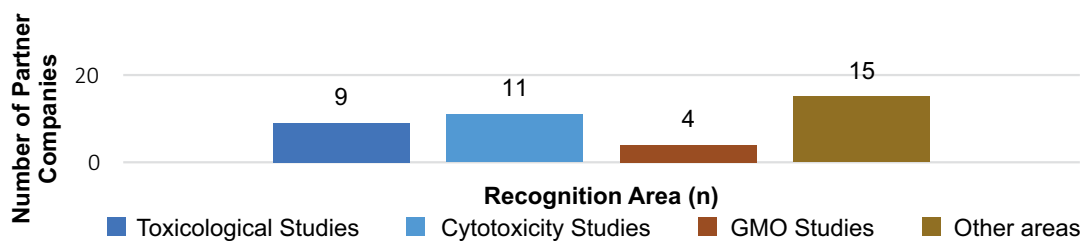


These findings underscore the importance of regional distribution and specialization within the GLP framework, providing insights into the landscape of GLP-compliant testing services in Brazil and guiding strategic decisions for GLP implementation and service prioritization at institutions like ISI-SAS.

Figures 1 and 2 highlight a notable scarcity of recognized Good Laboratory Practices (GLP) services in the North (0%) and Northeast (3.8%) regions of Brazil. Specifically, the Northeast region houses only 2 facilities, both recognized in the "Waste Studies" specialty area for "Pesticides, their components, and similar substances." This indicates a regional disparity in GLP service availability, with a concentration of recognized facilities primarily in the Southeast region. ISI-SAS's strategic specialty areas that align best with its portfolio include Toxicological Studies, Cytotoxicity Studies, and Studies with Genetically Modified Organisms (GMOs). These areas correspond to the core

activities and expertise of ISI-SAS, suggesting a natural fit for GLP implementation and service provision within these domains. Between August and November 2024, responses were collected from twenty customers regarding their GLP demands. Interestingly, most respondents indicated that their primary GLP demands lie outside Toxicological Studies, Cytotoxicity Studies, and GMO Studies—three strategic areas within ISI-SAS's scope. Among these alternative areas, Cytotoxicity Studies emerged as the most recommended (Figure 4). These findings underscore the importance of strategic alignment between GLP service offerings and organizational expertise. Additionally, they highlight the potential for expanding GLP services beyond traditional areas to cater to evolving market demands and capitalize on specialized capabilities within institutions like ISI-SAS.

The second-largest demand identified was for Toxicological Studies (Figure 4). However, it is

Figure 4. Number of partner companies that require GLP testing by recognition area.

noteworthy that the most selected test within this area, the Assessment of pyrogenic contamination, necessitates REBLAS accreditation. Consequently, it was determined that the implementation of cytotoxicity studies at ISI-SAS of SENAI CIMATEC is justified, driven by both customer demand and the scarcity of this service in the local market.

Following these assessments and a thorough analysis of normative documents related to Good Laboratory Practices (GLP), particularly referencing NIT-Dicla-035 [3], it was confirmed that ISI-SAS possesses the requisite infrastructure and qualified personnel necessary for implementing GLP for Cytotoxicity Studies in this sector. This includes ensuring the maintenance, calibration, and qualification of critical equipment and the preparation, review, and publication of documents to uphold the quality and adherence to GLP principles throughout the study lifecycle, from defining the study plan to disposing of inputs. An action plan has been structured and is currently in progress, with submission for recognition anticipated from mid-2024. However, several challenges have been identified, including the volume of documents to be prepared or reviewed relative to the number of capable employees, adapting shared spaces to GLP principles, instilling a culture centered on quality assurance, and managing the time required to procure inputs and equipment maintenance services. The action plan has achieved 50% completion and is expected to conclude in second half-year 2024.

Conclusion

The analysis conducted in this study revealed a significant need for recognized Good Laboratory Practices (GLP) services in the North and Northeast regions of Brazil, particularly evident in the absence of registered services for Cytotoxicity Studies within these regions. Conversely, there was a notable predominance of GLP-recognized services in São Paulo, accounting for 60% of such services. In light of these findings, the comprehensive analysis undertaken herein has substantiated and underscored the feasibility of implementing Cytotoxicity Studies at ISI-SAS. This strategic decision aligns with market demands, addresses regional service gaps, and leverages ISI-SAS's existing infrastructure and qualified personnel. We extend our gratitude to CNPq for the grant awarded and to Centro Universitário SENAI CIMATEC for their unwavering support in facilitating the implementation of Good Laboratory Practices (GLP) at ISI-SAS, SENAI CIMATEC.

References

1. INMETRO. Reconhecimento da Conformidade às BPL. <https://www.gov.br/inmetro/pt-br/assuntos/monitoramento-de-boas-praticas-de-laboratorio/reconhecimento-da-conformidade-as-bpl>. Accessed on March 8, 2024.
2. INMETRO Instalações de Teste Reconhecidas e os Respectivos Escopos. http://www.inmetro.gov.br/monitoramento_BPL/certificados/index.asp. Accessed on March 8, 2024.
3. INMETRO. NIT-DICLA-035. Princípios das boas práticas de laboratório – BPL. Versão 04. Outubro/2019.