



Gap Analysis as A Tool for Improving the Quality of Educational Laboratories an Applied Study of the Phantom Laboratory at the Faculty College of Dentistry, Gilgamesh University, in Accordance with GLP Requirements

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ARTICLE INFO	ABSTRACT
Published Online: 31 July 2026	The present research aims to do a systematic gap analysis to measure the degree of the compliance of the Dental Laboratory (Phantom) at Faculty of Dentistry-Gilgamesh University from the requirements of Good Laboratory Practice (GLP) and its conformity to the Iraqi standards for educational laboratory quality (edition 2022). The research is based on a strict checklist taken from the OECD/DAIDS/ICMR documents and linked with Iraqi standards. In addition to this framework, the scope and practical application of GLP principles in a laboratory setting can be elaborated further. The methodology includes self-assessment, internal auditing, calculation of compliance rates and gap size and formulation of a corrective action plan (CAPA) with specific timelines and responsibilities. The results showed that the largest gaps are concentrated in areas related to digital transformation in the laboratory: SOPs, data integrity, and computer systems. The findings demonstrate that this GLP-based gap analysis model is a practical framework for evaluating educational laboratory quality in accordance with Iraqi standards. Its application may support quality improvement, broader implementation across universities, and academic accreditation efforts.
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KEYWORDS: GLP, dental laboratories, gap analysis, quality assurance.	

I. INTRODUCTION

The Principles of Good Laboratory Practice (GLP) are a managerial quality control system covering the organisational process and the conditions under which non-clinical health and environmental studies are planned, performed, monitored, recorded, reported and retained (or archived).

The Principles of GLP define the responsibilities of test facility management, study director, study personnel and quality assurance personnel that are operating within a GLP system, and minimum standards concerning the suitability of facilities and equipment to perform studies, the need for standard operating procedures, documentation of raw data, study reports, the archiving of records, etc.

Building upon this framework, the scope and practical application of GLP principles in laboratory environment can be further clarified.

The Principles of Good Laboratory Practice (GLP) are defined as a set of regulatory and administrative standards aimed at ensuring the quality and integrity of data generated by non-clinical studies. These principles cover multiple

aspects of daily laboratory activities Including the design of test areas arose primarily to ensure the safety of GLP and storage to prevent contamination, cleaning procedures, and equipment calibration. Although regulatory products such as drugs and chemicals are tested through non-clinical tests, the application of their principles is required to enhance quality and reliability in any laboratory environment, including educational laboratories.

Assessing the degree of compliance with these principles requires the use of systematic quality evaluation tools.

Gap analysis is an essential tool in quality management systems, as it is used to identify differences between the current state of the laboratory and required standards or best practices. This analysis aims to uncover areas of non-compliance or deficiencies, enabling institutions to develop effective corrective action plans to achieve the objectives set in the context of educational laboratories. The application of gap analysis helps ensure that practical training and data collected are conducted in accordance with quality standards, which enhances confidence in the professional competence of graduate students.

Based on this approach, the present study employs gap analysis to evaluate compliance, with GLP requirements in an educational dental laboratory

Good Laboratory Practice (GLP) is a fundamental framework for ensuring the quality of laboratory outputs and the integrity of data in medical and research laboratories. With the digital transformation of educational dental laboratories (e.g., the use of scanners, CAD/CAM software, and digital measuring devices), there is a growing need to adopt systematic self-assessment methodologies to identify gaps and align processes with international and national standards. This research applies a comprehensive gap analysis to the dental laboratory (Phantom) at Gilgamesh University, based on a checklist linked to the Iraqi standard for educational laboratories 2022.

The practical context of this study is the phantom laboratory at the college of dentistry, Gilgamesh University.

Dentistry College at Gilgamesh University is concerned mainly with the health of the oral cavity. The college utilizes theoretical learning, preclinical training to graduate students who are capable of running their own clinics and serve their society. Phantom Lab is a simulation lab where dental students practice procedures on artificial (phantom) heads and teeth before working on real patients. It helps develop skills in (Cavity preparation and restoration and Crown preparation). This lab is important for building confidence and precision before clinical practice.

II. RESEARCH PROBLEM

There is no scientific assessment that determines the extent to which the current practices of the dental laboratory (Phantom) at the Faculty of Dentistry, Gilgamesh University, comply with the requirements of the Iraqi standard for good laboratory practice (GLP) in its updated version of 2022.

III. RESEARCH OBJECTIVES

1. Analyses the gap to measure the current level of compliance of the laboratory with the Iraqi standard for good laboratory practice (GLP) for 2022.
2. Identify points of non-compliance in each of the reference standard axes.
3. Develop a plan for implementing corrective and preventive actions (CAPA).
4. Provide recommendations for continuous improvement required in the laboratory.

IV. RESEARCH QUESTIONS

1. What is the level of compliance for each GLP axis?
2. What is the total gap? Where are the largest gaps concentrated?
3. What are the priority corrective and preventive actions to achieve rapid impact improvement?

V. SCOPE OF THE RESEARCH

Spatial: Dental Laboratory (Phantom) at the Faculty of Dentistry, Gilgamesh University, excluding other laboratories.

Temporal: From 1-5-2026 To 30-5-2026

Research limitations: The results depend on the accuracy of the records and evidence available at the time of the assessment, in accordance with the Iraqi standard for good educational laboratories (GLP) for 2022.

VI. LITERATURE REVIEW

Because of the importance of reviewing previous studies to identify the gap between what has been covered and what this research has achieved and the objectives it aims to achieve, in addition to stating the measures needed to address these gaps, a summary of ten published studies directly related to gap analysis according to GLP is presented below, indicating their relevance to the research topic: a. A summary of ten published studies directly related to gap analysis as per GLP and their relevance to the research topic is given below:

1. Cleland et al. (2024) established a harmonized risk-based surveillance model for DAIDS laboratories and proved that audit and self-assessment are effective and can minimize compliance variation.
2. Nguyen et al. (2024) examined factors contributing to non-compliance and recommended semi-annual review programs and specialized training tools.
3. EFSA (2024), 3. EFSA (2024), provided checklists for the verification of studies under GLP that can be directly converted into a gap analysis tool.
4. OECD (2023), on cloud data storage and information security requirements in a GLP context.
5. INAB (2023), presented a national model for a periodic laboratory inspection program, with clear timelines and evaluation criteria.
6. OECD (2021), Data integrity and ALCOA+ criteria, and the importance of traceability and secure archiving.
7. MHRA (2021), Data governance and digital compliance culture in medical laboratories.
8. DAIDS (2021), issued updated GCLP guidance with audit templates and detailed checklists.
9. ICMR (2021), steps for implementation of GCLP in resource-limited settings.
10. Venkatesh et al. (2023), A comparative review of the GCLP requirements as per WHO/ICMR/EMA documents was carried out.

As can be seen from the above, previous studies have made valuable contributions and provided important models, but most of them have focused on medical or general research laboratories, without sufficient coverage of educational dental laboratories. In addition, there is limited research linking international GLP requirements to Iraqi national standards for good educational laboratories.

VII. RESEARCH METHODOLOGY

1. **Type of research:** The research is descriptive-analytical approach and is based on a field assessment using the Gap Analysis Tool according to the Iraqi GLP standards for good educational laboratories.
2. **Research community and sample:** 2. The research community is the laboratories of the Faculty of Dentistry at Gilgamesh University, and the research sample is the laboratory (Phantom).
3. **Data collection tool:** The gap analysis form includes 15 main axes and 87 sub-items directly related to the paragraph number of Iraqi GLP standards for the year 2022.
4. **Method for calculating the gap:** The gap of each item was calculated by the following mathematical equation: Compliance ratio for gap size 100 %. Then the total ratio is calculated for each of the axes. Priorities are ranked by the size of the gap.
5. **Evaluation procedures:** These included the following:
- a. Collecting documents and records.
 - b. Field visit to the laboratory.
 - c. Interviewing officials and technicians.
 - d. Entering data into an Excel file dedicated to calculations.
 - e. Extracting the gap report and CAPA plan.

VIII. RESULTS OF RESEARCH

Table 1: Gap ratio between current status and Iraqi GLP requirements for 2022

No.	Axis	Number of items	Percentage % of Compliance	Size of gab %
1	Structure and responsibilities	8	75	25
2	Quality assurance	12	68	32
3	Facilities	6	80	20
4	Equipment and materials	10	60	40
5	SOPS	15	55	45
6	Data integrity	9	50	50
7	Reporting and documentation	8	70	30
8	Archiving	4	60	40
9	Computer systems	6	50	50
10	Risk and safety management	5	65	35
11	Continuous improvement plan	4	60	40

DISCUSSION: The results of the study showed that quality assurance in the research sample laboratory (Phantom) needs to be strengthened by developing a binding plan for implementing periodic internal audit programs and more accurate documentation of procedures. The results also showed that the largest gaps are concentrated in areas related to digital transformation in the laboratory: SOPs, data integrity, and computer systems.

IX. RECOMMENDATIONS AND CAPA PLAN

Table 2: Plan of Corrective and preventive actions required for improvement and development

Priority	Area	Corrective Action	Responsible	Time
1	Data integrity	Enable secure tracking and archiving	IT manager	1 month
2	SOPS	Update training procedures	Department head	2 months
3	Toolbar Computer systems	Review user permissions	IT & QA	Month
4	Quality assurance	Implement a semi-annual audit plan IT	QA	3 months

X. CONCLUSION

This research is an application model of the gap analysis according to GLP for the quality of the educational laboratory based on the Iraqi standards. This research can serve as a model for future researches in other laboratories, at the Faculty of Dentistry, University of the Future or in other universities. It can also be integrated into academic accreditation programs.

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University, comply with the requirements of the Iraqi standard for good laboratory practice (GLP) in its version updated in 2022. The research aims to address this gap and provide recommendations for continuous improvement in the laboratory.

APPENDIX (1)

Gap analysis form for the Phantom dental laboratory

Linked to the Iraqi standard for educational laboratory quality (2022)

The research problem is the lack of a scientific assessment that determines the extent to which the current practices of the (Phantom lab) at the Faculty of Dentistry, Gilgamesh

Focus	Question	Answer			Evidence - Attach as a document (official letter, document, documented procedures, other)	Proposed corrective action	Date of implementation of corrective action		Comments
		Yes	No	Partially					
Quality management and documentation	Is there a written and approved quality policy for the laboratory?								
Quality Management and Documentation	Are there updated standard operating procedures (SOPs) for all processes?								
Quality Management and Documentation	Are records kept for all activities for an appropriate period of time?								
Infrastructure and Safety	Is the design and space of the laboratory adequate for the activities and number of users?								
Infrastructure	Is there adequate ventilation								

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and Safety	and lighting?					
Infrastructure and safety	Is there a plan for managing medical and chemical waste, and is it being implemented?					
Equipment and calibration	Is there an up-to-date inventory list of equipment?					
Equipment and calibration	Is equipment calibrated regularly according to a defined schedule?					
Equipment and calibration	Is maintenance and calibration documented?					
Samples and measurement procedures	Are there written procedures for receiving, storing, and handling samples?					
Samples and measurement procedures	Are samples coded to prevent mix-ups?					
Samples and measurement procedures	Are gap measurements conducted according to standardized and repeated steps?					
Human resources and training	Do all laboratory staff have the required qualifications?					
Human resources and training	Are annual training plans prepared for laboratory staff?					
Human resources and training	Are there records documenting training and competence?					
Quality control and continuous improvement	Are internal quality control tests conducted regularly?					
Quality control and continuous improvement	Does the laboratory participate in external proficiency testing?					
Quality control and continuous improvement	Is there a plan for continuous improvement based on the results of previous administrative and audit reviews of the laboratory?					