

Implementing of Good Laboratory Practice (GLP) in Food Analysis Laboratories of Baghdad University

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Abstract: *In line with the instructions of the Department of Quality Assurance and Academic Accreditation at the University of Baghdad in implementing good laboratory practice in the University laboratories, this study was performed to show the competency of (21) scientific laboratories related with food analysis in implementing of the requirements of GLP. Results show differential weights between 14 to 89% depending of various factors such as lab infrastructures, facilities, and the activities of lab personals in implementing of GLP.*

Keywords: GLP, University, laboratories.

1. Introduction

Good Laboratory Practice identifies GLP is a quality system concerned with the organizational process and the conditions, under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported (1). It not only defines GLP as a quality system, but it also separate it against other quality systems by confining it to the organizational process and the conditions under which the whole process of a non-clinical health and environmental safety study has to be developed, from its inception and design till its final stage of reporting and archiving.

The aim of GLP principles is to promote the development of quality test data; there is a Quality Assurance program that the quality assurance responsibility is being performed in compliance with of GLP principles (2). In addition to that, comparable quality of test data forms is the basis for the mutual acceptance of data among countries and the measure certainly applies to the development and improvement of educational laboratories in scientific universities.

The benefits of implementing GLP in the laboratories of the University is to: Improve the level of educational laboratories, Increase the confidence in the test and measurement results, increase the confidence of the educational institution administration in the quality of the educational performance of their product, adjust the corresponding procedure is not for calibration or testing through the procedural way of corrective action and preventive action and achieve continuous development and improvement (3).

Laboratories which concerns in food analysis at the University of Baghdad divided between scientific departments of the colleges of Agriculture, Veterinary, Science, Education and Market Research and Consumer Protection Center (MRCPC) and others related departments.

For implementing GLP in food analysis laboratories at Baghdad University, it should be implemented GLP regulation by the laboratory. Accordance to the instructions of the Department of Quality Assurance at Baghdad University, all laboratories should fulfill GLP requirements in certain time starting from 2016. This matter was studied by each lab and it planned to implement (4).

2. Materials and Methods

To implement GLP in the laboratories of the University of Baghdad, a revision of GLP references performed and attending to workshops organized by the department of quality assurance at the University of Baghdad has been done for discussing how we can implement the requirements of GLP. Questionnaire has been prepared and submitted to (21) laboratories related with food analysis in different faculties at the University of Baghdad, to show the actual situation of the laboratory and what is the percentage can the surveyed laboratory obtain. The questionnaire contains the 10 clauses of GLP and the requirements of each clause, and it is given as questions that should be answered by the lab responsible. The percentage of the requirement of GLP implemented by each lab calculates in accordance to the data weight below:

Data Weight:

Number of clauses = 10

Number of requirements = 69

Value of each requirement of 100% weight = 1.4

To calculate the weight of each clause it has been used the following:

Number of requirements in the clause \times 1.4

2.1 Laboratory Infrastructure

The laboratory which food analysis performed at Baghdad University must be designed in accordance to the services provided by the laboratory and should be meet the requirements given in the guidance of good Iraqi lab higher education.

University laboratory should be designed with sufficient space suitable with the number of the students in the laboratory and meet the national standard of GLP announced by the Iraqi Ministry of Higher Education and Scientific Research. Ventilation system and lightning must have maintenance program according to the degree of the risk in the laboratory and that should put in a schedule.

The laboratory should be divided into reception room where sample received and the report of test results gives to the customer and test and analysis room and other room if required. The laboratory should be equipped with first aid box and guidance in the case of emergency to treat with chemical, biological, physical, electrical and mechanical risk (2).

2.2 Equipments, Standard Solutions and Reagent

Include: equipments, standard solutions, laboratory materials, Calibration, symbolization, storage system, and at least it should be apply the following requirements:

- a) All equipment and instruments should be symbolized and recorded all required data such as (the manufacturer, year of manufacturing, company name ... etc).
- b) Putting a timetable for the calibration of laboratory equipment and instruments.
- c) Equipments and instruments data undergo to a central program to build a database on a laboratory level (5).
- d) Laboratory chemical and biological materials stores in accordance with the international storage system, and they are symbolized according to (NEPA) American's system for protection from fires and accidents.
- e) Standard solutions keeps and stores according to the conditions of functions and calibration program of the equipment and within the limited temperatures.
- f) Equipment keeps safety after using and according to the instructions of using and maintenance.
- g) Standard solutions symbolizes with the date of validity (2).

2.3 Standard Operating Procedures

The standard operating procedures (SOPs) thus created included, among others: GLP position descriptions; document control; internal training; internal inspection; study plan elaboration; final report elaboration; and filling out a master schedule. Additional SOPs for describing technical experimental procedures, equipment use and maintenance procedures, and procedures for solution preparation were also created. It should be emphasized that for all documents approved, there were training programs administered to all professionals who would be utilizing the documents (6).

2.4 Establishing Quality System

To implement GLP in one laboratory, it is required from the laboratory manager to have a strategy to build quality system in the laboratory to manage all the operations done in the laboratory that meet the requirements of GLP. It is required to designate quality responsible in each laboratory follow up the GLP clauses and to implement these clauses

in the laboratory and writing the final report to the top manager if non-compliance cases founded in the work (7).

3. Results and Discussion

Questionnaire has been created in accordance to the criteria of Organization for Economic Co-operation and Development in Testing and calibration for non clinical laboratories (8). Questionnaire has been submitted to 21 university laboratories related in food analysis. The questionnaire created as questions addressed to the responsible of surveyed laboratories and contained the 10 clauses of GLP and its requirements. The questions and the answers of all surveyed laboratories are listed below:

Clause 1: Organization and Personals / Laboratory

Questions	Yes	No	Don't know
1. Are the tasks, duties, responsibilities and powers (i.e.: job description) identified strictly to the laboratory staff?	17	3	1
2. Is the quality policy put within the role and responsibilities of all employees towards quality results and customer satisfaction? Should it declared in Lab entrances?	15	5	1
3. Have the Laboratory administration announces its pledge front superior management to ensure the quality of training for students? And, is the pledge documented and declared?	11	8	2
4. Is the laboratory management capable for pledge to do all the requirements of good laboratory practice in effectiveness?	7	12	2
5. Are the ideal and selected scientific practices by lab management apply according to accurate study?	16	2	3
6. Does the laboratory management limits principles in quality adjusting through laboratory tests, implementation, monitoring, recording and archiving?	16	4	1
7. Is the laboratory management put a vision, mission and goals of laboratories with similar goals made in accordance with specialty?	18	2	1
8. Are each of administrative structure, laboratories representative of quality management and the location of the laboratory in educational system identified?	11	6	4

Clause 2: Quality Assurance Program

Questions	Yes	No	Don't know
1. Has the Laboratory management plan for self-assessment and analysis of the results of effects?	7	10	4
2. Has the laboratory placed half-annual plan for internal auditing of the laboratory procedures and practices?	9	10	2
3. Are the laboratory Personals trained strictly to apply the requirements of quality assurance in the laboratory and all of laboratory practices?	14	6	1
4. Is the laboratory management plays an active role to monitor the incorrect analytical results and then put corrective actions, in addition to its commitment to development and implementing management system and achieving continuous improvement?	19	2	0
5. Is the daily work of Laboratory administration systematic and structured to achieve technical competence in performing practices, tasks and functions assigned to the	17	1	3

employees? And are the roles and responsibilities referred in the quality manual?			
6. Is the laboratory administration conduct of reviewing actions within a half year, for determining the performance deviations and putting procedures and solutions for developing and performance improvement of system safety?	8	9	4

Clause 3: Facilities

Questions	Yes	No	Don't know
1. Are the protection kits for students available in the laboratory? And are the students trained to use them?	12	8	1
2. Is the laboratory equipped with Life protection requirements (ventilation, lighting, grounding ground, fire alarm system, sensors, self-extinguishing) and according to the characteristics of the laboratory and its risk?	3	18	0
3. Are the Guidance signs and warning for laboratory safety placed inside and outside the laboratory to raise awareness of the risks?	8	13	0
4. Is the laboratory equipped with first aid box and guidance for using in emergency situations when dealing with chemical, physical, biological, mechanical or electrical risk?	9	11	1
5. Is the laboratory designed with sufficient space in terms of the number of students and the laboratory experiments? And is it designed in accordance with the National Standards stated by the Ministry of Higher Education and Scientific Research-Iraq?	3	17	1
6. Are the laboratory staff trained to use fire distinguishes according to its characteristics and its use?	2	17	2
7. Is there any program used to remove lab containers after each practice? And are the containers from the closed type?	9	12	0
8. Is the maintenance program of ventilation systems and lighting applied according to the degree of laboratory risk? And is any timetable program used for the maintenance and prevention in the laboratory?	3	17	1
9. Is the laboratory divided into sampling room, lab analysis room and other room?	5	16	0

Clause 4: Equipments, Standard Solutions, Reagents And Materiales

Questions	Yes	No	Don't know
1. Have the instruments and equipment symbolized? And is it recorded all the required data such as (the manufacturer, year of manufacture, company name ... etc)?	15	4	2
2. Is there any timetable for calibration laboratory equipment and instruments?	10	6	5
3. Is the equipment and instrument enters to central program to build a database on a laboratory level?	6	12	3
4. Are the laboratory chemicals and biological materials stores in accordance with the international storage system? And are the chemicals and biological materials symbolized according to (NEPA) American's system for protection from fires and accidents.	4	12	5
5. Are the standard solutions keep and stores according to the conditions of functions and calibration program of the equipment and within the limited temperatures?	15	5	1

6. Is the equipment keep safety after using and according to the instructions of using and maintenance?	18	2	1
7. Are the standard solutions symbolizes with the date of validity?	16	3	2

Clause 5: Testing

Questions	Yes	No	Don't know
1. Is any assessment for testing and analysis procedures realized?	17	3	1
2. Are the conditions of laboratory experiments determined accurately?	15	6	0
3. Are the laboratory technicians trained accurately of the laboratory practice? And, are they examined of their proficiency performance and documenting results?	13	6	2
4. Is it takes into account accurate procedures in each of sampling, symbolizing and procedures for taking samples?	16	4	1
5. Do be sure of the cleanliness of the equipments, instruments, glasses and the concentrations of solutions, its type and using?	17	3	1
6. Are the specifications select from time to time for its impact of quality results?	12	6	3
7. Are the test methods and alternative test methods available completely?	10	7	4
8. Are the suitable tests methods determine within scientific review reports?	9	8	4
9. Do be sure of the validity of standard solutions and the solutions prepared within specific concentrations for experiences?	18	1	2

Clause 6: Test and References

Questions	Yes	No	Don't know
1. Has the laboratory a clear policy and procedures for testing or calibration? And, are the responsibilities and authorities specified in work management?	16	2	3
2. In the case of non-conforming action, is it applied to adjust the corrective action, repeating the experience, implementation of measure evaluation and identifying the possible sources in the reasons of non-conformity?	15	1	5
3. Is the laboratory management implements preventive action after each corrective action to prevent potential sources of non-conformity occurrence in the future? And, is the preventive action available for laboratory employees to raise the level of student performance?	9	5	7
4. Is the laboratory uses methods and procedures for all tests / calibrations within the scope of work (sampling, handling, transportation, storage and destroyed)?	15	5	1
5. Has the laboratory scientific procedures for reduction of various risks to students, and in particular: training of lab supervisor and to improve the efficiency of their performance?	13	8	0
6. Are the good laboratory facilities include (the correct performance of the tests and calibrations, including sampling, testing and calibration) in another places of educational institutions?	16	2	3
7. Does the laboratory management monitors and controls of the environmental conditions such as (sterilization, dust, gases, radiation,	13	8	0

humidity, heat, noise and vibrations) during a laboratory practices by students as an important part of good laboratory practice?			
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evaluating the performance of the lab activity as well as its employees to develop performance evaluating system?			
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Clause 7: Standard Methods

Questions	Yes	No	Don't know
1. Is the laboratory select and prove experimental methods and review them in accordance with the accreditation of good laboratory requirements?	18	2	1
2. Does the laboratory management determines the environmental conditions and safety through the implementation of laboratory practices for students?	14	7	0
3. Are the methods (operating procedures) easy to apply, transparent and understandable for students in work steps and the achievement of results and goals?	19	1	1
4. Are the laboratories practices considered as an essential and scientifically part in the study program (experimental part) for students?	17	3	1
5. Are the standard solutions uses for calibration of equipment before starting the laboratory practices by students?	16	2	3
6. Dose the laboratory documents the observations and negative indicators through executive action by the students and the development of preventive and corrective actions to prevent their occurrence?	15	3	3

Clause 9: Results Report

Questions	Yes	No	Don't know
1. Has the laboratory suitable procedures to adjust and avoid the error in the results of test, analysis and calibration through recording of data, operating and results?	15	4	2
2. Does the laboratory management work to correct the uncertainly in the results?	12	6	3
3. Does the laboratory management analyze the data and adjust the documents and perform the correct action into unconformity and unacceptable results?	14	7	0
4. Does the laboratory treat with results in transparency and clearly according to the instructions of the management of the scientific organization?	13	5	3
5. Does the laboratory record the deviations in the results or the exceptions and document that and determine the reasons in the method of testing, analysis, sampling and calibration?	12	7	2
6. Has the laboratory design of results report for each of testing and calibration implemented?	5	11	5
7. Does the results compare with other practices?	12	4	5
8. Does the laboratory management perform correction of the factors affected in the results?	6	11	4

Clause 8: Performance Evaluation

Questions	Yes	No	Don't know
1. Has the laboratory Placed an annual plan to evaluate the performance of employees in laboratories?	11	7	3
2. Does the laboratory apply the instructions in the evaluating of performance and in equalization of opportunities for Student in the laboratory?	10	6	5
3. Does the laboratory management looking for performance evaluation program as a means to raise the efficiency of laboratory employees and supervisors in the good laboratory to give a good opportunity for superiority?	11	6	4
4. Do the evaluation and study performance objectively and fully to build a base of corrective actions coinciding with the type and size of the negative indicators and the obstacles?	6	8	7
5. Has the laboratory specific standards in	6	8	7

Clause 10: Archiving, Recording and Storage of Reports

Questions	Yes	No	Don't know
1. Does the laboratory management implement procedures to adjust legal, technical and referential documents and each kind of manuals and reports?	15	5	1
2. Does the laboratory management implement procedures to adjust the seven registers according to GLP?	7	9	5
3. Does the laboratory management perform periodical review of documents and to mark the important one and taking procedures and solutions for developing and improving?	11	8	2
4. Does the laboratory management use colored seals to characterize different kind of documents and to achieve quality performance?	3	17	1

To calculate the % weight of each surveyed laboratory in concerns of implementing of the requirements of GLP, it has used the following, and the results obtained listed in table 1.

% weight = number of requirements in the clause × 1.4

LAB	Clause 1	Clause 2	Clause 3	Clause 4	Clause 5	Clause 6	Clause 7	Clause 8	Clause 9	Clause 10	Weight %
1	5.6	2.8	4.2	4.2	5.6	1.4	8.4	0	1.4	2.8	36.4
2	5.6	5.6	2.8	5.6	9.8	8.4	7.0	5.6	8.4	1.4	60.2
3	5.6	4.2	9.8	5.6	9.8	5.6	7.0	4.2	4.2	0	56
4	0	0	1.4	1.4	4.2	4.2	1.4	1.4	0	0	14
5	1.4	1.4	5.6	4.2	2.8	1.4	5.6	2.8	0	0	25.2
6	11.2	8.4	8.4	8.4	12.6	9.8	8.4	7.0	11.2	4.2	89.6
7	5.6	2.8	4.2	5.6	8.4	1.4	8.4	0	2.8	4.2	43.4
8	11.2	2.8	2.8	8.4	8.4	5.6	7.0	1.4	7.0	2.8	57.4
9	5.6	2.8	1.4	1.4	5.6	5.6	4.2	2.8	5.6	2.8	37.8

10	8.4	8.4	1.4	5.6	11.2	8.4	8.4	0	11.2	0	63
11	8.4	5.6	1.4	5.6	9.8	8.4	8.4	0	11.2	0	58.8
12	8.4	7.0	12.6	7.0	9.8	9.8	8.4	5.6	9.8	2.8	81.2
13	8.4	4.2	8.4	5.6	11.2	5.6	7.0	2.8	5.6	0	58.8
14	9.8	7.0	5.6	8.4	12.6	9.8	8.4	5.6	9.8	5.6	82.6
15	11.2	5.6	0	4.2	1.4	5.6	1.4	1.4	5.6	1.4	37.8
16	8.4	8.4	1.4	5.6	9.8	5.6	7.0	1.4	5.6	1.4	54.6
17	11.2	8.4	8.4	7.0	9.8	7.0	7.0	7.0	4.2	1.4	71.4
18	9.8	7.0	5.6	8.4	11.2	8.4	5.6	7.0	1.4	5.6	70
19	9.8	5.6	2.8	7.0	9.8	9.8	8.4	1.4	9.8	4.2	68.6
20	9.8	4.2	2.8	5.6	9.8	8.4	7.0	1.4	5.6	4.2	58.8
21	0	1.4	0	1.4	4.2	2.8	4.2	1.4	4.2	1.4	20.8

Table 1: % Weight of the laboratories in implementing of GLP

The results show differential in implementing of GLP in surveyed laboratories between (36.4% to 89.6% weight) depending of the facilities of each lab and its infrastructure and the activities of the lab personals in implementing the requirements of GLP. The study recommended to rehabilitation the infrastructure of these laboratories which has obtained low (% weight), and creating a new plan for establishing the quality management system in the laboratory.

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