Management Responsibility in Good Laboratory Practice

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http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

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Presentation Outline

- What is Good laboratory practice ?
- Who is Management
- Management responsibility as per principles of GLP
- Management responsibility in ISO 15189
- Management responsibility in CLSI, SLIPTA

Good laboratory practice (GLP)

What is Good Laboratory Practice (GLP) ?

Good laboratory practice (GLP)

In the experimental (non-clinical) research arena, **it refers to a quality system of management controls for research laboratories and organizations**

It was implemented to ensure uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.

Good laboratory practice (GLP)

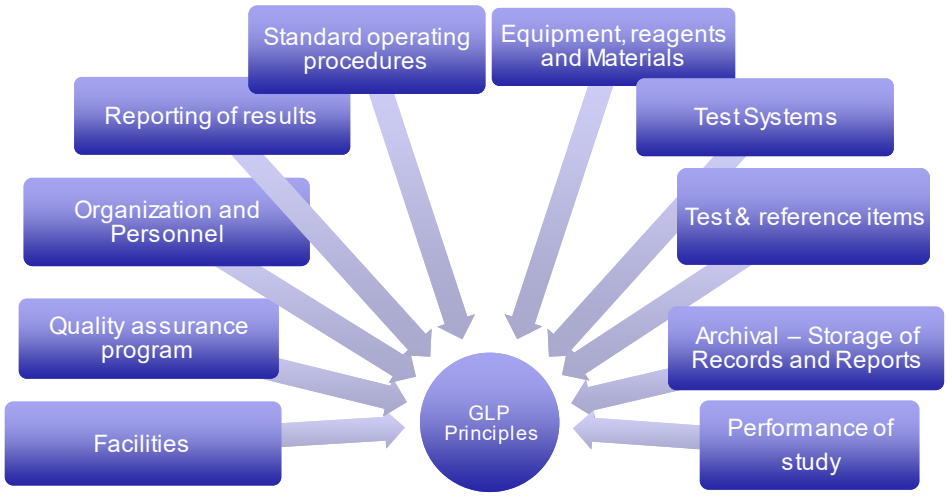
It is a **Quality system of management controls for research laboratories** (non-clinical) and organisations → now being extended to other laboratories

Good laboratory practice (GLP)

It embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived.

It helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.

Good laboratory practice (GLP)



Who is Management ?

Test facility management means the person(s) who has the authority and formal responsibility for the organization and functioning of the test facility according to the Principles of Good Clinical Practice.

Management responsibility in GLP

Without full commitment of management, GLP systems will not function as they should and will **lack credibility**.

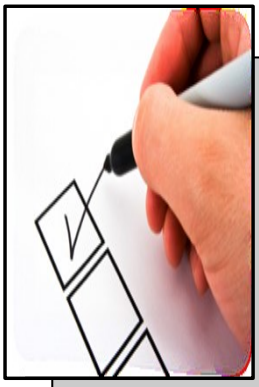
Managerial aspects are therefore **critical** for GLP implementation in a laboratory.

Laboratory management responsibilities and organisational requirements take up about **15% of the GLP**.

Management responsibility in GLP

1. A statement exists which **identifies the individual**(s) within a test facility who fulfil the responsibilities of management as defined by these Principles of Good Laboratory Practice

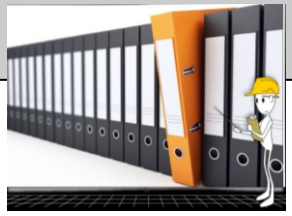
Management responsibility in GLP



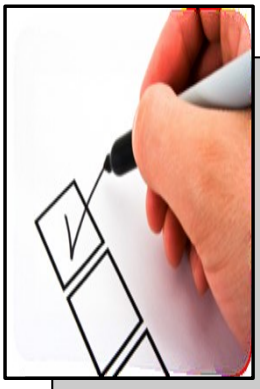
2. A sufficient number of **qualified personnel, appropriate facilities, equipment, and materials** are available for the timely and proper conduct of the study.

Management responsibility in GLP

3. **Maintenance of record** of the qualifications, training, experience and job description for each professional and technical individual.

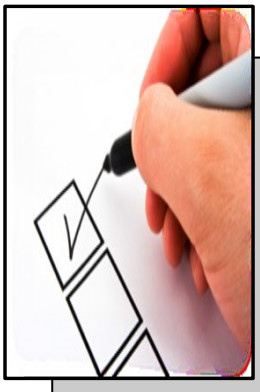


Management responsibility in GLP



4. Personnel clearly **understand the functions** they are to perform and, where necessary, provide **training** for these functions

Management responsibility in GLP



5. Appropriate and technically **valid standard operating procedures (SOPs)** are established and followed, and approval of all original and revised standard operating procedures are being done

Management responsibility in GLP

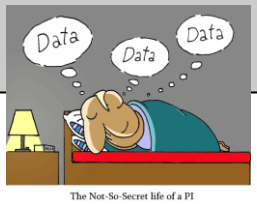
6. There is a **Quality Assurance Programme** with designated personnel in accordance with principles of Good Laboratory Practice

Management responsibility in GLP

7. For each study, an individual with the appropriate qualifications, training, and experience is designated by the management as the **study director** before the study is initiated. Replacement of a study director should be done according to established procedures, and should be documented.

Management responsibility in GLP

8. In the event of a **multi-site study**, that, if needed, a **principal investigator** is designated. Replacement of a Principal Investigator should be done according to established procedures, and should be documented.



The Not-So-Secret life of a PI

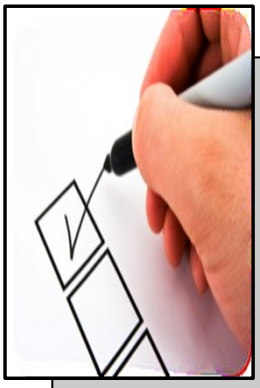
Management responsibility in GLP

9. **Documented approval** of the study plan by the study director

Management responsibility in GLP

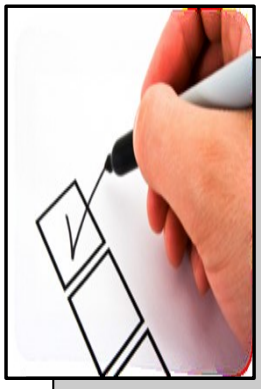
10. The study director has made the approved **study plan available to the quality assurance personnel**

Management responsibility in GLP



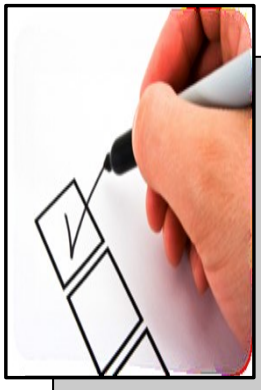
11. **Maintenance** of historical file of all Standard Operating Procedures (SOPs)

Management responsibility in GLP



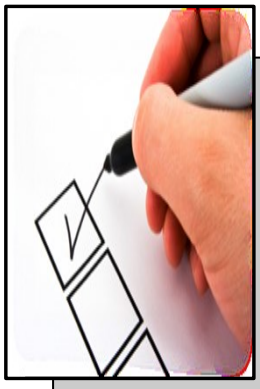
12. An individual is identified as responsible for the **management of the archive**(s)

Management responsibility in GLP



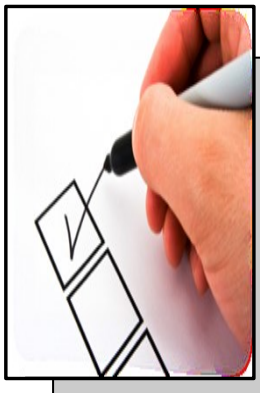
13. Maintenance of a **master schedule**

Management responsibility in GLP



14. Test facility supplies meet requirements appropriate to their use in a study

Management responsibility in GLP



15. For a **multi-site study**, clear lines of **communication** exist between the study director, principal investigator(s), the quality assurance programme(s) and study personnel

Management responsibility in GLP

16. Test and reference items are appropriately **characterized**

Management responsibility in GLP

17. Establish procedures to ensure that **computerized systems** are suitable for their intended purpose, and are validated, operated and maintained in accordance with Principles of Good Laboratory Practice

That's it ….

That's all as per principles of Good Laboratory Practice (GLP) !!

Question

Which kind of quality management system is GLP?

Universal quality management system

Statutory management system

Question

So, how does management responsibilities as per principles of GLP in a clinical diagnostic laboratory stack up to other standards and guidelines ?

Universal quality management systems

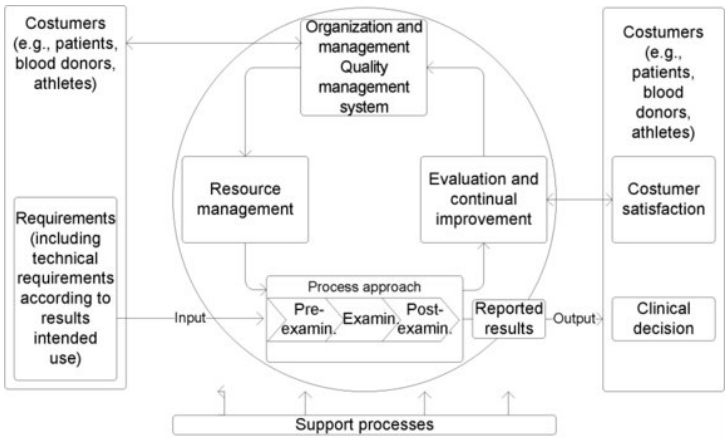
Standards (ISO)

Guidelines (CLSI, SLIPTA etc.)

Management responsibility as per ISO 15189

Which section of ISO 15189:2012 mentions about the management responsibility ?

Management responsibility as per ISO 15189



Management responsibility as per ISO 15189

The eight quality resources which are essential for GLP are **5M → Manpower, Management, Methodology, Mechanism, Material, 2E → Environment, Equipment, 1I → Information.**

ISO 15189:2012 version stresses on the above **resources** under various Clauses - **Management commitment** under **4.1**, **Manpower** is under **5.1**, **Methodology** to be adopted under **5.5**, **Mechanism** to be used under **4.2**, **Material** under **4.5**, **Environment** under **5.2**, **Equipment** under **5.3** and **information management** under **5.10**. The laboratory management must have a policy to procure quality resources

Management responsibility as per ISO 15189

All quality resources for GLP must be handled by only competent personnel with appropriate qualification, training and experience across all section of activities in the laboratory which **include pre examination 5.4, examination 5.5, and post examination 5.7**. All these should have a **quality assurance** which is detailed under **5.6** for GLP.

Covering all areas of laboratory activities from **patient selection 5.4 to result release 5.9 following reporting of results 5.8**, GLP requires the good documentation and control of all technical and quality records as proof of evidence for **GLP 4.13**. *Laboratory shall have the **plan B** in-case of system failure through **referral laboratory system 4.5.***

Management responsibility as per ISO 15189

All records need to be maintained on a pre prescribed format decided by the involvement of multistake holders for example the test requisition form (TRF) is designed in consultation with the clinicians who use the data generated by the laboratory **5.4**

Finally, GLP is just an implementation of all elements of the ISO 15189 with a continual improvement as detailed in **4.1.2** of the standard.

Compliances to GLP is frequently verified through **evaluation and audit** as detailed under **4.14** and management will **be reviewing at least annually** as per GLP under **4.15**.

Management responsibility (CLSI)

CLINICAL AND LABORATORY STANDARDS INSTITUTE ™

Management responsibility (CLSI)

Cultural

- Formulating and articulating a vision for quality
- Maintaining a quality policy as a formal statement of commitment
- Conducting business ethically and professionally
- Fostering a culture that supports the vision for quality

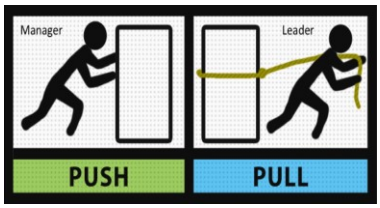
Structural

- Maintaining an appropriate scope of services
- Maintaining the legal identity of the laboratory
- Maintaining an appropriate organization structure with defined roles and responsibilities
- Designing and implementing a QMS

Functional

- Managing and allocating resources sufficient for scope of services and quality goals
- Planning for quality
- Assessing the effectiveness of QMS
- Communication quality related information

Leadership vs Management



Remember the difference between a manager and a leader; a manager says "Go!" - a leader says "Let's go!" – E.M. Kelly (adapted)

Leadership vs Management

Terms are used interchangeably in organizations, not considered synonymous generally.

Managers have formal positions within the organization.– Responsible for basic functions such as operational planning, organizing, staffing, directing, and controlling

Leaders influence attitudes, behavior, and the work of others toward achievement of a vision or goals.

It is generally accepted that management and leadership are distinct roles and modes of action and

They are complementary and both are necessary for the success of an organization

Leadership vs Management

Formal role

- Assigned; based on function (ie, what is done to achieve an outcome)
- Example: Laboratory Director, Quality Manager, Safety Officer

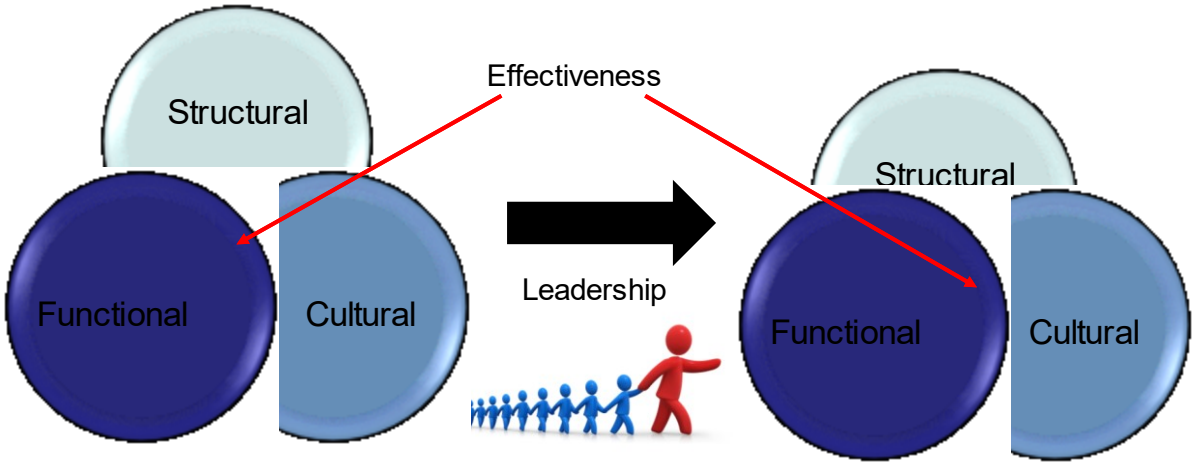
Informal role

- Assumed; how a leader conducts his/herself to achieve an outcome
- Example: visionary, mentor, quality “leader”

Both are important to:

- Fully realize a commitment to quality and good professional practice.
- Optimally shape the laboratory’s organizational dimensions of culture, structure, and function.

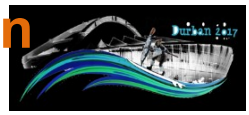
Importance of leadership



Question

Are you cultivating leaders or only managers in your laboratory ?

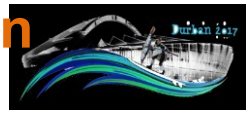
Management responsibility in SLIPTA



Stepwise Laboratory Quality Improvement Process Towards Accreditation

- A framework of auditing developed in line with the ISO 15189:2012 Standards and to a certain extent of the CLSI Laboratory Quality Management System Guidelines. It is used to measure and evaluate the progress of laboratory quality system and award a certificate of recognition (five star levels). It can be used at baseline, during supervision, and for monitoring and evaluation of laboratory progress towards accreditation.

Management responsibility in SLIPTA



Audit Score Sheet	
Section	*Total Points*
Section 1: Documents & Records	**28**
Section 2: Management Reviews	**14**
Section 3: Organization & Personnel	**22**
Section 4: Client Management & Customer Service	**10**
Section 5: Equipment	**35**
Section 6: Evaluation and Audits	**15**
Section 7: Purchasing & Inventory	**24**
Section 8: Process Control	**32**
Section 9: Information Management	**21**
Section 10: Identification of Non Conformities, Corrective and Preventive Actions	**19**
Section 11: Occurrence/Incident Management & Process Improvement	**12**
Section 12: Facilities and Biosafety	**43**
TOTAL SCORE	**275**

No Stars	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
(0 – 150 pts)	(151 – 177 pts)	(178 – 205 pts)	(206 – 232 pts)	(233 – 260 pts)	(261 – 275 pts)
< 55%	*55 – 64%*	*65 – 74%*	*75 – 84%*	*85 – 94%*	*≥95%*

Summary

GLP is the over all requirement of Good Quality Management System (QMS) of a medical diagnostic laboratory practices which is basically involved in testing activities and hence medical testing laboratories is an analytical in nature and not a clinical set-up. Hence basic scientists are prime decision makers in developing and sustaining analytical tools as part of GLP.

Good QMS means passionate and committed management (Owners or the Governors of the laboratory) having appropriate policies to select and procure quality resources.

The eight quality resources which are essential for GLP are following: 5M → Manpower, Management, Methodology, Mechanism, material; 2E → Environment, Equipment; I→ Information

Summary

Management has overall responsibility for ensuring that all documentation, personnel, procedures, supplies etc. are in compliance with principles of GLP.

The development and implementation of an effective Quality Management System is the primary responsibility of the Management.

The initiatives taken on the part of the management shows its commitment towards continual improvement of the laboratory processes.


thank you
gracias
danke
merci
obrigado
謝謝
ngiyabonga
teşekkür ederim
go raibh maith agat
dziękuję
bedankt
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kop khun krap
terima kasih
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dank je
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