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GENERAL PAPER

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A comparison of the complimentary and different issues in ISO/IEC 17025 and OECD GLP

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Abstract Laboratories with a quality system accredited to ISO/IEC 17025 have a definite advantage, compared to non-accredited laboratories, when preparing their facilities for the Organization for Economic Cooperation and Development good laboratory practice (OECD GLP) recognition. Accredited laboratories have an established quality system covering the administrative and technical issues specified in the standard. These issues include: internal audits, job descriptions and responsibilities, procedures for equipment/instrument maintenance and calibration, document control, handling of reagents, chemicals and reference materials, sample reception and sampling, validation of test methods, traceability and uncertainty of the test results, training of personnel, client complaints, corrective and preventive actions. Several of these issues are also required for OECD GLP recognition either with a different emphasis and/or with additional requirements. This article describes the complimentary and additional issues of ISO/IEC 17025 and the OECD GLP series of principles.

Keywords GLP · ISO/IEC 17025 · Quality system

Introduction

The main differences between an accredited laboratory according to ISO/IEC 17025 [1] and a research facility working according to the Organization for Economic Cooperation and Development good laboratory practice (OECD GLP) series of principles [2] are the types of projects that the laboratories deal with. OECD GLP projects are defined as studies. They are usually long-term, pre-determined experiments agreed upon by the sponsor before commencing the work whereas the accredited tests are generally short term, employing specific and different analytical methods requested upon submission by the customer, with unknown samples. Both facilities perform chemical, analytical and microbiological tests. Therefore an OECD GLP recognized laboratory wishing to obtain accreditation or, vice versa, an accredited laboratory applying for OECD GLP recognition, may use the available quality system with additional necessary requirements. This is similar to the conclusions of Hembeck in his article on "*GLP and other quality assurance systems*" [3], which showed a general comparison between good manufacturing practice, (GMP), good GCP, GLP and accreditation systems.

Making a rough estimate, there is probably about a 70% overlap of the requirements for ISO/IEC 17025 and OECD GLP. The aim of this article is to highlight the similarities between the ISO/IEC 17025 and OECD GLP directives as well as to identify the additional requirements.

This paper presents a short review of the quality system of an accredited laboratory, a GLP testing facility and their overlapping issues. The advantages of an accredited laboratory when preparing for GLP recognition and the additional GLP requirements for such laboratories is also shown. In addition, a comprehensive tabulated comparison according to the management and technical requirements of IEC/ISO 17025 is given in comparison to the requirements of the OECD GLP.

Accredited laboratories

Up to the end of 1999, laboratories were accredited according to ISO/IEC Guide 25 (EN 45001) which defined the requirements for evaluating the competence of testing and calibration laboratories At the end of 1999, the above standard was replaced with ISO/IEC 17025. ISO/IEC 17025 is a significant improvement on ISO/IEC Guide 25 (EN 45001), incorporating a vast amount of experience gained from working with the standards (including ISO 9000 series) and addresses, in depth new, and old issues which effect the test result such as: sampling, uncertainty, traceability, opinions and interpretations, service to the customer, calibration and more.

Accredited testing laboratories working according to the ISO/IEC 17025 include medical laboratories, building, construction and engineering laboratories, pesticide residue laboratories, and laboratories conducting pure material analysis, and tests for monitoring the environment, and more.

GLP testing facilities

Non-clinical studies include supporting tests for:

- Research in developing a new drug or active material
- Certifying a new pesticide
- Compliance of a new medical device, new equipment
- Monitoring air pollution, etc.

The GLP directives are usually prescriptive regarding the activities that need to be performed before, after and during a study. These GLP tests are pre-planned and documented in a detailed protocol. During the experiments there is pre-determined ongoing monitoring of the documents, the tests, the facility and the overall study.

Overlapping and unique issues

Subjects that are addressed in both ISO/IEC 17025 and the GLP directives include:

- Management and organization – definition of responsibilities, standard operating procedures (SOPs) for maintenance, calibration and use of equipment, procedures for the chain of custody (reception, registration and storage of test items/samples), training of staff, retention of valid reference materials, use of valid test methods and the test report/study report.

Areas unique to GLP include: Animal care, monitoring of a facility and the processes including the specific study, availability of the study plans and master schedules for all the studies, and a defined archivist.

Areas unique to ISO/IEC 17025 include: Processing of complaints, calculation of the uncertainty, service to the client, preventive actions and participation in inter-laboratory comparisons such as proficiency testing, traceability and uncertainty of the measurements, and customer review.

A comprehensive comparison according to the management and technical requirements of ISO/IEC 17025 to the requirements of the OECD GLP is summarized in Table 1.

Advantages of an accredited laboratory

An ISO/IEC 17025 accredited testing laboratory has an advantage when preparing for compliance to OECD GLP, since the quality system and a technical assessment of the different tests under accreditation have been assessed. There is a controlled documented quality system, equipment with the appropriate maintenance, calibration and operating instructions, valid reference materials, ongoing quality control tests and trained personnel (in ISO/IEC 17025 requirements). No less important is the mentality of the staff and management and that they are at ease with one quality system and have realized the benefits. Therefore, a laboratory wishing to expand its activities to include pre-clinical studies need only to fulfil the additional requirements for the OECD GLP recognition.

Additional requirements to the ISO/IEC 17025 for OECD GLP recognition

Table 2 describes the additional unique issues of GLP not included in detail in ISO /IEC 17025.

Organizational requirements: According to GLP directives the study director, quality manager and archivist are the three personnel who need to be formally appointed, and who are each individually responsible for the correct conduct in compliance to GLP.

The OECD GLP regulations have specific guidelines for the each of these positions (study director, quality manager and archivist) where the responsibilities are defined. More specifically:

a. The study director
   The single focus point of control for a study. They are responsible for the performance and OECD GLP compliance, the interpretation of the results and preparing the study report according to the OECD GLP requirements. The study director approves the study plan and any amendments. They ensure the technical validity and availability of the appropriate procedures and are in constant contact with the quality assurance unit (QAU).

Table 1 A comparison of the management and technical requirements of ISO/IEC 17025 and the Organization for Economic Co-operation and Development good laboratory practice (OECD GLP): QAU quality assurance unit, SOPs standard operating procedures, PT proficiency testing

Section of ISO/IEC 17025	Subject	Accredited laboratory	Recognized GLP facility
4.1	Organization and management	The laboratory should define: – Technical management – Defined quality manager for all activities of the laboratory.	For each study need: – Defined study director – Defined quality manager – Defined archivist
4.2	Quality system	Quality manual addressing each section of ISO/IEC 17025	Well-defined quality assurance programme including timetable for QAU checks
4.3	Document control	Establish and maintain procedures to control all documents that are part of its quality system and be uniquely identified and approved	Documented master schedule for all the studies Study plans, with relevant documented SOPs and reports
	Archiving	All obsolete documents should be removed Test results should be archived for X years	Defined person, procedure and space for archiving all documents and test items relevant to the study for X years.
4.4	Review of requests, tenders and contracts	Necessary for tests and calibrations	Not required by GLP
4.5	Subcontracting of tests and calibration	Defined requirements in the standard	Not required
4.6	Control of services and supplies	Defined requirements in the standard	Not required by GLP
4.7	Service to the client	Defined requirements in the standard	Interaction with the sponsor prior to commencing the study – signs study protocol
4.8	Complaints	Defined requirements in the standard	Not applicable
4.9	Control of non-conforming testing and/or calibration work.	On-going quality control	Part of the QAU programme on-going checks reviewed regularly and internal audits
4.10	Corrective action	Defined requirements in the standard	Defined as amendments to the study
4.11	Preventive action	Defined requirements in the standard	Not required
4.12	Control of records	Original observations (raw data), amending records and computer filing	Ensure the maintenance of a historical file of all the procedures.
5.1	General	Factors which contribute to the uncertainty, correctness and reliability of the test results	Uncertainty values are not required
5.2	Personnel	Defined requirements in the standard	Current training, knowledgeable in the principles of GLP.
5.3	Accommodation and environmental conditions	Sufficient to facilitate correct performance of the tests	Avoid cross contamination extra emphasis for studies which involve animals
5.4	Test calibration methods and method validation	Defined requirements in the standard	All methods have to be validated prior to use in a study
5.5	Equipment	Defined requirements in the standard	Apparatus used in a study should be periodically inspected according to the procedures.
5.6	Measurement traceability	Defined requirements in the standard	Information concerning source preparations data stability should be available.
5.7	Sampling	Defined requirements in the standard	No subsampling
5.8	Handling of the test and calibration specimen	Defined requirements in the standard	Chain of custody, test of stability through out the study, effects of storage conditions, etc.
5.9	Assuring the quality of the test and calibration results	Required in the standard – participation on proficiency testing (PT) programmes	On-going predetermined and ad hoc quality checks of the test item, study and facility. No PT required.

Table 2 GLP requirements – special issues

Subject	Accredited laboratory	Recognized GLP facility
Reagents and solutions	Defined in Section 5.6.3.2. Where possible measurement results should be traceable to SI units or to certified reference materials	Certified, fully traceable, with appropriate documentation from the customer or supplier regarding the expiry date, storage, stability and homogeneity, and purity. The analyst should also record these details in the study when used. All reference substances in GLP need to be registered on reception and usage uniquely identified as a reference or working standard
Control of changes	Defined in Section 4.3.3. The lab should define how changes are made in documents	Planned amendments to the study protocol should be documented and signed by the study director. Non-planned deviations should be maintained with the study
Animal-related laboratory work, forms a major part of GLP	No reference	Emphasized in detail
Archive facilities	As requested by the customer	Archive facility should be provided for the secure storage and retrieval of study plans, raw data, final reports, sample of test items and specimens. An archivist should be nominated for this activity.

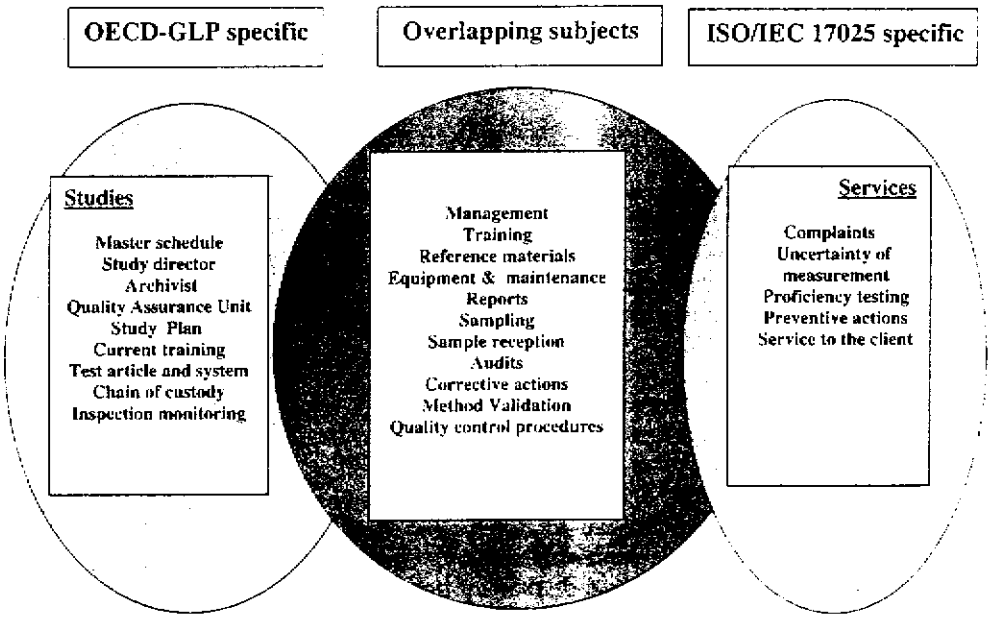

Fig. 1 A schematic diagram showing the overlapping and specific requirements between an ISO/IEC 17025 accredited testing laboratory and an OECD GLP facility

b. The quality manager
Defined in ISO/IEC 17025 (clause 4.1.5 i) however, requiring only that he/she "ensures that the quality system is implemented and followed at all times" with direct access to the highest level of management. The quality manager and QAU in OECD GLP have five main activities: Inspecting the study in process in real-time, auditing the records and documentation, monitoring, advising, and following up on corrective actions. They periodically write status reports on the study, highlighting problems and the corrective action taken. The quality assurance functions are defined as being independent from the study.

c. The archivist
ISO/IEC 17025 requires that the records are to be kept (clause 4.12) and should be retrievable, though no strict rules are defined as in OECD GLP. OECD GLP requires that an archivist be designated and that the appropriate resources be available for proper function of the archive.

To summarize, there are similar issues in the two quality systems that may compliment each other as well as some specific issues in both ISO/IEC 17025 and OECD GLP that need to be individually addressed. Figure 1 summarizes the overlapping specific issues of the two quality systems.

Conclusions

A laboratory that has implemented a quality system for accreditation according to ISO/IEC 17025 has a definite advantage when wishing to expand its activities to OECD GLP.

An accredited laboratory has approximately 70% of the administrative and technical issues of the GLP directives covered, while the additional 30% can be provided as an extension of the existing system. It is not necessary to maintain two separate systems but one can integrate the two systems, using the overlapping issues to an advantage.

References

1. ISO/IEC 17025 (1999) General requirements for the competence of testing and calibration laboratories. ISO, Geneva, Switzerland
2. OECD (1997) Series on principles of good laboratory practice and compliance monitoring No. 1. OECD
3. HW Hembeck (2002) Accred Qual Assur 7:266–268