



Implementation of OECD Principles in Test facilities complying with a Quality System Accredited to ISO/IEC 17025

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Quality System (description)

A model for gaining quality assurance related to design, development, production, testing, installation and service.

Quality management system within which the organisation operates and has the ability to provide the services as required **OECD-GLP** (Organization for Economic Co-operation and Development Good Laboratory practice) / **ISO/IEC 17025**



The ISO/IEC 17025 describes the Quality system (requirements) of a laboratory.

Addresses issues which affect the test result such as: sampling, uncertainty, traceability, opinions and interpretations, service to the customer, calibration and more.



The ISO/IEC 17025

Specified or self developed analytical methods which are requested upon submission by the customer, to analyze an unknown samples.

ISO/IEC 17025 accredited test methods are generally routinely used to generate test result

They also may be developed by the laboratory).



GLP testing facilities



Non-clinical studies that include supporting tests for:

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



GLP studies are:

Pre-determined experiments (more than one test method may be used) agreed upon by the sponsor before commencing the work.

Related to registration or license of product for use



The main difference between an accredited laboratory according to ISO/IEC 17025 and a research facility working according to the OECD-GLP series of principles are the type of projects that the laboratories deal with.



Subject	ISO/IEC 17025	OECD-GLP
Reagents and solutions	Defined in section 5.6.3.2 where possible 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



Subject	ISO/IEC 17025	OECD-GLP
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.



Subject	ISO/IEC 17025	OECD-GLP
Archive facilities	As requested by the customer	Defined requirements Archivist, which documents, test items and for how long. Requirements for all the peripheral support equipment, computer software



Subject	ISO/IEC 17025	OECD-GLP
Animal related laboratory work, forms a major part of GLP	No reference	Emphasized



OECD-GLP specific

Overlapping subjects

ISO/IEC 17025 specific

Studies

Master schedule
Study director
Archivist
Quality Assurance
Unit
Study Plan
Current training
Test article and
system
Chain of custody
Inspection monitoring

Management
Training
Reference materials
Equipment &
maintenance
Reports
Sampling
Sample reception
Audits
Corrective actions
Method Validation
Quality control
procedures

Services

Complaints
Uncertainty of
measurement
Proficiency testing
Preventive actions
Service to the client