Overview of Good Food Laboratory Practices

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• Good Laboratory Practice (GLP) was first introduced in New Zealand and Denmark in 1972.

• GLP was instituted in USA following cases of fraud generated by toxicology labs in data submitted to the FDA by pharmaceutical companies.
Why use GLPs?

• Generating **reproducible, accurate analytical results is important for laboratory success**, but isn’t necessarily easy to do.

• There are **processes and tools that are critical components of successful laboratory quality assurance programs**.

• In general many of the practices that lead to a successful quality assurance program are also required for general business success such as:
  • **good communication**
  • **engaged employees**
  • **management**
  • **a strong training program**
  • **a facility that supports work to be done in the lab**.
An Overview on Good Food Laboratory Practices

• A Good Laboratory Practice (GLP) process is an important component of all Quality Programs.

• It includes a set of principles that provides the framework within which the laboratory is planned, performed, monitored, reported and archived.

• It is applicable in all aspects of a laboratory including; implementing, validating and maintaining the laboratory compliance.

• This discussion will outline the basic principles of GLP with a particular focus on food testing.
Good Laboratory Practice

GLP is a set of principles
• provides a framework for
• food laboratory studies that are planned performed, monitored, reported and archived.

The standard ISO/IEC 17025:2005, used to accredit a laboratory, is an example of a code of good laboratory practice.
OECD - Principles of GLP

Non-clinical health and environmental safety study - intended for submission to appropriate regulatory authorities.

In the US the equivalent legislation is:

**US (FDA)**
CFR 21: Part 58 – Good Laboratory Practice for Nonclinical Laboratories studies

**US (EPA)**
CFR 40 Vol 7 Part 160 – Good Laboratory Practice Standards (Pesticides Programs)

CFR 40 Part 28 Part 792 Toxic Substance Control Act

In EU countries the equivalent legislation is:

Directive 2004/10/EC
4) Summary

27. While the OECD Principles of Good Laboratory Practice and ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories both set out requirements for quality management systems under which testing is conducted, they are, as a result of their evolution and history, documents with different purposes. It is therefore impractical, and in many cases would be inappropriate, to apply one of set of requirements with the intention of meeting the purposes of the other.

28. The OECD Principles of Good Laboratory Practice is used as a regulatory control mechanism to assure the quality and integrity of non-clinical health and environmental safety studies regulated under law. Such testing, for the most part, is complex and variable, and the OECD Principles of Good Laboratory Practice are specifically designed, as a set of principles, to be applied to individual studies to accommodate the complexity and variability of such studies.

29. ISO/IEC 17025 is an international standard intended to be applied to laboratory facilities conducting testing according to established or specifically developed methodology. The focus of the standard is on the on-going operation and management of the laboratory itself, and on the capacity of the laboratory to produce consistent and reliable results that are scientifically valid. ISO/IEC 17025 can, in theory, be applied to any testing laboratory in any scientific discipline including those performing non-clinical testing.
Elements of Good Laboratory Practice

Quality Assurance - Establishing Confidence in Reported Data.

• Standard Operating Procedures (SOP's)
• Statistical procedures for data evaluation
• Instrumentation validation
• Reagent/materials certification
• Analyst certification
• Laboratory facilities certification
• Specimen/Sample tracking

Documentation and Maintenance of Records. Accountability.
Why use GLPs?

• Generating **reproducible, accurate analytical results** is important for laboratory success, but isn’t necessarily easy to do.

• However, there are **processes and tools** that are **critical components** of successful laboratory quality assurance programs.

• In general many of the practices that lead to a successful quality assurance program are also required for general business success such as: **good communication**, **engaged employees and management**, **a strong training program** and a facility that supports the work to be done in the lab.
What GLP is Not

GLP, a data quality system, should not be confused with standards for laboratory safety - appropriate gloves, glasses & clothing to handle lab materials safely.

“It’s a grocery list, Brother Clarence!”

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An Example - ISO/IEC 17025:2005

- ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

- It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

- ISO/IEC 17025:2005 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025:2005, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

- ISO/IEC 17025:2005 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories.

- Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO/IEC 17025:2005.
ISO/IEC 17025:2005

General requirements for the competence of testing and calibration laboratories

• Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling.

• It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
ISO 17025 Quality Manual

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4 Management requirements

4.1 Organization

4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities or organizations providing recognition.

4.1.5 The laboratory shall

• have **managerial and technical personnel** who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties,
• including the **implementation, maintenance and improvement of the management system**,  
• and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations....
4 Management requirements

4.2 Management system

4.2.1 The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities.

- The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results.
- The system’s documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.
4 Management requirements

4.2 Management system

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement

• Shall be defined in a quality manual.

• The overall objectives shall be established, and shall be reviewed during management review.

• The quality policy statement shall be issued under the authority of top management.

Quality Manual
4 Management requirements

4.3 Document control

4.3.1 General

• The laboratory shall establish and maintain procedures to control all documents that form part of its management system, such as regulations, standards, other normative documents, test and/or calibration methods.
4 Management requirements

4.4 Review of requests, tenders and contracts

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

• a) the requirements, including the methods to be used, are adequately defined, documented and understood;
• b) the laboratory has the capability and resources to meet the requirements;

4.4.2 Records of reviews shall be maintained.
4 Management requirements

4.5 Subcontracting of tests and calibrations

4.5.1 When a laboratory subcontracts work, whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis, a competent subcontractor is one that, for example, complies with this International Standard for the work in question.

Contracts
4 Management requirements

Procedures

4.6 Purchasing services and supplies

4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations.

• Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.
4 Management requirements

4.7 Service to the customer

4.7.1 The laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory’s performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

Cooperation
4 Management requirements

4.8 Complaints

• The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.
4 Management requirements

4.9 Control of nonconforming testing and/or calibration work

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing, or the results of this work, do not conform to its own procedures.

The policy and procedures shall ensure that:

• a) the responsibilities and authorities for the management of nonconforming work are designated and

• actions are defined and taken when nonconforming work is identified
4.10 Improvement

• The laboratory shall *continually improve the effectiveness of its management system* through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
4 Management requirements

4.11 Corrective action

4.11.1 General

• The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system.

4.11.2 Cause analysis

• The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

Root Cause
4 Management requirements

4.12 Preventive action

4.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified.

4.12.2 Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

Actions Effective
4 Management requirements

4.13 Control of records

4.13.1 General

• 4.13.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.

• Quality records shall include reports
4 Management requirements

4.14 Internal audits

4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure,

- conduct **internal audits of its activities** to verify that its operations continue to comply with the requirements of the management system and this International Standard.
4 Management requirements

4.15 Management reviews

4.15.1 In accordance with a predetermined schedule and procedure, the laboratory’s top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities.

Review schedule
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5 Technical requirements

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- human factors (5.2);
- accommodation and environmental conditions (5.3);
- test and calibration methods and method validation (5.4);
- equipment (5.5);
- measurement traceability (5.6);
- sampling (5.7);
- the handling of test and calibration items (5.8).
5 Technical requirements

5.2 Personnel

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment,

- perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.
- When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing
- specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.
5 Technical requirements

5.3 Accommodation and environmental conditions

5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions.
5 Technical requirements

5.4 Test and calibration methods and method validation

5.4.1 General

• The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope.

• These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated.
5 Technical requirements

5.4.2 Selection of methods
5.4.3 Laboratory-developed methods
5.4.4 Non-standard methods
5.4.5 Validation of methods
5.4.6 Estimation of uncertainty of measurement
5.4.7 Control of data

Validation Methods
Criteria tested during method validation

- Accuracy
- Precision
- Specificity
- Sensitivity
- Repeatability
- Reproducibility
- Applicability
Validation

• 5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness.
5 Technical requirements

5.4.6 Estimation of uncertainty of measurement

5.4.7 Control of data

Measurement Uncertainty
5 Technical requirements

5.5 Equipment

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.

Required
5 Technical requirements

5.6 Measurement traceability

5.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.
5 Technical requirements

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

• The laboratory shall have a programme and procedure for the calibration of its reference standards.

• Reference standards shall be calibrated by a body that can provide traceability.
5 Technical requirements

5.5 Equipment

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.
5 Technical requirements

5.7 Sampling

5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration

- The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken.

- Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

“Critical”
5 Technical requirements

5.8 Handling of test and calibration items

5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.
5 Technical requirements

5.9 Assuring the quality of test and calibration results

5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

5.10 Reporting the results

• The results shall be reported, usually in a test report or a calibration certificate.

Test Reports
Test Reports

5.10.2 Test reports and calibration certificates

• Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:
  • a) a title
  • b) the name and address of the laboratory
  • c) unique identification of the test report or calibration certificate (such as the serial number)

5.10.9 Amendments to test reports and calibration certificates
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AOAC Accreditation Guidelines for Laboratories (ALACC)

The “Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals - An Aid to the Interpretation of ISO/IEC 17025:2005 (2015)” (ALACC Guidelines) provide detailed information to aid in assessing the essential quality requirements for performing microbiological and chemical analyses of food, dietary supplements, and pharmaceuticals.

The revision includes dietary supplements for the first time.

The document is closely aligned with ISO/IEC 17025 and provides a section-by-section interpretation of the general ISO/IEC 17025 requirements.

http://www.aoac.org/aoac_prod_imis/AOAC/AOAC_Member/PUBSCF/ALACCCF/ALACC_M.aspx
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  - **a facility that supports work to be done in the lab**.
Explore cutting-edge research, networking opportunities, practical solutions, resourceful safeguards, and innovative technologies for advancing the grain science community.

AACC International Membership Benefits:

- **AACC PRESS Resources**
  - 10% off member discount
  - Hot-topics articles and industry trends in *Cereal Foods World*
  - Discounted subscription to *Cereal Chemistry*

- **Analytical Resources**
  - Approved Methods of Analysis
  - Check Sample Program

- **Volunteerism**
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