Technical Specifications

TS4.1 - Laboratory Testing

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GMP+ International

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1. Introduction

All GMP+ certified companies have quality assurance plans. This internal monitoring plays an important role in the wide range of GMP+ Feed Safety Assurance standards. Some of that monitoring is carried out by means of laboratory testing. High-quality laboratory testing is an essential element of feed safety assurance. This document was drawn up to ensure that consistently high quality levels of laboratory testing are achieved.

This document broadly consists of the following three elements:

a. minimum requirements of the laboratory's quality system, derived from EN 17025;
b. the application of officially recognized methods (or methods providing equivalent performance) thereby ensuring uniformity;
c. participation in inter-laboratory testing (ring test), on the basis of proficiency.

1.1. Scope of this document

This document specifies the requirements for a quality assurance system in which a GMP+ certified laboratory can ensure that the results of the analyzes of feed are sufficiently reliable.

1.2. Application

This document applies to GMP+ certified laboratory which carries out analyzes within the framework of the GMP+ FSA module.

Certification will be awarded according to the type of activity as well as the analytical method and matrix employed.

In this document the words 'laboratory' and 'GMP+ certified laboratory' are used interchangeably. Both terms refer to the organization which has implemented the quality system.

In addition, the word 'laboratory' sometimes refers to the physical building or to the area where the analysis takes place.

Certification under this GMP+ FSA standard may be combined with accreditation under ISO 17025.

2. Organisation and Quality Policy

2.1. Quality system

The GMP+ certified laboratory must have a quality system in place which includes the organization and documentation of:

a. responsibilities;
b. authorizations;
c. procedures;
d. processes; and
e. provisions made in relation to the management and guaranteeing the reliability of the analytical results.

Responsibility for the proper structure and operation of the quality system rests with the directors of the business.

2.2. Organizational diagram

An organizational chart must be provided to show how the GMP+ certified laboratory fits into the organization of the business.

The GMP+ certified laboratory and its personnel must have a position independent of any activities related to the production and trading of feed carried on elsewhere in the business.

The manager of the quality system must have direct access to the company directors.

Internal audits must be carried out by a person who is independent of the activities to be audited. This person must have adequate knowledge of the activity to be audited.

2.3. Management of the quality system

There must be a procedure in place to govern authorizations in connection with amendments, modifications, additions or reviews of the quality system.

A manager must be appointed within the business to be responsible for managing and distributing the manual and keeping it up to date (see *§3.2* for requirements for the manual).

3. Documentation

3.1. Documented information

All the matters indicated by the GMP+ certified laboratory in the quality system must be retained as documented information or clearly observable.

Everyone in the laboratory involved with any element of the quality system must be aware of this and actively work towards its achievement.

3.2. Manual

One of the requirements for the proper functioning of the quality system is that it must be set down in a manual. Only in this way does the cohesion among the critical points and the quality of the results of analysis become transparent for the GMP+ certified laboratory.

The manual provides an ongoing reference source for the implementation and maintenance of the quality system. The manual must demonstrably be kept up to date (see *§ 2.3* for who is responsible for this).

3.3. Date and Authorization

The documented instructions and procedures must be dated and authorized by a person nominated by the directors of the business.

4. Facilities and Environmental conditions

4.1. Environmental conditions

The environmental conditions where the analytical procedures are carried out must not affect the accuracy and precision of the analytical results.

4.2. Regulating access

There must be a procedure controlling access to the laboratory, approved by the directors, which will ensure that the integrity of the results is not affected.

The following matters must be dealt with, as a minimum:

a. sample storage is secured against unauthorized access;
b. data is secured;
c. the laboratory must be accessible only for laboratory personnel. Other persons may only enter the room in the presence of laboratory personnel.

4.3. Utilities

Provision must be made for:

a. the reception of sample material;
b. the storage of samples;
c. the cleaning of glasswork and other equipment;
d. the preparation and storage of chemical reagents and similar;
e. the carrying out of the tests, including the preparation of samples.

These provisions must be appropriate given the goals of the quality system.

5. Personnel

The laboratory personnel are of crucial importance in managing and guaranteeing the quality of the analytical results. The personnel must therefore have the knowledge and capabilities required for their assigned tasks in this context.

In order to achieve this, it must be ensured that:

a. their tasks, responsibilities and authority are made clear to them, in writing;
b. there is an established procedure in place to ensure that all personnel involved are aware of the necessary instructions and standards. They must be kept informed at least in writing, on a regular basis, and certainly in the event of essential modifications. This also applies to temporary personnel;
c. personnel receive adequate initial and follow-up training. This must be apparent from the personal files and/or a training program.

6. Equipment

6.1. Items to retain as documented information

The following matters must be retained as documented information with regard to the equipment and tools which might affect the outcome of the analytical work:

a. an inventory of the equipment available, stating the method of identification employed;
b. a maintenance system, stating the frequency and nature of the maintenance work to be carried out, including adjustment, calibration and validation, and stating who is authorized to carry out such activities. The calibration must be able to be derived from primary standards;
c. the suitability of quality inspection equipment for its particular purposes: in the event of faults in equipment: the measures that are and must be taken in relation to the use of the equipment, as well as the assessment of the validity of inspection results obtained previously.

6.2. Logbook

For each equipment, the following items must be documented in a logbook:

a. the maintenance activities;
b. repaired faults;
c. calibrations;
d. adjustments and validations as specified under *§6.1*.

Malfunctioning equipment must be marked as such (“quarantined”).

7. Samples, Standard, Reference and Auxiliary material

7.1. Specifications

Specifications must be available for the required quality of standard and reference materials and auxiliary material (chemicals). These must be retained as documented information.

7.2. Check

Standard, reference and auxiliary materials must be checked on delivery to establish that what was ordered was in fact received.

7.3. List of authorized suppliers

There must be information available on the quality and reliability of suppliers of standard, reference and auxiliary materials. A list of authorized suppliers must be drawn up on the basis of this information.

Checks must be carried out on the usability of critical standard, reference and auxiliary materials. Frequency of checks is dependent on the extent to which the standard, reference and auxiliary materials are critical for the outcome of the analyses. A procedure must be laid down for this.

7.4. Identification

Standard, reference and auxiliary materials must be uniquely identified and provided with an expiry date and storage instructions where these are important for quality.

7.5. Precautionary measures

Precautionary measures must be in place at all stages of storage, sample preparation, sample processing and investigation, in order to avoid any possible unfavorable effects on the results of analysis. Instructions must be available for these purposes, and these must be kept under review.

7.6. Instructions

Instructions must be available covering receipt, shelf life / storage duration and destruction of samples and standard, reference and auxiliary materials.

8. Instructions

8.1. Instructions and Description

Instructions must be available to cover:

a. the operation, maintenance, calibration and adjustment of equipment;
b. the handling of samples (see §7.6);
c. the realisation of the testing (the analysis), including the control provisions to be carried out. A control sample must be included in each series, the frequency is matched to single or duplicate control tests, the way in which the results of the control provisions are interpreted and the records and reports of the results. The responsibility for acceptance and reporting of analytical results must be clearly set out.

The under TS 4.1 *Laboratory testing* executed analyses must be validated. Depending on the type of analysis, at least the following performance features must be determined:

Type of analyses	Minimum performance features
Qualitative method	Demonstrable level, selectivity, specificity, robustness.
Quantitative method, high concentration	Correctness, repeatability, reproducibility, linearity, selectivity, specificity, robustness.
Quantitative method, low concentration	Correctness, repeatability, reproducibility, demonstrable level, determination level, selectivity, specificity, robustness.

Any test instructions must include at least a description of the following:

a. equipment;
b. reagents;
c. other auxiliary materials, and;
d. acceptance criteria for the analytical results obtained.

It must also be stated whether and when the determination must be carried out on a single or duplicated basis. In the case of single analysis there must be sufficient guarantees built in to ensure the quality of the analytical result, for example through the inclusion of additional control analyses.

8.2. Familiarity with the instructions

a. The current instructions must be known to the personnel involved.
b. Work must be carried out in accordance with the (current version of the) instructions.

9. Registration, Reporting and Retaining

9.1. Registration

The following data must be unambiguously recorded:

a. the identity of the sample (type, source, sample number);
b. date of receipt of sample;
c. testing methodology adopted;
d. results of analysis; in the case of microbiological analysis, stating the quantity used in the test;
e. results of confirmatory tests (if applicable);
f. results of control analyses. Determination and evaluation to be in accordance with the methodology described under §10.2 and §10.3;
g. any irregularities detected;
h. names of those carrying out the investigation and authenticating the results.

The records must be secured (see §4.2) so as to prevent their unintended loss, and any amendments must be verifiable.

9.2. Reporting

Results may be reported only by authorised persons on behalf of the GMP+ certified laboratory. The following items must be reported per sample:

a. identity of the sample;
b. sample number;
c. any batch or reference number (provided by the principal);
d. date of receipt of the sample;
e. final result or results;
f. any remarks;
g. report date by the person responsible for drawing up the report;
h. authorisation by the person responsible for the report;
i. person for whom the report is intended;
j. the testing method used including the version number (possibly reclaimable).

9.3. Retaining documented information

All data which might be significant in reconstructing how a particular result was achieved must be retained. The following items must be retained as documented information (possibly in electronic form) for at least 3 years:

a. the records mentioned in §8.1;
b. a copy of each of the reports mentioned under §9.2;
c. the equipment log-books mentioned under §6.2;
d. results of internal inspections and checks;
e. replaced documents (manual, procedures, instructions etc).

9.4. Protection data

There must be adequate security to prevent unauthorised access to and amendment of information.

10. Quality control plan and Internal audits

10.1. Quality control plan

The GMP+ certified laboratory must draw up a quality control plan to include all relevant checking recorded in the quality system. The results must be compared to the company's internal standards.

The quality control plan must include at least the following elements:

a. identification of critical points, in a logical and systematic sequence;
b. the required checks, and their frequency;
c. persons responsible for carrying out checks.

10.2. Documentation

The results of the quality control plan must be documented on inspection forms developed for the purpose, stating the following as a minimum:

a. items to be inspected, and the results;
b. the section of the GMP+ certified laboratory involved;
c. inspection date;
d. name of inspector;
e. actions taken.

The GMP+ certified laboratory must carry out an investigation into the cause of any irregularities, and to rectify these. The action taken, the motivation and the results must be retained as documented information.

10.3. Frequency

Internal audits must be carried out at least once a year.

10.4. Reporting

The results, their evaluation and the actions taken must be reported to the directors of the GMP+ certified laboratory. The (final) responsibility for taking action in the case of irregularities rests with the directors of the business.

11. Ring test

11.1. Participation

The GMP+ certified laboratory must take part in inter-laboratory tests (ring tests) dealing with the analytical methods used by the GMP+ certified laboratory and must be based, where possible, on proficiency testing.

11.2. Administration

For each testing activity, the laboratory's results, as compared with the mean calculated from the relevant ring test must be retained for a minimum of 3 years. The results must show the deviation from the mean, expressed as multiples of the spread ("s") calculated for the ring test in question, and presented as a summary or graph.

11.3. Instigation of testing

The laboratory must carry out an investigation into the cause of deviations and rectify them, where the following occurs:

a. one deviation of more than 3 x s, or;
b. two consecutive times with a deviation of more than 2 x s on the same side of the average, or;
c. or four consecutive results of more than 1 x s on the same side of the average.

This action taken, the motivation and the results must be retained as documented information.

12. Outsourcing

Analytical work may only be outsourced to a laboratory approved for this under the GMP+ FSA module. See TS 1.2 Purchase.

Operations which are outsourced are not eligible for certification.

Where analytical work is outsourced to third parties, the report to the principal must make clear that the analysis was not carried out in-house, but outsourced.

13. Complaints procedure

The GMP+ certified laboratory must have a system in place for the recording and handling of complaints.

14. Quality control of the Testing and Calibration results

The GMP+ certified laboratory must have procedures in place for quality control to monitor the validity of the analyses and calibrations carried out.

The details must be documented in such a way that trends are noticed and, where practically possible, statistical methods can be used to assess the results.

This monitoring must be evaluated periodically and modified where applicable. During this periodic evaluation the analysis methods used must also be evaluated.

A check must be carried out on whether use is made of the most current version of a method and whether there is a need to (re)validate the method.

Risk Management tools

That was a lot of information to digest and one might ask, what is the next step? Luckily we can offer support for the GMP+ Community when doing this. We provide support by means of various tools and guidances but as each company has a shared responsibility to feed safety, and therefor tailor-made solutions cannot be offered. However, we do help by explaining requirements and providing background information about the requirements.

We have developed various supporting materials for the GMP+ Community. These include various tools, ranging from Frequently Asked Questions (FAQ) lists to webinars and events.

Supporting materials related to this document (Guidelines and FAQs)
We have made documents available which give guidance to the GMP+ requirements as laid down in the module GMP+ FSA and GMP+ FRA. These documents give examples, answers to frequently asked questions or background information.

Where to find more about the GMP+ International Risk Management tools?
Fact sheets
More information: GMP+ Platform
Product list
More information: Product List
Risk Assessments
More information: GMP+ Platform
GMP+ Monitoring database
More information: GMP+ Monitoring database
Support documents
More information: Support documents

We enable every company in the feed chain to take responsibility for safe and sustainable feed.

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