Specific Certification Conditions Multisite processes GMP

You wish to have your company certified in a multi-site-oriented approach. This requires the fulfillment of specific accreditation-related requirements, which can be taken from the following points. If individual criteria are not met, each company / organization unit must be individually certified.

Multisite certification is possible (OPTION 1):

a. At a participant with a main office with 100% subsidiaries, or
b. At a group of companies which have joined together as a quality community.

Note:

Multi-site organization need not to be a unique legal entity, but all sites must have a legal or contractual link with the main office of the organization and be subject to a common management system, which is laid down, established and subject to continuous announced surveillance and internal audits by the central office. This means that the central office has rights to require that the sites implement corrective actions when needed in any site. Where applicable this should be set out in a formal agreement between the central office and the sites.

Guidance: Multi-site certification is reserved for companies which are part of the feed sector. Companies, participating in a multi-site organisation, must demonstrate this.

Multi-site certification is not to be used if various independent companies have joined together in a branch organisation, union, federation, association, via an independent consultancy office or similar.

This applies for the activities:

a. Transport of feed, the scope Inland waterway transport and short sea shipping of feed is excluded from multi-site certification
b. Trade in feed
c. Storage and Transshipment of feed
d. Affreightment
e. FRA activities

Note:

In a group of companies in which the above activities take place, in addition to the general requirements (see under A) which apply to a multi-site certification, there must also be compliance with the requirements under B.

For unprocessed goods (i.e. grain, seeds and pulses) which are collected, handled, stored or transported with own transport, the minimum requirements for multi-site certification, as laid down in a separate section under Certification, can be used.

Guidance: For a definition of collection see GMP+ A2 Definitions and Abbreviations.

a. If, for example, a group contains multiple production locations and storage locations, the production locations in this group cannot be certified under multi-site but perhaps the storage locations can.
b. If both collection and transport (incl. affreightment) takes place at locations, the certification of this may also be combined under the multi-site requirements.
c. If a participant or group of companies does not fully comply with the criteria, no use may be made of the following form of certification. A form of audit time reduction may possibly be requested. See GMP+ C6 Assessment and Certification Criteria for GMP+ Certification, annex 2.
d. These requirements do not exclude audits on the basis of reduced audit times. See GMP+ C6 Assessment and Certification Criteria for GMP+ Certification, annex 2.

A) General requirements

1) General

a. All locations fall under the same quality system which is managed centrally (referred to hereafter as the main office). This quality system complies with the relevant GMP+ standards and there must be compliance at all locations with the relevant GMP+ requirements (see also the guidance under C) Certification).
b. The same methods and procedures are used at all the locations.
c. Corrective actions may be imposed from the main office on all branches.
d. There must be a written agreement between the participating subsidiaries and the main office. This agreement must be signed by all the participating parties and the signed agreement must be present at the main office and available to the auditor. The statement will include at least:
    1. a commitment by the participant to the main office that it will comply with the requirements set in the quality system.

2. that corrective actions imposed by the main office are binding
3. that the above applies to all feed activities (and therefore those which are carried out more or less independently).

e. All the locations are included in the program of internal audits.

f. The main office must show that it is able to collect data from every location, to analyse the data and, where necessary, to implement changes with respect to:
   1. System documents and changes
   2. Management review
   3. Complaints handling
   4. Corrective actions
   5. Planning of internal audits and improvement measure

Guidance: Central management of the training plan is one of the possibilities.

2) Requirements for the internal auditor

The internal auditor must:

a. Be independent and may not check his own daily activities

b. Have demonstrable knowledge of feed safety systems through training or work experience

c. Have demonstrable knowledge through training and/or work experience of the field of work which will be audited

3) Requirements for the internal audit

a. An internal audit will be carried out at least yearly (1 x per 12 months) at all locations.

b. The internal auditor will have to carry out an internal audit in which all the aspects of the feed safety system are addressed. Use will preferably be made of the checklist used by the certification bodies.

c. The internal audit reporting must be drawn up in such a way that the certification body can make use of this information.

B) Additional requirements

The following additional requirements apply to a group of companies.

4) Trade

If not all feeds are traded via the main office but via a multi-site location, this trade in feeds must be completely guaranteed by the main office. During the internal audit, (the trading of) these feeds will also be included.

5) Transport

A transport company can only be certified under multi-site requirements if the transport company carries out all the feed activities for the main office exclusively. If this is not the case, the transport company must be independently certified.

Guidance: A production participant and a number of transport companies may unite in a quality community, for example. The certification can take place under multi-site requirements.

C) Certification

If a main office has a different GMP+ scope to one of the locations or companies, the main office must also additionally be certified for this scope

Guidance: If the main office is a production participant (GMP+ B1 Production, Trade and Services) and the other companies have a transport scope (GMP+ B4 Road Transport) and/or trading scope (GMP+ B3 Trade, Collection and Storage & Transshipment) etc., the production participant must also be certified for this scope (transport and/or trade) because the management and control of the feed safety management system lies centrally with the production participant.

In the event of multi-site certification the audit frequency for the locations (with the exception of the main office) is lowered where each location must be visited at least once per three years.

Guidance: In determining the locations which must be visited the certification body will use a random selection system. Account will be taken of:

a. The results of the internal audit as carried out by the main office

b. The activities which take place at the various locations

Ehe ein Zertifizierungsaudit stattfinden kann, müssen die Verträge zwischen dem Hauptstandort und den teilnehmenden Unternehmen sowie der interne Auditbericht der Zertifizierungsstelle zur Beurteilung vorgelegt werden können.

In an initial audit the main office and ⅓ of the locations must always be visited be-fore a certificate can be issued.

If a new location joins a participant or a group of companies, a verification of the relevant subjects must take place at the main office and the new location must be audited.

Unprocessed products (i.e. grain, seeds and pulses)

This multi-site construction is applicable for transport and storage for unprocessed products. Trade is excluded, also as transport and storage of processed products.

If a multi-site participant consists of more than 20 sub locations and there are only unprocessed products involved, another method to calculate the minimum frequency and audit times can be used:

- The requirements as laid down for the internal audit will be the same as in a regular multi-site certification; the internal audit program must cover all sites every year, including sites that are not used the whole year round.
- All sites with unprocessed goods must be located in the same country or in the bordering regions of neighbouring countries.
- The random sampling for the external audit can be risk based. All sites, including sites that are not used the whole year round, must be part of the random sampling of the external audit. For the external audit the main office will be audit every year. The sub locations will be audited during the certification period (3 years) as follows:
  a. Up to 20 sites; all sites
  b. From the 21st site, every fifth site.

The sub locations will be chosen randomly. The certification body may divide the sub locations into groups or districts.

Extra points of interests

As all locations / companies must work in accordance with the same methods and procedures and under the same quality system, the review of the documentation can remain limited to verification of the presence of up to date documentation and the completeness of the HACCP documentation with respect to the audited location.

During audits of locations where storage is done the following GMP+ requirements must assessed:

a. verification and administration of received products
b. process control: Good Housekeeping, control measures with respect to critical points
c. tracking & tracing
d. delivery, verification of loading compartments
e. inspections and records
f. delivery of feeds
g. if transport activities also take place, the operational aspects must also be assessed
h. complaints and nonconformities

During audits of locations where transport is done the following GMP+ requirements must assessed:

a. reception of transport orders incl. product category classification
b. journey sheets; identification of loading compartments, products, cleaning, loading and unloading addresses, etc.
c. inspection of the trucks present
d. administration, use of third parties, instructions with respect to GMP+ product categories
e. if storage activities also take place, the operational aspects must also be assessed
f. complaints and nonconformities

During audits of locations where trading is done the following GMP+ requirements must be assessed:

a. trading methods with respect to purchasing and delivery of feeds (possibly including the review of contracts)
b. method of verification and administration
c. tracking & tracing
d. inspections and records
e. complaints and nonconformities

An overview must be included in the GMP+ report showing when all the locations / companies were audited.

If serious nonconformities are observed at the main office, the whole participant or quality community does not meet the requirements for GMP+ certification. If nonconformity is observed at the level of a location, this can influence the location and/or the main office. This is to be assessed by the certification body.

A GMP+ audit report/checklist must be uploaded in the GMP+ Company Database for all multi-site locations in which only nonconformities will be described for a multi-site location. Also conform checklists must be uploaded in the GMP+ Company Database.

Only one certificate (or temporary acceptance where appropriate) will be issued for multi-site. This certificate will have an annex with the companies which belong to the multi-site. An individual location or participant can also receive a certificate.