Description of the Assessment

DIN EN ISO 22716 Cosmetics – Good Manufacturing Practice (GMP)

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If you should require any further information then please do not hesitate to contact us. We will be please to help you.

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The Assessment based on Standard ISO 22716 consists of the offer and contract phase, the audit preparation, performance of the audit, issue of the certificate and surveillance/re-assessment.
The auditors are selected by the Head of the Certification Body of TÜV NORD CERT GmbH in accordance with their approval for the particular branch (or the sector in the case of ISO 22716) and their qualification.

1 ASSESSMENT

1.1 Audit Preparation

Following conclusion of the contract, the auditor prepares him/herself for the audit based on the client questionnaire and the calculation sheet and discusses and agrees the further procedure with the client.

During preparation for the surveillance or re-assessment audit, organisations are obliged to inform the Certification Body of important changes in their structural and procedural organisation.

A preliminary audit is also available an option.

The preliminary audit is performed in order to

- audit the management system documentation of the client (organisation structure, documented procedures, internal audits),
- assess the site and the site-specific conditions of the client and hold discussions with the personnel of the client's organisation in order to determine readiness for the main audit,
- assess the status of the client and the client's understanding with regard to the requirements of the Standard, in particular with regard to identification of key services or performance, important aspects, processes, objectives and the operation of the measures to fulfil the requirements of the Standard,
- gather necessary information with regard to the scope of the management system, the processes and the site(s) of the client as well as with regard to associated legal and official aspects and their fulfilment (e.g. quality-related, environment-related, occupational health and safety aspects of the activities of the client, associated risks etc.),
- assess the allocation of resources for the main audit and also agree the details of the main audit with the client.
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If nonconformities are established in the preliminary audit these must be corrected by the client before the main audit.

If it is not possible to confirm that the client is ready for the main audit, the assessment procedure is aborted after the preliminary audit.

The Lead Auditor is responsible for coordination of the activities of the preliminary audit and if applicable for the coordination of the participating auditors with each other.

1.2 Audit

The client receives an audit plan that has been previously agreed between the client and the auditor.
The audit begins with a kick-off meeting, in which the participants introduce themselves to each other. The audit procedure is also explained. During the audit in the company/organisation, the Auditors inspect and assess the effectiveness of the measures for implementation of the requirements of DIN EN ISO 22716.
It is the task of the auditors to investigate the practical use of the management system based on the documented procedures and to audit it for fulfilment of the requirements of the Standard. This is achieved through questioning the employees, viewing the other applicable documents, records, orders and guidelines as well as by inspecting relevant areas.
A final meeting takes place at the end of the on-site audit. At least those employees who have management functions in the company/organisation and whose areas were involved in the audit take part in this meeting. The Lead Auditor reports on the individual elements and explains positive and negative findings. If nonconformities are identified, the Lead Auditor can only recommend issue of the certificate following acceptance or verification of the corrective actions by the audit team, see Section 7, “Management of Nonconformities”. This must be discussed and pointed out in the final meeting.
Documentation is by means of the audit checklist and is augmented by further records (e.g. audit questionnaire and hand-written records).

1.3 Award of Certificate

The certificate is issued following positive review of the assessment procedure by the Head of the Certification Body or by his/her Deputy or other persons appointed for the task. The reviewer may not have taken part in the audit.
The certificate can only be issued when all the nonconformities have been corrected, i.e. when the corrective actions have been accepted or verified by the audit team.
The certificates are valid for 3 years.

2 SURVEILLANCE AUDIT

Surveillance audits have to be performed once a year during the period of validity of the certificate.
The surveillance audits have to be carried out by the set date / the audit relevant date.

- The audit-relevant date for the annual surveillance audit which follows the first auditing may not be later than 12 months after the last day of the main audit.
- The audit-relevant date is the basis for all surveillance audits.
- Every surveillance audit, including review, acceptance and, if applicable, verification of the actions for correction of nonconformities, writing of the audit report and release by the certification body must be completed at the latest 3 months after the audit-relevant date.
- Within the framework of annual surveillance, a surveillance audit can take place at the earliest 3 months before the audit-relevant date.

Permissible tolerance for performance of the annual surveillance audit:
Audit-relevant date -3/+0 months.
Following the surveillance audit, the client receives a report (audit checklist).

3 RE-ASSESSMENT

Re-assessments must be carried out so that gap-free continuation of the certification is ensured. The audits for the re-assessment must – including review of the actions for correction of nonconformities – be completed before expiry of the period of validity of the certificate.
A review of the documentation of the management system of the company/organisation takes place in the re-assessment, along with an on-site audit. The results of the previous surveillance programme(s) over the term of the assessment must be taken into consideration. All the requirements of the Standard are audited. The audit method for the re-assessment is the same as for a first audit.

4 EXTENSION OF SCOPE AUDIT

If the scope of the existing certificate is to be extended, it is possible to undertake an extension audit. The extension audit can be performed within the framework of a surveillance audit or reassessment audit, or on a specific and independent date specially arranged for the purpose.
The extension audit does not change the period of validity of a certificate. Any exceptions must be justified in writing.

4.1 Short Notice Audits

It may be necessary for the certification body to conduct audits of certified clients at short notice to investigate complaints, or in response to changes, or as follow up on suspended assessments. In such cases,

- the Certification Body lays down the conditions under which these short-notice visits are to be conducted
- it is not possible for the client to object to an audit team member or members.

5 TRANSFER OF ASSESSMENTS FROM OTHER CERTIFICATION BODIES

Certificates from other certification bodies are not recognised. Takeover of clients from other certification bodies always start with the minimum time and cost of a re-assessment.

6 ASSESSMENT OF COMPANIES WITH MULTIPLE LOCATIONS (MULTI-SITE)

If a company or organisation that maintains several sites is assessed according to ISO 22716, these sites must also be audited. The auditing of companies/organisations with several production sites/branches/locations etc. with similar activity profiles and which run under a unified management system can be carried out using a sampling procedure.

Each site must be audited at least once within the period of validity of the certificate.

The central office is audited each year.

7 MANAGEMENT OF NON-CONFORMITIES

A root cause analysis must be performed by the company/organisation for each nonconformity and corresponding corrective actions must be implemented.
Deviation and nonconformity management is carried out using the audit checklist. In the case of NC-B nonconformities, the organisation documents the corrective actions in the audit checklist. The auditor reviews the suitability of the actions to establish their effectiveness. Actions resulting from NC-B nonconformities must be implemented within one year and are checked by the auditor in the next audit.
In the case of NC-A nonconformities a re-audit may be necessary. The re-audit must take place within 90 days. If this time limit is not fulfilled, the audit is considered to be failed. No certificate can be issued, or the existing certificate is withdrawn.