Certification agreement - general contract conditions - GMP+ FC SCHEME Certifications

CERTIFICATION STIPULATIONS

Introduction

The agreement basis between Bureau Veritas Certification Netherlands and the company in relation to obtaining and maintaining GMP+ FC SCHEME certification is based on a certification agreement. This Agreement is divided into *general contract conditions*, which lay down the general rights and obligations in connection with certification, and s*pecific conditions*, which lay down the specific matters relating to the individual service. A Certification Agreement is only valid when both parties have accepted the specific conditions. Any amendments will be attached as Appendices to the specific conditions. The conditions in the specific conditions are always more binding than similar conditions in the general contract conditions.

NECESSITY OF THIS AGREEMENT

Certification of a product is a means of providing assurance that it complies with specified standards and other normative documents. Bureau Veritas Certification Netherlands as certification body holder of licenses, certificates and marks of conformity shall exercise proper control over the ownership of these items. Thus policies and procedures under which the certification body operates shall not be abused in a misleading manner. Therefore it is necessary to clarify the duties of the certified organizations. The terms of this contract and the contract itself do not abolish or displace the company's contract with the local office. This contract shall be qualified as an additional acknowledgement with Bureau Veritas Certification Netherlands, which stipulates the duties between the company and Bureau Veritas Certification Netherlands.

1. Bureau Veritas Certification Netherlands's obligations :

As a party to this agreement Bureau Veritas Certification Netherlands shall provide the service in accordance with the specific conditions and the rules we are subject to GMP+ FC SCHEME. If the conditions for Bureau Veritas Certification Netherlands's certification activities are changed in a way, which affects the agreed certification basis, Bureau Veritas Certification Netherlands will make sure that the certification basis will be updated for the individual company. If such changes result in revision of the procedure for the certification, this procedure will be updated and sent to all contract holders.

1.1 Issuance of certificate

Based on an evaluation of the audit findings and conclusions and any other relevant information Bureau Veritas Certification Netherlands will make the certification decision and will issue a certificate if the decision is positive. The certificate will detail the standard to which the company has been found compliant at the time of audit and the scope of the processing activities.

1.2 Suspension, withdrawal or cancellation of the certificate

Bureau Veritas Certification Netherlands reserves the right to suspend, withdraw, reduce, extend or cancel the certificate at any time and will give 3 months written notice or such shorter notice as the situation may require depending upon the information available to Bureau Veritas Certification Netherlands. If such actions are deemed necessary the company will be fully briefed and will be given every possible opportunity to take corrective action. Bureau Veritas Certification Netherlands reserves the right to publish the fact that such action has been taken.

1.3 Confidentiality

All information concerning the company will be treated in strictly confidence. Information as required will be submitted to GMP+ International as detailed below.

2. The company's obligations:

Bureau Veritas Certification Netherlands shall require that the company:

a) always complies with the relevant provisions of the GMP+ FC certification programme;
b) makes all necessary arrangements for the conduct of the certification and surveillance audits, including provision for examining documentation and access to all areas, records (including internal audit reports) and personnel for the purpose of evaluation (e.g. testing, inspection, assessment, surveillance, reassessment) and resolution of complaints;
c) The company shall allow accreditation authorities and/ or scheme owner to be present at the certification audit and surveillance visits in order to enable the authorities to assess the quality management system of Bureau Veritas Certification.
d) makes claims regarding certification only in respect of the scope for which certification has been granted;
e) does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification which the certification body may consider misleading or unauthorized;
f) upon suspension or cancellation of certification, discontinues its use of all advertising matter that contains any reference thereto and returns any certification documents as required by the certification body;
g) uses certification only to indicate that activities are certified as being in conformity with specified standard;
h) endeavours to ensure that no certificate or report nor any part thereof is used in a misleading manner;
i) in making references to its product certification in communication media such as documents, brochures or other advertising, complies with the requirements of the certification body and of GMP+ International.
j) In case of a determined non-compliance of a permitted level of a contaminant, the company is obliged to notify an EWS report within 12 hours after confirmation of the contamination, to its Certification Body, competent authority, and GMP+ International

2.1 Complaints to suppliers of certified products

Bureau Veritas Certification Netherlands shall require the certified company to:

a) keep a record of all complaints made known to the company relating to a product's compliance with requirements of the relevant standard and to make these records available to the certification body when requested;
b) take appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification;
c) document the actions taken.

2.2 Certification maintenance

The company is requested to inform Bureau Veritas Certification Netherlands promptly of any significant changes to its product(s)/services or its organisation that impact the certified activities or any other circumstances, which may affect the validity of its certification. For example: Changes of sites, extra sites, fixed shifts, process changes, changes in ownership, changes of scope etc. Bureau Veritas Certification Netherlands will then take the appropriate action, such as arrange for the conducting of a special visit and/or changing the certification.

By signing this agreement Bureau Veritas Certification Netherlands shall get the permission of the company to inform GMP+ International about the contract established between Bureau Veritas Certification Netherlands and the company as well as about the results (also in detail) of the audit and the certification against GMP+ FC SCHEME. This concern passed as well as failed audits. Bureau Veritas Certification Netherlands is obliged to immediately transmit any information about audit results (also in detail) as electronic data to the GMP+ International office.

The company irrevocably empowers Bureau Veritas Certification Netherlands to make results of GMP+ FC SCHEME-audits available through their online database (GMP+ Company Portal).

The company shall (in case) allow and assist accreditation authorities to be present at any audit in order to enable the authorities to assess the quality management system and performance of Bureau Veritas Certification Netherlands.

The company shall (in case) allow and assist auditors representing GMP+ International performing or participating in audits as a part of **GMP+ FC SCHEME Integrity Program**.

2.3 Termination of the agreement

2.3.1 Termination

Either party may terminate this agreement. If the agreement is terminated – regardless of the reason – the certificate(s) issued and any artwork handed over shall be returned at the end of the period of notice. Hereafter the company is no longer allowed to refer to the approval in its business documents.
The company will be removed from Bureau Veritas Certification Netherlands' directory of valid certifications and placed in the directory of suspended or withdrawn certifications. The company also will be removed from the GMP+ FC SCHEME Company Database of valid certifications.

2.3.2 Notice

Either party at 3 months' notice can terminate the agreement.

2.3.3 Termination by default

Either party can terminate the agreement with immediate effect in the event of serious breach of the agreement, if one of the parties goes into liquidation or if a receiver or administrator takes over all or part of the obligations of one of the parties under this agreement.

2.4 Liability

"Bureau Veritas Inspection and Certification The Netherlands B.V. (CI000020) is accepted by GMP+ International to carry out GMP+ services. Bureau Veritas Inspection and Certification The Netherlands B.V. maintains operational, financial and legal responsibility for GMP+ services where performed by the Bureau Veritas Group members for GMP+ participants certified by Bureau Veritas Inspection and Certification The Netherlands B.V. "

Except in the case of gross negligence on the part of Bureau Veritas Certification Netherlands, Bureau Veritas Certification Netherlands shall not be liable for any loss or damage caused by our staff during the provision of a service.

In the event of gross negligence, the extent of any loss, damage or other for which Bureau Veritas Certification Netherlands shall be liable will be limited to an amount not exceeding the fee agreed by Bureau Veritas Certification local office and the company for the particular service in respect of which the negligence arose.

2.5 Force Majeure

Bureau Veritas Certification Netherlands shall not be liable should it be prevented from fulfilling its obligations due to any matters beyond its control.

2.6 Law

Dutch law shall govern this agreement. Any disputes arising between the parties, which the parties cannot settle themselves, shall be settled by arbitration or by a Dutch court.

2.7 Appeals

Should the company wish to appeal against the decisions of Bureau Veritas Certification Netherlands it should do so in accordance with the Bureau Veritas Certification Netherlands appeal procedure, a copy of which is available on request.

2.8 Use of logo

Use of the GMP+ logo needs to be in accordance with GMP+ A3.

3. GMP+ International Supervision of Certification bodies:

3.1 General Information

The Supervision Program is valid for all GMP+ FC SCHEME standards.

There are possible types of supervision or extra audits to which the company is obliged to cooperate in:

1. Parallel audit, where the auditor from GMP+ independently performs a full audit on the certified site.
2. Witness Audit to check the working practice of the auditor, meaning that an additional auditor from GMP+ FC SCHEME Office will participate during an audit of the company, only to witness the work of the certification body auditor.
3. Any additional audit activities initiated by GMP+.

3.2 GMP+ International Supervision Program - Additional Information - incl. no costs for companies.

The Integrity Program does not lead to additional costs for the companies; all costs are paid by GMP+ International or the certification body. GMP+ International has settled all processes of the Supervision Program with certification bodies with a signed general agreement.

4. The certification process

The details of the services to be provided will be agreed between the company and the local office of Bureau Veritas Certification. In case the term manday (MD) is used for calculation of audit time, it is to be considered that one manday equals 8 hours. To provide a general guide, outlined below are the key stages of the certification process.

4.1 One stage certification audit

The initial certification audit of a company is performed in one step.

The audit includes amongst an audit of the documentation of the management system of the company and an evaluation of the planning and performance of internal audits and management reviews. The audit will also address the full implementation of all the requirements to the management system.
To enable the auditor to prepare for the audit, the audited company shall forward a copy of the management system two weeks before planned audit day.

Bureau Veritas Certification local office will provide an audit programme prior to the commencement of the audits and state any further demands, which seem necessary for the company to obtain the certification in question.
The Bureau Veritas Certification local office audit team will meet with the client's management to discuss the details of the audit process and consider possible issues relating to the performance of the audit. The Bureau Veritas Certification local office audit team will discuss any Non-conformities, observations, and opportunities for improvement if and when they identified during the audit.
The Bureau Veritas Certification local office audit team will prepare and present to the client's management a report of the audit after review by Bureau Veritas Certification Netherlands.

4.2 Unannounced audit for production companies in Europe

In case the company is a production company, the following additional requirements apply:

1. One of the surveillance audits to be held at the production company, needs to be unannounced.
2.
    a. In case the production company is situated in The Netherlands, no notice shall be given.
    b. In case the production company is situated in Germany, no more than one day (24 hours) notice shall be given.
    c. In case the production company is not situated in The Netherlands or Germany, but is situated in another European country, no more than two days (48 hours) notice shall be given.
3. The company submits 15 days per year on which the unannounced audit cannot be held.
   The submission will be to the local contracting office from Bureau Veritas.
   This shall be done at the beginning of the certification year in which the unannounced audit shall take place.

4. The unannounced audit cannot be cancelled unless the auditor was not able to carry out the audit and approval was given by Bureau Veritas Certification Netherlands to have the audit cancelled.

4.3 Non-conformity

Bureau Veritas Certification auditors will only identify non-conformities that will help the company to improve their management system and to ensure that the requirements in the standard are fulfilled.

Non-conformities can be raised as Critical, Major and Minor non-conformities (NCR's). Critical NCR's must be solved immediately and may prevent certification. In certain cases the certificate is immediately withdrawn and the company is excluded for a period of at least one year. Major non-conformities are raised e.g. if a requirement in the standard or major parts of it are not described or implemented and must be solved within 4 weeks. Minor non-conformities must be solved before within 6 months and is verified during next audit. A non-conformity can be upgraded when the corrective action is not implemented. In case of a critical non-conformity GMP+ International is informed immediately via the GMP+ coordinator.

Corrective actions for all non-conformities shall be carried out to the agreed date, and the implementation must be accepted by the auditor. In connection with the first certification and extension (recertification) the corrective actions of major non-conformities shall be accepted by Bureau Veritas Certification local office be- fore recommendation of certificate issuing can take place. For minor non-conformities a suggestion of a correc- tive action shall be approved before the recommendation. The same is in force for uploading of surveillance reports.
In relevant cases (many implementation non-conformities, serious nonconformities) Bureau Veritas Certification local office reserves the right do an on-site a follow-up (compliance) visit.