General Certification/Inspection Regulations

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Table of Contents

1. General Remarks
2. Expiration or termination of a certificate
3. Advertising, publication of certificates, reports and information, use of the marks
4. Storage period
5. Infringements of the certification and inspection regulations
6. Document Annex
7. Supporting Documents
8. Document History

1. General

1.1 These General Certification/Inspection Regulations apply to audits and certifications in accordance with the valid individual contracts, audit criteria and audit objectives.

1.2 With each order the client acknowledges the current version of the Terms and Conditions, the price list and these general Certification/Inspection Regulations. Existing contractual relationships are subject to the current version of these documents. The client informs the blue inspection body GmbH before the award of the contract if the system intended to be audited or certified has already been the object of a comparable order addressed to another inspection/certification body.

1.3 The current valid versions of the general business terms and conditions, the price list as well as the general Certification/Inspection Regulations can be viewed on the internet at www.blue-inspection.com.

1.4 The Inspection Review Board (IRB) of blue inspection body evaluates the documents of the auditors or experts. IRB makes the decision on issuing of certificates and is the point of contact in the event of a dispute concerning the certification. A complaint procedure is available.

1.5 Audit reports and assessments according to GMP guidelines refer to the date of issue of the current revision of each guideline or standard.

1.6 The client agrees that auditors/assessors of blue inspection body and/or accreditation bodies take part and witness audits in the premises of the audited company.

1.7 blue inspection body GmbH might provide reports as hard copies as well as electronically generated documents. In this case, the hard copy of the audit report is to be regarded as the legally binding document.

1.8 Certified companies agree that blue inspection body is responsible and retains authority for decisions relating to certification, including the granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring following suspension, or withdrawing of certification.

1.9 The transfer of a certification from another certification body to Blue Inspection Body requires the provision of sufficient information from the applicant. This process is performed in accordance with the requirements of the mandatory document IAF MD2 (current version; IAF = International Accreditation Forum). The information required by this document will be requested by Blue Inspection Body and must be provided by the applicant requesting the transfer.

2. Expiration or termination of a certificate

2.1 A certificate can be invalidated, if:

2.1.1 An indicated period of validity is expired.

2.1.2 The holder of a certificate or report terminates its membership in the assessment system of blue inspection body by the end of calendar year in writing.

2.1.3 The holder of a certificate or report objects to the terms and conditions, the general certification and inspection regulations or the price list, in writing.

2.1.4 about the property of the owner of a certificate or report a procedure according to the insolvency order is opened or one, on the opening of such a procedure directed application in the absence of capital is rejected.

2.1.5 The inspected/certified company stops business operations.

2.1.6 the legal requirements themselves, the requirements of the accreditation body or the state-of-the-art of science and technology on which the certificate or the report were based are changed.

2.1.7 the business relationship between the manufacturer of an active ingredient or medicinal products and the owner of a certificate or report as a subcontractor is cancelled.

2.2 The Inspection Review Board (IRB) may terminate, suspend or invalidate a certificate or a report without notice, in particular if:

2.2.1 A certified company does not fulfil the certification requirements - including the requirements applicable to the effectiveness of the management system.

2.2.2 The certified company does not permit the performance of the surveillance or re-audits in the required frequency: Surveillance audits shall be conducted at least once a calendar year, except in recertification years. The date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.

2.2.3 The certified company has voluntarily requested a suspension/termination.

2.2.4 delusive or otherwise unacceptable advertising is practised, in particular with the certificate or the report, or the certificate or the report are misused or if legal requirements are not kept during production and marketing of a product respectively.

2.2.5 if defects of the products are ascertained using quality assurance instruments or essential premises of the audited system are not (longer) in place.

2.2.6 A product (e.g. Active Pharmaceutical Ingredient / Excipient) is no longer subject to the original audit criteria (e.g. GMP guideline), or incorrect audit criteria have been applied.

2.2.7 the audit of the manufacturing facilities, the quality control laboratories, the warehouse and other relevant areas is not allowed. Same is valid if a surveillance audit initiated from the contract giver in spite of a written request cannot be carried out within 4 weeks or if deficiencies are not eliminated in an agreed time schedule by suitable corrective actions.

2.2.8 payment requests of blue are not paid from the owner of the certificate or the report in spite of reminders. Also on partial non-payment all certificates and reports can be suspended.

2.2.9 The holder of the certificate or the report violates these General Certification/Inspection Regulations.

2.2.10 a Warning Letter or non-compliance report by a Regulatory Body has been issued, which shows that a certified company does not fulfil the certification requirements.

2.3 In the event of invalidation, suspension or restriction of a certificate/report it is unacceptable to continue or promote the certification. Invalidations, suspensions or restrictions may be published; a further advertising or other use of the certificates/report or references to blue inspection body GmbH is not permitted in the above cases. An invalidated certificate must be returned to blue inspection body GmbH.

2.4 When problems which led to the suspension of a certificate are not resolved in the period specified by blue inspection body GmbH, this will result in the withdrawal of the certification or restriction of the scope of certification.

2.5 blue inspection body GmbH is not liable for any kind of disadvantages for the customer or audited company resulting from the non-issuance, invalidation, restriction or suspension of a certificate/report, except in cases of intent and gross negligence

2.6 Blue inspection body GmbH may restrict the scope of a certificate of the customer in order to exclude those parts that do not meet the requirements.

3. Advertising, publication of certificates, reports and information, use of marks

3.1 The certificates/reports may only be used to advertise for the audited company. The holder of the certificate/report on the audited company is fully responsible for the permissible use. Audit reports may only by displayed in full text and with the date of issue. The use of the report or the name blue inspection body for advertising purposes requires written approval.

3.2 For consumer information and advertising purposes blue may publish the name of audited companies and the clients, unless otherwise specifically agreed upon in writing.

3.3 The use of the sign/mark of the certification authority (blue logo) requires written approval. Details on the use of marks have to be defined in additional contractual arrangements. It is not permitted for a certified company to use the sign/mark of blue inspection body in laboratory test, calibration or inspection reports or certificates.

3.4 The use of any statement on product packaging or in accompanying information of the certified company (especially related to the type of management system certified by blue inspection body and the name of blue inspection body) requires written approval. Details on the use of such information have to be defined in additional contractual arrangements.

3.5 The above mentioned requirements for certified companies also apply when making reference to the certification status in communication media such as the internet, brochures or advertising, or other documents. Upon withdrawal of certification, the client is required to discontinue the use of all advertising matter that contains a reference to certification. The client is required to amend all advertising matter when the scope of certification has been reduced.

3.6 Certified clients are not allowed to use the management system certification (ISO 9001 / EXCiPACT) in such a way as to imply that blue inspection body certifies a product (including service) or process. It is furthermore not permitted to imply that the certification applies to activities and sites that are outside the scope of certification. It is strictly forbidden for the certified client to use its certification in such a manner that would bring blue inspection body and/or the certification system into disrepute and lose public trust.

4. Storage Period

Documents are kept by blue inspection body GmbH for 10 years based on the expiry of the certificate or the report. Further legal provisions shall remain unaffected. Especially no claims can be made or can be asserted against blue inspection body GmbH for damages, if the contracting entity or the audited company is not able to provide related documents or returns documents which are no longer in unmodified form.

5. Infringements of the general certification and inspection regulations

Blue is entitled to demand up to € 250,000 (two hundred and fifty thousand euros) contractual penalty in the case of a culpable breach of the holder of a certificate/report against this general inspection/certification regulation. The same applies in particular if improper advertising is done or a certificate or a report is being misused.

The holder of the certificate or the report has to bear the costs which are invoiced to blue inspection body by an accreditation body directly if the corresponding costs are caused by a culpable breach of the holder of the certificate or the report, in particular against this general inspection/certification regulation. This also applies in particular if blue acts on the behalf of a regulatory authority or based on other information and if such causes turn out to be justified.

6. Document Annex

Attachment: Extract of the certification and inspection procedure in the non-SOP-format

7. Supporting Documents

SOP "Issuing and withdrawal of certificates"

8. Document History

Version	Reason for the change
01:	First Version (based on SOP BLUE 3.3-00)
02:	Introduced information about the Trade Mark
03:	Translation into English version and alignment with SOP “Issuing and withdrawal of certificates”
04	Revision and corrections/clarifications Additional Requirements added in section 3
05	New requirements concerning transfer of certifications and the date of the first surveillance audit

Training by Reading

By signing this document, the acknowledgement and understanding of this Standard Operating Procedure as well as the commitment to implement the contents, if required, is officially confirmed.

The signature of the originator, reviewer and authorizer of the document is considered to be the confirmation of training.

Name of the employee	Date	Signature