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REGULATIONS FOR AWARDING AND MAINTENANCE OF CERTIFICATION IN ACCORDANCE WITH THE EXCiPACT CERTIFICATION SCHEME

1. CERTIQUALITY DESCRIPTION

CERTIQUALITY S.r.l. is a Certification Body that operates according to the general criteria defined by the standards of the UNI CEI EN ISO/IEC 17000 series and in particular by the ISO 17021-1 standard and, as an independent Body, provides requesting Organisations with services aimed at assessing and certifying the conformity of their Management Systems with the provisions of the reference standards.

Certiquality does not offer any consultation service, either directly or through agency relationships with sub-contractors, to support Organisations setting up a Management System or prepare the relevant documentation.

The legal nature of Certiquality is described in its Articles of association.

Certiquality's activities are financed by the application of Certification fees.

2. PURPOSE AND SCOPE

These Regulations define the relationships between CERTIQUALITY S.r.l. - hereinafter referred to as Certiquality - and the Organisations aiming at achieving and having registered the Certification of their Management System in accordance with the EXCiPACT scheme – hereinafter referred to as EXCiPACT.

The enforcement of these Regulations is supervised by the Committee for Safeguarding Impartiality, appointed by Certiquality's Board of Directors, which include members from all the parties involved in the Certification.

The certificate issued by Certiquality is the document whereby Certiquality certifies that the requesting Organisation employs a Management System compliant with the EXCiPACT scheme.

3. DEFINITIONS

The definitions provided in UNI EN ISO and UNI CEI EN standards and the definitions for the following terms used in the text, shall apply.

As far as the specific terms concerning Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Warehousing Practices (GWP) of excipients are concerned, the definitions mentioned in the document Certification Standards for Pharmaceutical Excipient Suppliers: Good Manufacturing Practices (GMP) – Good Distribution Practices (GDP) – Good Warehousing Practices (GWP) - Requirements for Auditor Competency and Third-Party Organisations Providing Certification of the Management System issued by EXCiPACT asbl shall apply.

3.1 Organisation

Term used to indicate the Subject submitting an application for Certification.

3.2 Operative unit

Corporate facility where the activities, for which the Management System is being certified, are carried out.

3.3 Production site

The whole area where the activities controlled by an Organisation are carried out, along with neighbouring and connected worksites or warehouses for raw materials, by-products, intermediate goods, finished goods and waste materials, and any facility and plant, fixed or otherwise, used to carry out the abovementioned activities.

3.4 Team in charge of the management system evaluation

Personnel appointed by Certiquality to evaluate the Organisation's Management System.

3.5 Assessment, evaluation and audit are used as synonyms

3.6 EXCiPACT absl: Non-profit, independent organisation that has developed and owns the property of the EXCiPACT Certification Scheme with its annexes Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) and Good Warehousing Practices (GWP).

3.7 Classification of non-conformities

(original definition in English from the 'Certification Standards for Pharmaceutical Excipient Suppliers' document and from the ISO 17021-1 standard):

- Life Threatening: A nonconformity or other situation which has produced product that is harmful to the human or veterinary patient or a product which if released would be harmful to the human or veterinary patient.
- Critical: The excipient poses significant risk to patient safety. Remediation before further excipient is produced would be indicated and/or a recall should be considered.
- Major: Nonconformity that affect the capability of the management system to achieve the intended results.
- Minor: Nonconformity that does not affect the capability of the management system to achieve the intended results.

4. GENERAL CONDITIONS

4.1 Certification is available to all Organisations that produce or distribute or warehouse, in their original, closed packaging, excipients intended to the pharmaceutical sector.

4.2 For the Certification procedure to be initiated by Certiquality, the requesting Organisation must:

- have a Quality Management System certificated under accreditation in accordance with the ISO 9001 Standard for the production and/or distribution and/or warehousing of excipients. As an alternative, the Organisation shall demonstrate to be regularly audited according to the requirements of the NSF/IPEC/ANSI-363-2014 US National Standard document;
- should the ISO 9001 certificate not be issued by Certiquality, the Organisation undertakes, upon signature of these Regulations, to send a copy of the valid certificate and to provide annual evidence of the maintenance of the existing certificate;
- have a management system complying with the EXCiPACT scheme in its Good Manufacturing Practices (GMP), Good Distribution Practices (GDP) or Good Warehousing Practices (GWP) variants;
- describe the abovementioned System in appropriate documents;
- accept the rules set forth by these Regulations and the conditions communicated by Certiquality.

4.3 Acceptance of the application, issue and maintenance of the Certification thereof are subject to the payment of the prescribed fees. Failure to fulfil such obligations by the established deadline shall lead to the suspension or revocation of the Certificate, pursuant to the provisions set forth in Sections 8 and 9.

4.4 The Organisation undertakes to keep its products complying with all applicable legal and compulsory requirements (such as directives, laws and regulations). It is Certiquality's responsibility to verify on the basis of a sampling that is congruent with the audit time, that the Organisation is aware of, and capable of managing for all the compulsory aspects connected to the management system involved in the certification.

4.5 Certification requirements may change as a result of:

- amendments to the reference standards by EX-CiPACT Asbl;.
- amendments to the Certification issuance conditions by Certiquality.

Certiquality shall promptly notify the certified organisations and/or organisations waiting to be certified, defining the date on which the new changes come into force, along with a reasonable interval of time to allow Organisations to comply with the new provisions.

Organisations that do not wish to adjust their Management System to changes may waive their Certification provided that they give notice thereof to Certiquality in accordance with the procedures set forth in Section 10 of these Regulations.
In the event of amendments to the EXCiPACT certification scheme, Certiquality reserves the right to verify the compliance of the Organisation's Management System with the new provisions of the regulations.

All audit expenses are at the certified Organisation's expense.

4.6 Certiquality keeps a list of certified Organisations that is available on the website: www.certiquality.it.. Certiquality makes data public even in the case of suspension, revocation and waiver of certification, where requested.

The references of the certified Organisation, including the contact e-mail, are communicated to EXCiPACT Asbl for the purposes of publication in the section of certificated companies on the EXCiPACT website (www.excipact.org).

5. MANAGEMENT SYSTEM CERTIFICATION PROCEDURE

5.1 Request of Certification Offer / Certification application and acceptance of the offer

Organisations that intend to obtain certification must request an offer to Certiquality by filling an application and enclosing the required documentation.

Certiquality proceeds with a formal examination of the documentation presented in order to verify the completeness and accuracy of the general information, then it prepares and sends the offer.

The signature and acceptance of the offer finalizes the contract between the parties.
The Organisation undertakes to abide by and accept the provisions in these Regulations, and subsequent amendments, that is part of the offer and it declares to know its content.

Certiquality's regulations are available on the website: www.certiquality.it.

All the conditions governing the issue of Certification to national Organisations shall apply

also to foreign Organisations, unless other specific provisions are defined by Certiquality in international agreements.

In the case of bids, in accordance with the specific regulations set forth in the terms and conditions of the call for bids, procedures or documentation different from those referred to in these Regulations may be followed.

Certification activities cannot be started if the contract has not been signed for acceptance by the Organisation.

The certification is issued and maintained only in the presence of a valid certification contract.

5.2 Certification issue

5.2.1 Following the acceptance of the offer, Certiquality agrees with the Organisation the period for conducting the audit. Acceptance of the contract does not constitute either a direct or an indirect obligation to certify.

Certiquality appoints the Audit Group and notifies the Organisation. The Organisation may, however, request in writing the replacement of one or more auditors whenever there exist plausible reasons that are not directly related to the professionalism of the inspectors. Said reasons must be provided.

One member of the Group serves as Team Leader.

The Audit Group may also be constituted by one member only, for small and medium-sized Organisations.

The initial certification audit is conducted in two stages:
- Stage 1, aimed at evaluating the documentation and the degree of preparedness of the Organisation to carry out stage 2. During stage 1, moreover, the scope of certification and the duration of the certification, renewal and surveillance audits are confirmed. Based on the outcome of stage 1 Certiquality reserves the right to increase the duration of audits as a result of information made unavailable at the time of the offer request. Modifications, if any, are notified to the Organisation.

At the end of stage 1, the audit team sets the dates for stage 2.

No more than 6 months may pass between stage 1 and stage 2; if it happens, stage 1 must be repeated.

At the end of stage 1, the audit team informs the Organisation about any failures which could lead to a postponement of stage 2.

An appropriate amount of time must pass between the stage 1 and stage 2 audits to ensure that any failures reported during stage 1 have been corrected, however it shall not exceed 6 months.

- Stage 2, aimed at assessing the implementation and effectiveness of the management system of the Organisation.

The audit team starts the assessment activities of both stages by holding an opening meeting with the senior management of the organisation, where the audit plan is explained.

5.2.2 The audit can be carried out only if the Organisation has a fully operative Management System compliant with the requirements of the EXCiPACT Scheme and, in particular, the Organisation shall have performed one full cycle of internal audits and the senior management shall have carried out at least one review.
The Organisation shall ensure that:

a) all documents relating to the Management System to be certified, including all the records relating to the enforcement of the Management System are made available to Auditors;
b) auditors can access all the premises and production systems of the organisation, where the activities in the certification scope are carried out;
c) for outsourced activities falling within the scope of certification, auditors can access the premises and production systems of the involved suppliers;
d) auditors receive assistance during the audit;
e) access is granted to the Information System of the company, in line with the audit requirements.

5.2.3 The purpose of the stage 2 audit is to verify the compliance with the requirements of the EXCiPACT scheme and all the processes and activities forming the object of certification.

5.2.4 Upon completion of the audit, the Audit Team meets to discuss the findings and process collected data.

During the closing meeting and in the presence of the Organisation's senior Management, the Audit Team reports on the audit results and the detected findings about the compliance of the management system with the requirements of the EXCiPACT scheme, detailing deviations, if any.

On this occasion, the Organisation has the chance to deal with the The Audit Team and to clarify its position about the reported results.

The Audit Team issues a preliminary report that includes the detected non-conformities. It is not allowed to communicate potential improvement areas with regards to the requirements of the EXCiPACT scheme.

The final report is provided by Certiquality to the Organisation within 4 weeks from the audit closure.

The preliminary report and the final report prepared by the leader of the Audit Team and handed over to the Organisation do include the audit results.

5.2.5 Should non-conformities be detected, the Organisation shall submit to Certiquality an implementation schedule detailing the necessary corrective actions that will be taken to meet the requirements for the purposes of the Certification issue.

Furthermore, the Organisation shall provide Certiquality with evidences of the progressive implementation of the plan of corrective actions consistently with the set deadlines.

Presence of non-conformities classified as 'Life-Threatening', 'Critical' or 'Major' prevents the certification issue.

The assessment of the implementation of the plan of corrective actions, drawn up by the Organisation to correct non-conformities, is carried out as follows:

- in the event of 'Life-Threatening' or 'Critical' non-conformities, Certiquality carries out an additional audit at the Organisation before issuing the certification;
- in the event of 'Major' non-conformities, Certiquality verifies the documentary evidences provided by the Organisation. In the absence of the abovementioned documentary evidences or if they are inadequate, Certiquality reserves the right to perform an additional audit

at the Organisation before issuing the certification.

The additional audit to assess the correction of 'Life-Threatening' or 'Critical' non-conformities shall be completed by Certiquality within 6 months from the last day of the stage 2 audit. Otherwise, Certiquality conducts a new audit with a duration equal to the one of stage 2 before issuing the certification.

The effectiveness of the plan of corrective actions implemented by the Organisation is assessed by Certiquality during the subsequent audit.

5.2.6 The documentation relating to the evaluation steps of the Management System shall be submitted to the resolution of Certiquality's Technical Commission for the purpose of Certification issue.

Following the positive resolution by the Technical Commission, Certiquality issues a certificate of compliance with the EXCiPACT scheme.

On the basis of the audit outcome, the Technical Commission may request an additional audit to annual audit aimed at the prompt verification of the critical points recorded.

5.2.7 Multi-site organisations

In the event of certification to the EXCiPACT - GMP or GDP scheme, Certiquality:

- audits every site during the first certification, surveillance and renewal stages of the certification. Certiquality does not carry out a sampling of the sites for which the Organisation is applying for certification;
- issues a certificate for each site for which the Organisation is applying for certification.

In the event of certification to the EXCiPACT – GWP scheme, Certiquality issues only one certificate that includes all the sites for which the Organisation is applying for certification. Furthermore, during the audits following the first certification audit, Certiquality can carry out a sampling provided that the following requirements are fulfilled and maintained:

- certification audit closed with no 'Major' non-conformities;
- audit of each site at least once every 3 years;
- in the event of a 'Major' non-conformity, compulsory performance of annual audits at the involved site until the non-conformity has been corrected;
- suspension or direct revocation of the issued certificate, in the event of a 'Life Threatening' or a 'Critical' non-conformity in one or more sites, or in the event of impossibility to comply with the requirements of the EXCiPACT scheme.

For certification maintenance and renewal purposes, Certiquality reserves the right to extend audits to all the sites of the Organisation certified to the EXCiPACT – GWP scheme.

If an Organisation has been granted with the multi-site certification in accordance with the EXCiPACT – GWP scheme, the Organisation shall periodically inform Certiquality and in particular the auditor before each audit, about the list of the operative units in place, specifying for each of them the type of excipient stored.

Issuance of multi-site certification by Certiquality entails the commitment by the Organisation to implement all the requirements of the EXCiPACT – GWP scheme in all the operative units covered by the certification.

5.2.8 Certiquality informs EXCiPACT asbl about:

a) the decision to grant the certification to the Organisation;

b) administration information that will be used by EXCiPACT asbl to issue the certification fee to the Organisation.

After the Organisation has paid all the due fees, Certiquality:
- issues the certificate and sends it to Organisation;
- registers the Organisation in the Registry of Certiquality certified Organisations;
- transmits all the information regarding the certificate status to EXCiPACT asbl and to all parties requesting the same information;
- publishes the information on its website.

5.3 Surveillance of certified organisations

The resolutions of the Technical Commissions are promptly communicated to the Organisation by Certiquality. The month indicated in the communication is the deadline to carry out the surveillance audit and shall be met by certified Organisations. Surveillance audits are carried out at an annual frequency. The first surveillance of the first 3-year certification period shall be compulsorily carried out within one year from the date of the certification resolution. No postponements can be granted for the first surveillance. The following audits are carried out within 12 months from the previous audit.

In exceptional cases, in order to meet some justified company needs (to combine the surveillance audit with other certification extension and/or renewal audits, or with audits concerning the same Group, for justified organization or logistics reasons, etc.) the date of audit performance can be postponed up to a maximum of 4 months, provided it is carried out within the calendar year of reference (unless in case of different provisions for specific schemes), sending a written and reasoned request to Certiquality. Certiquality reserves the right to assess the acceptability of the request.

The months granted for postponement will then be made up during the following audit in order not to reduce the established audit periodicity.

Only one request for audit postponement can be made in the 3-year period.

In the event of failure to comply with these provisions, Certiquality will start the procedure for the suspension and subsequent revocation of certification.

In the event of irregularities (that is, for example: delays, partial payments, missed payments) by the Organisation regarding the fees due to Certiquality for the activities carried out by Certiquality in accordance with these Regulations, Certiquality reserves the right to suspend any activity of its competence, and it is understood that such activities will be resumed only further the payment of any fees due by the Organisation.

Certiquality checks the certificated management system in order to assess the steady compliance with the requirements of the EXCiPACT scheme.

The Team leader contacts the Organisation in order to agree upon an audit date and plan.

Surveillance audits are carried out in one single step and they cover at least half of the management system so that the whole management system implemented for excipients is reviewed during the two surveillance audits planned in the 3-year period of validity of the certificate of compliance with the EXCiPACT scheme.

During surveillance audits, Certiquality's auditors must be allowed to verify that the conditions that have led to the issue of the certification to the EXCiPACT scheme have not changed, in particular that the conditions affecting the ability of the

management system to achieve its objectives, operating in compliance with the EXCiPACT scheme have not changed.

The Audit Team issues a preliminary report that includes the detected non-conformities. It is not allowed to communicate potential improvement areas with regards to the requirements of the EXCiPACT certification scheme.

The final report is transmitted by Certiquality to the Organisation within 4 weeks from the audit closure.

Should non-conformities be detected, the Organisation shall submit to Certiquality an implementation schedule detailing the corrective actions necessary to meet the requirements for maintaining the Certification.

Presence of non-conformities classified as 'Life-Threatening' or 'Critical' prevents the maintenance of the certification and entails the start of the certificate suspension procedure. The Organisation shall submit in any case a plan of corrective actions, whose implementation is assessed by Certiquality by a supplementary audit conducted at the Organisation.

In the event of 'Major' non-conformities, the certification can be maintained exclusively following the submission, by the Organisation, of a plan of corrective actions and following an audit by Certiquality. The audit is carried out by examining the documentary evidences provided by the Organisation. In the absence of the abovementioned documentary evidences or if they are inadequate, Certiquality reserves the right to perform an additional audit at the Organisation in order to maintain the certification.

If the Organisation has not effectively corrected the 'Minor' non-conformities detected in the previous audit, Certiquality's auditors issue a 'Major' non-conformity.

In the event of 'Minor' non-conformities the Organisation shall submit a plan of corrective actions to Certiquality, that verifies their adequacy and reserves to ask for documents to support the correction of non-conformities and to perform an additional audit to complete its assessments.

Furthermore, the effectiveness of the plan of corrective actions implemented by the Organisation will be assessed by Certiquality during the subsequent audit.

Failure to take the required corrective actions may lead to the start of the suspension and/or revocation process of the certificate, pursuant to art. 8 and 9 of these Regulations.

5.4 Extraordinary audits

Unplanned, extraordinary surveillance audits, with minimum advice of two working days, could be carried out when Certiquality deems it appropriate. For example: to assess the correct management of complaints received by Certiquality; to check the impacts coming from organizational changes; for requests coming from Control Bodies (in this case the bodies can attend the audit); following reports of incidents or serious measures taken that involved the Organisation.
In these cases the Organisation cannot ask to replace the auditors appointed by Certiquality.
The fees for unplanned extraordinary surveillance audits will be at the expense of the Organisation.

6. VALIDITY OF THE MANAGEMENT SYSTEM CERTIFICATION

6.1 Renewal

The Certification issued by Certiquality is submitted to a periodical monitoring, with a frequency of at least once a year, and to a full review of the Management System every three years. The certificate issued indicates the three-year date of expiry.

Every 3 years, Certiquality shall perform a renewal audit, which consists in:

- a documentation review;
- an in-depth inspection entailing an assessment of all the requirements of the EXCiPACT scheme and all the processes and products pertaining to the scope of the certificate of compliance with the EXCiPACT scheme in order to allow maintenance;
- an overall assessment of the performances of the management system in the three-year period.

Renewal audits are generally carried out in a single stage. In the event of significant changes to the Organisation or its management system, Certiquality reserves the right to carry out the renewal audit in two stages.

The renewal audit must be carried out within 36 months from the last day of the certification audit or from the previous renewal audit.

At the end of the audit, the Audit team issues a preliminary report that includes the detected non-conformities. It is not allowed to communicate potential improvement areas with regards to the requirements of the EXCiPACT certification scheme.

The final report is transmitted by Certiquality to the Organisation within 4 weeks from the audit closure.

Should non-conformities be detected, the Organisation shall submit to Certiquality an implementation schedule detailing the corrective actions necessary to meet the requirements for the renewal of the certification.

Furthermore, the Organisation shall provide Certiquality with evidences of the progressive implementation of the plan of corrective actions consistently with the set deadlines.

Presence of non-conformities classified as 'Life-Threatening', 'Critical' or 'Major' prevents the certification renewal.

The assessment of the implementation of the plan of corrective actions, drawn up by the Organisation to correct non-conformities, is carried out as follows:

- in the event of 'Life-Threatening' or 'Critical' non-conformities, Certiquality carries out an additional audit at the Organisation before renewing the certification;
- in the event of 'Major' non-conformities, Certiquality verifies the documentary evidences provided by the Organisation. In the absence of the abovementioned documentary evidences or if they are inadequate, Certiquality reserves the right to perform an additional audit at the Organisation before renewing the certification.

If the correction of 'Life-Threatening', 'Critical' or 'Major' non-conformities cannot be assessed by Certiquality before the certificate expiry, the validity of the certificate cannot be extended.

After expiry, the certificate is not valid anymore and the obligations provided for in art. 7.3 of these Regulations shall apply.

The certification to the EXCiPACT scheme can exclusively be restored after an assessment of the correction of 'Life-Threatening', 'Critical' or 'Major' non-conformities, to be carried out by Certiquality.

In this exceptional case the renewed certificate highlights the period in which it was not valid.

Certification maintenance is subordinate to the application of the provisions set forth in art. 12 of these Regulations.

6.2 Certiquality informs EXCiPACT asbl about:

a) the decision to grant the renewal of the certification to the Organisation;
b) administration information that will be used by EXCiPACT asbl to issue the certification fee to the Organisation.

After the Organisation has paid all the due amounts, Certiquality:

- issues the certificate and sends it to Organisation;
- registers the Organisation in the Registry of Certiquality certified Organisations;
- transmits all the information regarding the certificate status to EXCiPACT asbl and to all parties requesting the same information;
- publishes the information on its website.

6.3 Transfer

In the event of an application concerning the transfer of the management system certification by an Organisation having a valid certificate issued by another Certification Body recognized by EXCiPACT asbl, the scheduled procedure is the following one:

- transmission, by the Organisation, of the signed offer sent by Certiquality for the certification transfer;
- Pre-transfer review by Certiquality. During the Pre-transfer review the following aspects are analysed: reasons for the transfer request, audit reports issued by the former Certification Body in the last three-year period, in order to check the reliability level of the implemented management system, complaints, situation of the Organisation regarding aspects of legislative compliance (for example, authorizations and disputes, if any), management system documentation, certification scope, in order to confirm it, validity and status of the previous certificate;
- upon conclusion of the Pre-Transfer Review the documents are submitted to the assessment of the Technical Commission. Following the resolution with positive outcome, the certificate of compliance with the EXCiPACT scheme is issued, with the date indicated by the former Certification Body as date of first issue.

The three-year planning can be reviewed or the planning of the former Certification Body can be applied.

The three-year extension of the certificate is carried out by performing an audit having the same duration as a new certification audit.

The certificate must be transferred before its expiry.

A transfer of certificates is allowed only for certificates issued by Certification Bodies whose recognition status by EXCiPACT asbl has not been suspended, revoked or expired.

In these cases, the certification transfer is carried out by a new certification audit.

7. RIGHTS AND DUTIES OF CERTIFIED ORGANISATIONS

7.1 After the certification achievement, the Organisation can advertise the attainment of the

same in the ways it deems most appropriate, provided that proper reference is always made to the scope and limitations of the Certification obtained according to the provisions set forth in art. 17 of these Regulations. Having ascertained the improper use of the Certification, Certiquality shall take all measures to prevent its continuation and safeguard its interests and the interests of EXCiPACT asbl.

7.2 Certification is issued to the Organisation on the basis of the EXCiPACT scheme, and only for the activities certified and the operative units mentioned in the Certificate. It cannot be transferred to other units.

Organisations wishing to extend the scope shall submit a request to Certiquality, that sets up a suitable extension procedure.

Certiquality must be notified of any changes related to identification and Organisational data or ownership, changes in corporate structure or slight changes in the description and editorial aspects of the subject of Certification, and this may allow the maintenance of Certification, with issue of a new certificate, where needed. According to the extent of such changes, Certiquality reserves the faculty to request further documentation or perform further audits on site, in order to verify that the changes do not affect the conformity of the Management System.

7.3 Certified Organisations shall agree:

- to keep their structure compliant with the requirements of the EXCiPACT scheme;
- to keep the certification of their Quality Management System in accordance with the ISO 9001 standard or, as an alternative, to undergo periodical audits in accordance with the document NSF/IPEC/ANSI-363-2014 US National Standard. In the latter case, the Organisations shall make available the audit report to Certiquality;
- to accept, at their own expenses, the evaluation audits necessary to maintain the validity of the issued Certification;
- not to use their certification, including audit reports and marks, in such a way as to damage the reputation of Certiquality and/or of EXCiPACT asbl and/or of the certification system, thus compromising the public's trust in same;
- to allow Certiquality's auditors and observers or experts, if any, as well as auditors sent by EXCiPACT asbl to access its facilities and information system to verify Certiquality work, assisting them during audits. Should the Organisation refuse to admit Certiquality's observers or control and accreditation Bodies accompanying Certiquality's auditors, Certiquality may refuse certification issue, or suspend or revoke Certification;
- to implement the corrective actions required to correct the reported deviations to the requirements of the EXCiPACT scheme;
- to record all the customers' complaints concerning EXCiPACT and the related corrective and preventive actions undertaken, making them available to Certiquality and its auditors during surveillance and renewal audits;
- to cease exhibiting or making any other use of the Certification documents and, if applicable, of the Certiquality or EXCiPACT asbl symbols and logos immediately after the expiry, suspension, revocation, waiver and consequent withdrawal of the Certification; in the event of reduction of the certification scope, all relevant documents shall be amended;
- to authorize Certiquality to notify the audit results and transmit the relating reports to EXCiPACT asbl;
- to make the audit report available to its customers asking for it;

- to authorize Certiquality to reply to the requests for authentication of certificates and audit reports by third parties with no need of a previous consent;
- to inform the Competent Authorities of the countries where the excipient is put on the market, in case Certiquality detects non-conformities categorized as 'Life Threatening'. Certiquality informs EXCiPACT asbl about such non-conformities

7.4 Obligation to provide information regarding any legal and/or administrative proceedings in progress

Certified Organisations undertake to:

- inform Certiquality within 5 days from the event, by e-mail, registered letter with return receipt or P.E.C. (certified e-mail), of any non-conform situation recorded by monitoring Authorities, any suspension or revocation of authorisation, concessions, etc. relating to the production/distribution of products and/or services connected to the certification. 'Life Threatening' or 'Critical' non-conformities to the GMP and GDP requirements detected by a Competent Authority are included, too;
- immediately notify Certiquality of any legal and/or administrative proceedings in progress, regarding the subject of certification, within the limits posed by law;
- give immediate notification of any serious events or accidents or environmental damage;
- keep Certiquality informed of the developments of the aforesaid proceedings.

As regards the above, Certiquality reserves the faculty to conduct appropriate and timely extraordinary audits and to take actions to suspend, reduce or revoke the issued certification, on the basis of the impacts on the Organisation's Management System.

8. CERTIFICATION SUSPENSION

In case of problematic situations or persistence of deviations after the term agreed for their correction, Certiquality can suspend the Certification.

Examples of such severe deficiencies include the following:

- when monitoring reports a non conformity with relevant requisites, but a revocation is not deemed necessary;
- when monitoring reports 'Life Threatening' or 'Critical' non-conformities;
- when the Organisation does not submit the evidence relating to the management of 'Major' non-conformities issued during audit within the prescribed timeframes;
- when the Organisation refuses to undergo periodical audits in accordance with the provisions set forth in Art. 5.3;
- when the Organisation refuses to undergo additional or supplementary audits, including the ones needed to assess the effectiveness of the plan of corrective actions implemented to correct 'Life Threatening' or 'Critical' non-conformities;
- when the Organisation fails to notify Certiquality of significant amendments to its Management System and/or organisation;
- when the Organisation has not anymore a valid certification to the ISO 9001 standard for the production and/or distribution and/or warehousing of excipients.
- when the improper use of the Certification persists, including the certificate and audit reports issued by Certiquality, as well as symbols or logos owned by Certiquality or EXCiPACT asbl.
- in the event of any other failure to comply with the provisions of the EXCiPACT scheme , these Regulations or Certiquality's procedures;
- when Public Authority orders prejudice the implementation of the Management System in compliance with the EXCiPACT scheme;
- when inspections by Competent Authorities have detected significant deviations from the requirements of GMP and/or GDP that seem to be 'Life Threatening' or 'Critical' non-conformities;

- in the event of persistent failure to comply with the requirements of a Competent Authority;
- in the event of violation of mandatory requirements regarding the products and processes covered by the certification according to the EXCiPACT scheme;
- when the Organisation fails to notify Certiquality pursuant to par 7.4;
- if payment of services already provided by Certiquality has not been made, with respect to any type of service performed by Certiquality, whether or not related to the certification; when the Organisation is in default more than once in the same three-year period, certification could be immediately revoked;
- when the Organisation has not paid the certification fee issued by EXCiPACT asbl pursuant to art. 12 of these Regulations.

Following the resolution of the Technical Commission, the suspension is notified by registered letter with return receipt, indicating the start date of validity, the duration, the prohibition to promote any activity related to the use of certification, including its utilization for taking part to calls for tenders, and the conditions for revoking the suspension.

The certified Organisation shall be responsible for undertaking prompt and adequate actions to correct any failure to comply with Certiquality's provisions and for providing Certiquality with formal notification of the proposed or implemented corrective actions.

Certiquality immediately informs EXCiPACT asbl about the suspension of certification with the related reasons for suspension.

Suspension shall only be repealed when Certiquality has ascertained a satisfactory restoration of the compliance with the certified requisites. Certiquality reserves the faculty to perform an audit on site for the reinstatement of the certification, having the same duration as a renewal audit.

If the causes that have led to the suspension are not removed within the set deadline, then Certiquality shall submit the revocation proposal to the resolution of the Technical Commission.

In exceptional cases, and only once during the same three-year certification period, the Organisation may request for certification to be suspended for a maximum period of six months; such decision is submitted to the resolution of the Technical Commission.

9. CERTIFICATION REVOCATION

9.1 The revocation and consequently the cancellation and withdrawal of the Management System Certification is approved by Certiquality's Technical Commission as a result of:

- failure to remove the causes that have led to the suspension of the Certification within the deadline defined by Certiquality;
- when the cases indicated in par. 8 are of such a severe nature as to warrant immediate revocation;
- persistence of default beyond one month from receipt of the administrative suspension sent by Certiquality by registered mail with return receipt;
- breach of laws or legally binding regulations regarding the products or processes object of certification.

The decision to revoke the Management System Certification shall be notified to the Organisation by registered mail with return receipt.

Certiquality immediately informs EXCiPACT asbl about the revocation of certification with the related reasons for suspension.

9.2 Following revocation the Organisation undertakes:

- to return or destroy the original certificate issued by Certiquality;
- not to use any copies or reproductions thereof;
- not to use the audit reports issued by Certiquality;
- to remove from the letterhead, technical documents and advertising materials any and all references to or symbols of the certification issued by Certiquality, including any logos owned by EXCiPACT asbl;
- notify customers, particularly with reference to call for tenders, by the same means used to inform them of the attainment of the Certification.

9.3 Certiquality deletes the Organisation from the lists of certified organisations.

In the case of revocation due to administrative reasons, the Organisation, which pays for its arrears within one month, may request reinstatement of the Certification, provided there are the technical conditions for the reinstatement.

The withdrawal of the Certification shall not entitle the Organisation to reimbursement of the amounts already paid of any kind and entails payment of a penalty, as set forth in Section 12.1.

10. CERTIFICATION WAIVER

The Organisation may waive its Management System Certification by sending a written notice (by P.E.C. or registered letter):

a) in the event of amendment of the reference standards, as set forth in Section 4.5 of these Regulations;
b) in the event it disagrees with the reviews of these Regulations;
c) in the event it disagrees with the amendments of the financial terms defined by Certiquality;
d) in the event of: cessation of activity or transfer of the Company branch, to which the Certification of the Management System refers, to a different juridical subject, legal provisions, bankruptcy or winding up of the Organisation.

If the waiver originates from the transfer to a different juridical subject, the contract shall continue to be valid until the end of the three-year period, subject to verification by Certiquality of the maintenance of all the conditions that led to certification.

In cases a), b), and c), notification shall be sent by the Organisation no later than 1 month from the date in which Certiquality has notified the amendments.

The waiver shall become effective from the date on which Certiquality gives notification of its acknowledgement of the waiver, with contextual termination of certification validity.

After the last surveillance audit, the Organisation can waive at the expiry of the three-year period of certification, giving a formal notice at least 3 months in advance. Should waiver occur later, the Organisation shall pay the fee set forth in Section 12.1 as compensation.

The Organisation can waive its certification at any time, but it will be bound to pay the fee set forth in Section 12.1 as compensation.

In the event of waiver, the Organisation undertakes to comply with the obligations set forth in Section 9.2.
In the event of waiver for reasons other than those listed above, the Organisation shall pay a penalty, as set forth in Section 12.1.

11. CONFIDENTIALITY

All records (documentation, letters and communications) relating to the activities connected with the Certification of the applicant Organisation's Management System shall be regarded confidential and made available only in accordance with the provisions of the agreed internal procedure.

All Certiquality's collaborators who come into possession, while performing their work, with the aforementioned documents shall be obliged not to divulge them.

Access to and consultation of certification-related documents is reserved to those Certiquality functions involved in the certification course, the certified Organisation and the personnel of EXCiPACT asbl. In the case of information relating to the Organisation must be disclosed under legal obligations, Certiquality shall give notification thereof to the Organisation.

Except in these cases, Certiquality will not disclose information on certified Organisations without the authorisation of same.

Certiquality in any case operates in full respect of the provisions set forth in Legislative Decree 30 June 2003, no. 196 (processing of personal data).

12. CONTRACTUAL FINANCIAL CONDITIONS

12.1 Fees

The offers prepared by Certiquality are based on the financial principles and criteria defined by the Board of Directors.

Contracts have three-year validity and renewal rules are defined in the specific contract signed by the parties.

All requests relating to the amendment of the audit schedule, made by the Organisation, may entail the payment of a supplementary fee, which shall be defined in accordance with the higher expenses incurred.

If the request is made in the 5 working days prior to the agreed date, Certiquality reserves the right to charge a sum equal to 50% that envisaged for the audit.

Payment for any services performed by Certiquality shall be owed by the Organisation notwithstanding failure of the certification for reasons not attributable to Certiquality itself.

As provided in Sections 9 and 10 of these Regulations, should the certificate be waived or withdrawn, the Organisation shall pay to Certiquality a penalty of an amount equal to 20% of the total contract price for the three-year term, provided, however, that such penalty shall be no less than 500 € and no greater than 5000 €.

12.2 Payment terms

Fees for the activities carried out in connection with the Certification and Certification maintenance shall be paid to Certiquality according to the instructions provided time after time on the invoices issued.

Failure to comply with the aforementioned obligations shall lead to apply the provisions set forth in art. 8 and 9 of these Regulations.

12.3 Certification fee

The Organisation shall pay the certification fee due to EXCiPACT asbl, owner of the EXCiPACT scheme.

The certification fee is due by the Organisation upon certification and upon every 3-year renewal.

The amount is defined by EXCiPACT asbl and it may periodically change. Changes are immediately notified to certificated Organisations.

The issue of the certificate is bound to the execution of the payment of the certification fee.

13. LIABILITY

The Organisation undertakes to guarantee the completeness and truthfulness of the documents and information made available to Certiquality's appointed auditors.

Certiquality is expressly exonerated from all liability in the event of lacking or incomplete transmission of data or data that does not correspond to the company's actual situation.

Certiquality has the responsibility to verify that the Organisation's Management System is able to effectively manage its compliance with laws and compulsory regulations in relation to the products provided, despite the fact that it does not assume any direct responsibility regarding the adequacy of the technical choices adopted for such reasons by the Organisation – which remains the only liable party – or the ascertainment of compliance with legal requirements.
Certiquality's certification of a Management System does not relieve the Organisation from the legal obligations originating from the supply of products, processes and services nor from the Organisation's contractual obligations with its customers, with the exception of any Certiquality responsibility or guarantee obligation.

More specifically, the parties agree that Certiquality shall not be responsible for defects of products, processes and services supplied by the Organisation to third parties; in the cases referred to by the Legislative Decree no. 206 dated 6/09/2005 (Consumer Code) and subsequent modifications and additions and in Directive EEC 85/374, disciplining the liability for damages caused by defective products, nor for systemic or occasional behaviour of the Organisation in violation of laws and/or Regulations.

Certiquality shall not be liable for inadequacies or damages of any kind originating from the Organisation's activity or by its products, processes or services.

Certiquality shall not be liable for any inaccuracy contained in the database of Accreditation and Control bodies, in particular when such data are transferred by them to other bodies.

14. APPEALS

The involved Organisation may appeal against Certiquality's decisions.

Such appeal must be sent by registered letter to Certiquality within 30 days from the notification of such decision. Certiquality shall provide written confirmation of the receipt of such appeal.

Certiquality shall submit such appeal to a dedicated committee which shall render a reasoned decision within 30 days. Upon justification the appeals committee may render its decision within 60 days.

The decisions of the Committee are formally communicated to the Organization.

Upon granting of the appeal, the relevant decision is cancelled or revoked.

In case of non acceptance of the appeal, the Organization may consult EXCiPACT asbl, whose decision is final.

Expenses shall be paid by the losing party.

15. DISPUTES

The only competent court for any disputes relating to the application or interpretation of these Regulations shall be the Court of Milan.

16. COMPLAINTS

Any person may submit communications/complaints regarding any behaviour of Certiquality or the certified Organisations that may be regarded as not being in line with the requirements of the EXCiPACT scheme.

Said communications/complaints must be made by letter, email or fax; telephone communications must subsequently be made in writing by the notifying party.

Certiquality informs EXCiPACT Absl on receipt of communications/complaints concerning the EXCiPACT scheme, also providing information about the outcome.

Certiquality undertakes to keep the notifying party informed of the outcome of the complaint. If not satisfied with the outcome of the complaint, the complainant may seek the advice to EXCiPACT Absl, whose decision shall be final.

Depending on the received communications/ claims, EXCiPACT Abl may require Certiquality to withdraw the certificate issued.

Anonymous communications/complaints will not be considered by Certiquality.

17. USE OF CERTIFICATION LOGOS

Following the attainment of the Certification, the Organisation can advertise of the same in the ways it deems most appropriate, provided that proper reference is always made to the scope and limitations of the Certification obtained according to the provisions of REG 02 “Regulations for the use of certificates and logos”.

Moreover, the certificated Organisation is authorized to use the logo made available by EXCiPACT asbl, together with the Guidelines that includes the criteria for its use.

The use of the EXCiPACT logo is allowed on letter paper, business cards, leaflets, advertisements and other promotional material.

The EXCiPACT logo cannot be used on the product or otherwise be strictly associated with the product, so as it can be understood that the product itself is certificated.

If it finds that the organization uses the wrong way EXCiPACT logo, Certiquality informs EXCiPACT absl.