Requirement specification
Certification of individuals:
AUDITOR / LEAD AUDITOR – PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRY

1 Introduction

This document is developed by the Scheme Committee for certification of auditors and lead auditors of quality systems related to pharmaceutical and medical device industry.

This requirement specification covers both requirements for certification as Auditor/Lead auditor Pharmaceuticals and certification as Auditor/Lead Auditor Medical devices. The certifications contains two parts; requirements related to knowledge about auditing and knowledge about regulatory requirements. Requirements related to auditing is the same in both certifications but requirements related to regulatory requirements are specific for each certification.

This requirement specification lays out the requirement for certification of individuals doing 1st and 2nd party audits of quality systems in pharmaceutical and medical device companies. The scope for this requirement specification is limited to these areas and do not cover requirements for other audit perspectives such as environmental or occupational health and safety. Procedures and requirements related to certification of individuals for audit has been established in Sweden since 1997 (i.e. environmental auditors).

The scheme committee for the certification of auditors consists of established actors within the pharmaceutical and medical device area and they have documented knowledge and experience within this area.

The requirements listed below are related to existing requirements in applicable regulations and standards for this industry in addition to the requirements for certification of individuals as described in ISO 17024. All requirements related to auditing are based on the standard ISO 19011.

The certification is intended for persons doing audits within pharmaceutical and medical device industry. A successful exam will lead to certification as:

- Auditor Pharmaceuticals
- Auditor Medical Devices

or

- Lead Auditor Pharmaceuticals
- Lead Auditor Medical Devices.

Depending on the training and experience a person has of performing and lead team members, the certification can be as Auditor or Lead Auditor.

Within the pharmaceutical and medical device industry there are high expectations on documented competence. The regulations and standards does not lay out the details of the required competence, only states that the company has the responsibility to ensure “suitable” competence for the task. Certification as Auditor/Lead Auditor Pharmaceuticals/Medical devices will be evidence of acknowledged, documented qualifications to perform audits. The qualification consists of both competence related to auditing techniques (as per ISO 19011) and to applicable regulations and standards (see further description in Annex 5). Through accredited certification of auditor´s a system will be founded to facilitate independent evaluation of competence. The Certification Manager is responsible to evaluate if the candidate has the qualifications needed for the requested certification.

1.1 Owner of the requirement specification

SBQ has together with the Scheme Committee developed this requirement specification. SBQ is the owner of the document and has the responsibility to continuously maintain and develop it to ensure continued applicability related to affected requirements e.g. changes in ISO 19011, medical device directives, requirements related to pharma.)

1.2 Establishment of the requirements

The requirement specification has been developed by the Scheme Committee. This group is put together to ensure that the requirements are anchored on the market and that certification fulfils a need for objective evidence on suitable qualifications.

The sum of experience in the Scheme Committee represents many years of different positions in pharmaceutical and medical device industry. It represents both big and small companies in the industry, different roles (such as training, auditing, certification bodies, technical advisors etc.) and long experience of different regulatory requirements and standards.

2 Background and objective with certification

The requirement to show documented evidence of competences for persons performing audits within the pharmaceutical and medical device industry increases constantly. These requirements originate both from competent authorities and from the industry itself. The competence requirements, regardless if audits are done internally, at a supplier site or on contract, include both auditing techniques and relevant regulations and standards.

Certification as Auditor/Lead Auditor Pharmaceuticals/Medical Devices has been developed to ensure that auditors within pharmaceutical and medical device companies has enough competence to perform audits in a fashion that is appropriate and adapted to this industry and by so ensure that the result of the revision may identify critical gaps and manage this in a systematic and effective way. (For description of requirements related to competence and qualifications in regulations and standards, see Annex 5)

2.1 Knowledge and experience – auditing techniques

Regulations for both pharmaceutical and medical device industry contain requirements to perform internal audits / self inspections (also called internal revision). These requirements also include audit of critical suppliers. Through audits, companies shall ensure fulfillment of requirements and subsequently a safe product.

Audits has to be performed in a systematic, independent and documented way with the aim to identify objective evidence and to be able to evaluate the revision or the results of the revision to find out to what level the audit criteria have been fulfilled. To understand how this shall be planned, executed and followed up, knowledge about the audit process is needed.

EN ISO 19011 “Guidelines for auditing management systems” is an internationally well known standard for auditing. The standard outlines guidance on managing the audit program, plan and perform audits of management systems and lays out competence requirements on auditors and auditing teams. Since the standard EN ISO 19011 represents the only established method for auditing at this time will the requirements for knowledge about auditing techniques for certification as Auditor/Lead Auditor Pharmaceuticals/Medical Devices be based on the guidance in EN ISO 19011.

2.2 Knowledge about regulatory requirements

The regulatory requirements on the quality system have a very central role within the pharmaceutical and medical device industry. The requirements cover a major part of the organization and the aim is to control the activities so that applicable regulatory requirements are fulfilled. Compliance with requirements will contribute to a functioning product that is suitable for use. If requirements aren’t fulfilled, authorizations to put the pharmaceutical/medical device product on the market can be withdrawn.

During audits of pharmaceutical and medical device organizations **shall all applicable regulations and product specific requirements related to quality systems be the audit criteria**. The auditor needs to be able to identify applicable requirements, have good knowledge about these requirements and be able to interpret these requirements for the audited organization. The auditor must also have the ability to evaluate the compliance with the requirements. To handle this, both general and specific knowledge about applicable requirements is needed. **For the certification of Auditor/Lead Auditor Pharmaceuticals/ Medical Devices, knowledge about regulatory requirements and applicable standards and guidance for pharmaceuticals or medical devices is included.**

3 Definitions and references

3.1 Definitions

Certification:	Shall be performed by one or more accredited certification organizations (when the requirement specification for Auditor/Lead Auditor Pharmaceuticals/Medical Devices has been accepted) and will mean that the trainee has knowledge related applicable requirements.
Certification organization:	A company accredited to do the certification.
Examination:	Exam designed to verify knowledge and documented experience in accordance with this requirement specification.
Initial certificate:	Certificate given after the first approved certification.
Initial knowledge:	The knowledge level needed to fulfill the requirements for initial certificate.
Tools:	Written documents of choice.
Examiner:	Person competent to conduct and score an examination where the examination requires professional judgement.
Recertification	Shall be performed by one or more accredited certification organizations and will mean that the previously certified person has maintained knowledge and experience.

4 Annexes

- Annex 1: Detailed theoretical requirements for Auditor/Lead Auditor Pharmaceuticals/Medical Devices
- Annex 2: Detailed requirements on practical experience from audits
- Annex 3: Recertification requirements to maintain the certificate
- Annex 4: Signature list
- Annex 5: Description of regulatory requirements

5 General requirements for certification

Language:	Swedish and English
Type:	Initial certificate
Duration	5 years initial certificate
Experience	Active work for at least three (3) years within the pharmaceutical or medical device industry and basic knowledge about regulatory requirements and quality system within the pharmaceutical and medical device industry (i.e. GMP for drugs/medicinal products, medical device directives within EU, ISO 13485 or GMP/QS for medical devices) or equivalent. See Annex 5 Performed the stated number of audits as per Annex 2 The requirement on experience is not related to the person's position

6 Examination

The examination is based on a passing result in a written exam and enough practical experience from audits, meaning following:

- Applicants shall have passing results in a theoretical exam, consisting of two parts. One part relates to audit theory according to ISO 19011 and the other part relates to applicable regulations and standards of pharmaceutical or medical device organizations. The requirements for each area are specified in Annex 1 to this document.
- Sufficient, documented and verified practical experience within the industry and from planning, performing and reporting audits in pharmaceutical or medical device organizations. The requirements on practical experience are specified in Annex 2 to this document.

The experience from auditing will result in either a certification as Auditor or Lead Auditor (see Annex 2)

6.1 The two parts of the exam

The two parts of the exam are:

1. Auditing techniques (all certifications)

2a. Regulatory requirements Pharma (for certification as Auditor/Lead Auditor Pharmaceuticals)

2b. Regulatory requirements Medical devices (for certification as Auditor/Lead Auditor Medical devices)

The two parts will be handed out at the same time and the individual can choose how much time to spend on each exam. After elapsed time, the exam leader will gather the exams from all participants.

The knowledge evaluated during the exam is comprehension of the subject and the relevant terminology within this industry. The knowledge shall be applied on practical scenarios.

6.2 Issuance of certificate

Participants in the exam passing 70% of the maximum level for each part and with accepted documented audit experience will be approved.

Participants in the exam have the right to re-write the exam maximum three (3) times if the required level of points aren't achieved. After that, proven participation in training is required to re-write the exam.

Relevant practical experience shall have been gathered over a period of five (5) years before the exam and latest within one (1) year after the exam.

After certification as Auditor, certificate as Lead Auditor can be issued if additional practical experience has been submitted and approved. The certificate will be issued if conditions for re-certification are fulfilled. No new theoretical exam is needed.

7 Certificate validity

7.1 Specific requirement for renewal

The certificate period of validity is five (5) years. After five years the certificate holder can apply for a re-newal for additional 5 years.

7.1.1 Recertification- surveillance for renewed certificate

Surveillance is done to ensure that the certified auditor fulfils the requirements the certificate contains. For re-certification, an approved test, approved documented experience of audits and participation in relevant competence improvement training (see Annex 3) is needed. Audit experience shall be verified by employer or similar by a signature. Relevant competence improvement shall be verified by certificates or similar. The certification organization makes an evaluation that the training is relevant for the certification.

7.2 Withdrawal of certificate

Withdrawal of certificate can be done if the certifying organisation becomes aware of that the certificate holder no longer fulfils the requirements for certification and do not within a suggested timeframe takes action to maintain the competences.

A certificate can also be withdrawn if it is misused. Misuse can be misrepresentation of the scope of the certificate, misleading marketing, and untruthful statement about certification process. Serious misuse can lead to legal action. Withdrawal can also become necessary as a result of non-professional conduct.