Annex 2:

DETAILED REQUIREMENT – PRACTICAL AUDITING EXPERIENCE

The persons experience from leading, planning, performing and documenting audits will form the basis for the certification as Auditor or Lead Auditor. Following is the practical experience required, in conjunction with the theoretical knowledge as per Annex 1, for each certificate respectively. There is no difference between the requirements on practical experience between Pharmaceutical or Medical Device

1. Auditor Pharmaceuticals or Medical Devices

1.1 Number of audits

1.1.1 Option 1

Within the last five (5) years before certification exam and one (1) year after the certification exam have performed at least six (6) quality system audits (internal or external), whereof at least three have been external (e.g. at a supplier or as contracted party). Total time for audit shall be at least 48 hours*.

Or

Option 2

Within the last five before certification exam and one (1) year after the certification exam have performed at least ten (10) quality system audits. Total time for audit shall be at least 80 hours*.

* Only time onsite is counted as audit time, time for preparation, travel and report writing is not included.

1.2 Content of audits

1.2.1 The audits shall have been done in pharmaceutical organization for applicants of Certification as Auditor/lead Auditor Pharmaceutical or in medical device organizations for applicants of Certification as Auditor/Lead Auditor Medical Device

1.2.2 The audit criteria shall have included applicable regulatory requirements and standards in pharmaceutical organization for applicants of Certification as Auditor/lead Auditor Pharmaceutical or in medical device organizations for applicants of Certification as Auditor/Lead Auditor Medical Device.

1.2.3 The audits shall have included preparation, document review, audit on site and reporting of audit results.

1.2.4 The audits criteria and activities shall relate to the industry field mentioned in the application. For each certificate (Pharmaceutical or Medical Device) the applicant must show that the audits are related to the corresponding industry.

1.3 Verification of experience

The experience of the applicant shall be submitted in a form where details about audits are documented and there is a named reference that can testify the verity of the submitted information.

2. Lead Auditor Pharmaceuticals or Medical Devices

2.1 General

2.1.1 Fulfill requirements for Pharmaceuticals or Medical Devices (requirement 1.1 and 1.2)

2.2 Lead and coordinate an audit team

2.2.1 Shall during at least four (4) audits, in total 32 hours*, have been working in an audit team coordinated by another Lead Auditor, and

2.2.2 Shall have performed at least four (4) audits , in total 32 hours*, (internal or external) as Lead Auditor and coordinated an audit team of at least one more individual.

Or

2.2.3 Shall have performed at least eight (8) audits, in total 64 hours*, (internal or external) as Lead Auditor and coordinated an audit team of at least one more individual.

* Only time onsite is counted as audit time, time for preparation, travel and report writing is not included.

2.3 Verification of experience

The experience of the applicant shall be submitted in a form where details about audits are documented and there is a named reference that can testify the verity of the submitted information.