

Annex 3:

RE-CERTIFICATION – REQUIREMENTS TO MAINTAIN CERTIFICATION

1. Maintained certification

1.1 Continued work experience

1.1.1 The certificate holder shall have been working in pharmaceutical or medical device industry during at least three (3) years of the five (5) years validity period equaling at least 60% duty during 5 years.

1.1.2 See additional clarification regarding competence in Annex 5

1.2 Performed audits

1.2.1 The certificate holder shall during the validity period of five (5) years have performed at least six audits. The total audit time shall be at least 48 hours*. The audits shall have been performed during three different years and the latest audit shall not be older than 15 months.

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

1.3 Continuous education

The certificate holder shall during the validity period of five (5) years have participated in at least 40 hours documented professional development in a, related to the certificate, applicable* form of training, seminars, conferences, self studies, coaching, meeting participation or other relevant activities. This professional development shall have been performed during at least three different years (not all professional development during one single year). At least two of the education activities shall include a verification of training effectiveness with a passing result.

* Auditing techniques, regulatory and standards training for pharmaceutical or medical device industry.

2. Re-certification

2.1 Validity of the certificate

2.1.1 Issued certificate is valid for five (5) years after approved exam.

- 2.1.2 If the certificate holder hasn't been professionally active within the pharmaceutical or medical device industry for more than two (2) years continuously shall a new theoretical exam be done (Annex 1).
- 2.1.3 If the certificate holder does not fulfill the requirements for re-certification shall a new theoretical exam be done and proof of practical experience as per Annex 2 be submitted and approved.

2.2 Re-certification

- 2.2.1 After the expiry of the validity period for the certificate, the certificate holder shall submit proof of documented experience as per 1.1, 1.2, 1.3 above to the certifying organization.