To be completed by the certification organisation

Certificate number:	
Application received date (YYYY/MM/DD):	

APPLICATION FORM FOR INDIVIDUAL CERTIFICATION TEST

Auditor / Lead Auditor Pharmaceuticals / Medical Devices

This form is used for registration for the certification test for Personal Certification as Auditor / Lead Auditor - Pharmaceuticals / Medical Devices organized by SBQ Certification AB. Your application must be submitted to SBQ no later than 30 days before the certification test date.

Send the completed and signed application (scanned pdf or digitally signed) by e-mail to info@sbq.nu

Fill out the form on the following pages with your experience and training in the subject.

The application will then be processed by SBQ, which will indicate whether your application is properly filled out and if your experience in the subject is sufficient for certification. Note that you can perfom the certification test even if your experience is not enough (additional experience can be completed within one year).

The registration is binding upon receipt and approval by SBQ. The fee for certification is 530 Euro excl. VAT.

APPLICATION FORM

To be completed by person applying for certification

Name:	Social security no (or other identification no):
Company:	Phone (work):
Address:	Phone (mobile):
Post code and City:	Email:
Invoice address (if other):	

I am applying for individual certification:

- ☐ Auditor Pharmaceuticals
- ☐ Lead Auditor Pharmaceuticals
- ☐ Auditor Medical Devices
- ☐ Lead Auditor Medical Devices

To ensure the link between application and certification (with respect to the same person), we need your social security number or other identification number. The personal identification number is used by SBQ for traceability to your certificate. Your personal information will not be used for other purposes. In accordance with the GDPR, this application for certification is the legal basis and the agreement underlying our handling of your personal data.

Continue your application by filling out the form on the following pages, as well as approve and sign your application on the last page.

Work experience (Describe the experience five years back

	No 1	No 2	No 3	No 4	No 5	No 6	No 7
Company / organisation and department:							
From – Until. (YYYY/MM):							
Position:							
Industry:	☐ Pharmaceuticals ☐ Medical Device ☐ Other (specify below)	☐ Pharmaceuticals ☐ Medical Device ☐ Other (specify below)	☐ Pharmaceuticals ☐ Medical Device ☐ Other (specify below)	☐ Pharmaceuticals ☐ Medical Device ☐ Other (specify below)	☐ Pharmaceuticals ☐ Medical Device ☐ Other (specify below)	☐ Pharmaceuticals ☐ Medical Device ☐ Other (specify below)	☐ Pharmaceuticals ☐ Medical Device ☐ Other (specify below)
Reference **Name:** **Relation (for example manager):** **Email:**							

Training related to audit, regulations, and quality / GMP Pharmaceuticals and / or Medical Devices

(Describe training five years back in time)

	No 1	No 2	No 3	No 4	No 5	No 6	No 7
Course / training title							
Training organisation:							
Date (YYYY/MM):							
Length of training:							

Experience of auditing (Describe audits carried out five years back in time)

No	Date (YYYY/MM)	Total time of the audit * (hours)	Which total time on the premises of the audited site **	Contact information for the company / organisation revised	Your role in the audit	No of persons in the audit team	Internal or External Audit	Audit criteria (eg ISO 13485, GMP part I, GMP part II, the IVD MDD)	Contact data for the person confirming audit execution *** (If other than in column 4)
1				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:
2				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:

* Total number of hours that actively audit work was ongoing ie, including time for preparation, document review, on-site audit, report-writing and follow-up

** Number of hours that the audit was in progress from the opening session to the closing meeting

*** This person should confirm that the audit has been conducted in a proper manner and that the information provided is accurate

No	Date (YYYY/MM)	Total time of the audit * (hours)	Which total time on the premises of the audited site ** (hours)	Contact information for the company / organisation revised	Your role in the audit	No of persons in the audit team	Internal or External Audit	Audit criteria (eg ISO 13485, GMP part I, GMP part II, the IVD MDD)	Contact data for the person confirming audit execution *** (If other than in column 4)
3				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:
4				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:

* Total number of hours that actively audit work was ongoing ie, including time for preparation, document review, on-site audit, report-writing and follow-up

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5				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:
6				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:

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7				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:
8				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:

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9				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:
10				Company / organisation: Contact: Address: Phone: Email:	☐ Auditor ☐ Lead Auditor		☐ Internal ☐ External		Company / organisation: Contact: Address: Phone: Email:

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APPLICATION FORM FOR INDIVIDUAL CERTIFICATION TEST

Auditor / Lead Auditor
Pharmaceuticals / Medical Devices

Declaration and signature

I hereby apply for certification as Auditor / Lead Auditor - Pharmaceuticals / Medical devices. With the signature of this document, I certify that the information provided is correct. I also agree that the application is binding upon receipt and approval by SBQ, and that the fee of 530 Euro excl. VAT will be charged.

My signature also means that I allow the SBQ certification organisation to save my personal data in accordance with GDPR.

Date:_____ Signature:_____

Name in block letters: _____