To be completed by the certification organisation

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

APPLICATION FORM FOR INDIVIDUAL RE-CERTIFICATION AS

Auditor / Lead Auditor

PHARMACEUTICALS / MEDICAL DEVICE

This form is used for registration to re-certification, for people who previously has certified as Auditor/Lead Auditor - Pharmaceuticals / Medical Devices through SBQ Certification AB.

Your application (scanned pdf or digitally signed) should be sent by email to info@sbq.nu

On the following pages, fill in the information required to prove your continued experience and expertise within the area. Have you submitted annual updates, it is sufficient with the information from of the past year.

The application will be processed by SBQ within 2-3 weeks. You will recieve feedback from us whether your application is properly filled out and if your experience in the subject is sufficient for re-certification. If you are approved, you will recive an updated certificate.

If your experience is not sufficient according to the current requirements document (see www.sbq.nu) you have the opportunity to register for a renewed Certification Test, see www.sbq.nu for more information.

The registration is binding upon receipt and approval by SBQ. The fee for certification is 300 EURO.

APPLICATION FORM

To be completed by person applying for re-certification as Auditor/Lead Auditor

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 re- 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)

1.	Company/organisation:		Reference:	
	From– until (YYYY/MM):		Name:	
	Position:		E-mail:	
	Industry:	Pharmaceuticals ☐ Medical Device ☐ Other ☐	Relation: (for example manager, co-worker)	
2.	Company/organisation:		Reference:	
	From– until (YYYY/MM):		Name:	
	Position:		E-mail:	
	Industry:	Pharmaceuticals ☐ Medical Device ☐ Other ☐	Relation: (for example manager, co-worker)	
3.	Company/organisation:		Reference:	
	From– until (YYYY/MM):		Name:	
	Position:		E-mail:	
	Industry:	Pharmaceuticals ☐ Medical Device ☐ Other ☐	Relation: (for example manager, co-worker)	
4.	Company/organisation:		Reference:	
	From– until (YYYY/MM):		Name:	
	Position:		E-mail:	
	Industry:	Pharmaceuticals ☐ Medical Device ☐ Other ☐	Relation: (for example manager, co-worker)	
5.	Company/organisation:		Reference:	
	From– until (YYYY/MM):		Name:	
	Position:		E-mail:	
	Industry:	Pharmaceuticals ☐ Medical Device ☐ Other ☐	Relation: (for example manager, co-worker)	
6.	Company/organisation:		Reference:	
	From– until (YYYY/MM):		Name:	
	Position:		E-mail:	
	Industry:	Pharmaceuticals ☐ Medical Device ☐ Other ☐	Relation: (for example manager, co-worker)	

Training related to audits, regulations and GMP/quality for pharmaceutical / medical device (last 5 years *)

	Course / training title:	Training organisation:	Date (YYYY/MM):	Length of training:
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				

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

1.

Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
Total time of the audit* (hours):		Company/org.:		
Which total time on the premises of the audited site ** (hours):		Contact person:		
Your role in the audit:	Auditor ☐ Lead auditor ☐	Address:		
Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

2.

Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
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Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

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

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

*** This person should confirm that the audit has been conducted correctly and that the information you provided is accurate

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

4.

Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
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Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

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Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

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Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
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Experience of auditing (Describe audits carried out five years back in time)

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Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
Total time of the audit* (hours):		Company/org.:		
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Your role in the audit:	Auditor ☐ Lead auditor ☐	Address:		
Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

8.

Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
Total time of the audit* (hours):		Company/org.:		
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Your role in the audit:	Auditor ☐ Lead auditor ☐	Address:		
Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

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Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
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Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

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

10.	Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
	Total time of the audit* (hours):		Company/org.:		
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	Your role in the audit:	Auditor ☐ Lead auditor ☐	Address:		
	Internal or External audit:	Internal ☐ External ☐	Phone no:		
	No of persons in the audit team:		E-mail:		
	Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

11.	Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
	Total time of the audit* (hours):		Company/org.:		
	Which total time on the premises of the audited site ** (hours):		Contact person:		
	Your role in the audit:	Auditor ☐ Lead auditor ☐	Address:		
	Internal or External audit:	Internal ☐ External ☐	Phone no:		
	No of persons in the audit team:		E-mail:		
	Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

12.	Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
	Total time of the audit* (hours):		Company/org.:		
	Which total time on the premises of the audited site ** (hours):		Contact person:		
	Your role in the audit:	Auditor ☐ Lead auditor ☐	Address:		
	Internal or External audit:	Internal ☐ External ☐	Phone no:		
	No of persons in the audit team:		E-mail:		
	Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

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

13.

Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
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Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

14.

Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
Total time of the audit* (hours):		Company/org.:		
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Your role in the audit:	Auditor ☐ Lead auditor ☐	Address:		
Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

15.

Date (YYYY/MM):		Contact information for the company/organisation re-vised:		Contact data for the person confirming the audit execution*** (if other than contact)
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Internal or External audit:	Internal ☐ External ☐	Phone no:		
No of persons in the audit team:		E-mail:		
Audit criteria: (eg. ISO13485, GMP Part 1, GMP Part 2, IVD, MDD)				

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*** This person should confirm that the audit has been conducted correctly and that the information you provided is accurate

APPLICATION FORM FOR INDIVIDUAL RE-CERTIFICATION AS

Auditor / Lead Auditor

PHARMACEUTICALS / MEDICAL DEVICE

Declaration and signature

I hereby apply for re-certification as Auditor / Lead Auditor. With the signature of this the document, I certify that the information provided is correct. I also accept that the application is binding upon receipt and approved by SBQ.

I accept that the fee of 300 EUR will be charged (25% VAT will be added for Swedish companies, for companies within the EU, the "Reverse charge" tax rule is applied).

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

Date:_____ Signature:_____

Name in block letters:_____