Updated in December 2020

New Audit Firm Application Checklist

Thank you for expressing your interests in becoming one of the PSCI approved audit firms. To start with, we recommend you get familiar with PSCI Audit Protocols:

- PSCI Audit Guidance document
- PSCI Self-Assessment Questionnaire
    - Full template for Type B&C suppliers: Excel version, Word version.
    - Abbreviated template for Type A suppliers: Excel version, Word version.
    - Corrective Action Plan Template: Excel version, Word version.

Then please prepare the documents as per the checklist below and send them to PSCI Secretariat (info@PSCInitiative.org) to initiate your application process.

Document checklist

- Company overview presentation, suggest consisting of following aspects:
    - *Current areas of activity (besides auditing)*
    - *Local/regional/global presence (which countries)*
    - *Expertise & experience with audits in the pharma sector (covering the pillars of the PSCI audit protocol, i.e. Business Ethics, Labor & Human Rights, Health & Safety, Environmental Protection and Management Systems.)*
    - *Type of auditors (e.g. only inhouse auditors, or also use of freelancers) *If freelancers are used, how are the necessary qualifications as well as confidentiality ensured and maintained.*
    - *Number of auditors' CVs included in your application and auditors' area of expertise (e.g.* 1 social auditor, 3 HSE auditors)
    - *Your quality assurance system regarding audits (e.g. selection of auditors, internal training, checking of audit reports etc)*
    - *Open questions:*
        - *How do you review auditors' performance internally? Do you collect feedbacks from your clients and how you do it?*
        - *Is there a firewall between auditing and certification/consulting business (if applicable)?*
        - *And other questions that the PSCI Audit Committee would like to address.*
- CV of your auditors
    - Please use the CV templates in the Appendix
    - You should include an example for a typical social/ethical auditor, and some examples for HSE auditors, preferably those who have conducted audits of active pharmaceutical ingredient sites or pharmaceutical finished forms (tablets, etc)
    - If you are not sure of PSCI's expectation of 3rd party auditors, please refer to Chapter 4: Auditor Qualification in PSCI Audit Guidance document.
- A sample redacted PSCI audit report (if applicable)

Updated in December 2020

New Audit Firm Application Process

New audit firm applications are to be reviewed on a quarterly basis, overseen by Auditor Training sub-team under Audit Committee.

The overall application process consists of the following steps:

New application

For audit firms that express interests in becoming PSCI approved audit firms, they need to prepare required documents according to the above document checklist and PSCI Audit Guidance document.

1st round of review

Upon audit firms submitting their application materials, PSCI Secretariat (Carnstone) will start 1st round of review, mainly looking at questions left unaddressed, lack of supporting documents or clarifying on certain points.

2nd round of review

Once Carnstone has reviewed audit firms' submission, Carnstone to take it to Audit Committee and make some initial recommendations.

Review Call (quarterly)

The application will be shared with the Audit Committee for comments and feedback.

At the same time, Carnstone to schedule the review call as per the availability of PSCI members and representatives from the audit firms in question.

** To make this process more transparent, apart from auditor training sub team, member companies who advocate for audit firms in question and member volunteers (expertise of topic area covered) are encouraged to sit on the review call.*

On the call, audit firms to present and answer questions from PSCI members.

Decision Making

PSCI members who joined the review call to exchange comments and make initial proposal to whether accept or decline the application. Audit Committee steering group to make the final decisions.

Follow up

Carnstone to follow up on getting back to audit firms regarding application results and facilitate audit firm agreement signing and file management.

Carnstone will also update the Audit Committee and the wider membership of any new audit firms that have been approved.

Re-initiate application process

For any audit firms that have been rejected in the application process, they can submit another new application after a minimum period of 12 months. The application will be reviewed in the most upcoming quarterly review cycle. They should follow the application process listed above.

Sometimes, audit firms are approved only to carry out audits on certain topics (e.g. HSE, social) and in certain countries based on the information they have submitted for the application. The audit firms are eligible to submit a new application to be approved to conduct audits on other topics and countries, after a minimum period of 12 months since their previous approval. The application will be reviewed in the most upcoming quarterly review cycle. The application process is the same as listed above.

Appendix 1: CV template – for HSE auditors

**Orange text indicates minimum experience requirements as per recommendations by Audit Committee.*

Auditing for Core Suppliers, External Manufacturers, Component & Material Suppliers, Service Providers and Manufacturers		
	Auditor's Information	
Auditor Details	Name of Auditor	
	Location of Auditor	
Educational Qualification	Bachelor's Degree in chemistry, chemical engineering or similar (Yes/No and specify the type of degree)	
	Master's Degree in chemistry, chemical engineering or similar (Yes/No and specify the type of degree)	
Language Proficiency	Proficient in local language (specify languages)	
	Proficient in English (written and spoken)	
Professional experience	Total no. of years of Industrial Experience	
	No. of years of experience in Pharmaceutical Industry (if any)	*Minimum 3 years relevant experience in either chemical or pharma industry for type B&C supplier audits (e.g. HSE, manufacturing, engineering, development)*
	No. of years of experience in Chemical Industry (if any)	
	No. of years of experience in other Industry (Please specify which Industry)	
	Total no. of years of HSE auditing experience	
	No. of years of experience in Auditing Pharma Companies (if any)	
	Total no. of HSE audits conducted in last 2 years	*Minimum 12 HSE audits every two years (Exception may apply on a case by case basis)*
Other requirements	Knowledgeable in local regulations related to Health, Safety & Environmental (please explain)	
	Knowledge of specific HSE topics like Industrial Hygiene, Process Safety Management, Dust Explosion Hazards, Hazardous Waste Management, Control of Pharmaceuticals in Wastewater (P.I.E) - Please explain	
	Demonstrated Proficiency against the requirements of ISO 14001, OHSAS 18001 and Health, Safety and Environmental regulations and standards of the country - Please explain	

Any Additional Comments by Auditing Company	
Review by PSCI Audit Committee	

Appendix 2: CV template – for Social auditors

**Orange text indicates minimum experience requirements as per PSCI Audit Guidance or recommendations by Audit Committee.*

Auditing for Core Suppliers, External Manufacturers, Component & Material Suppliers, Service Providers and Manufacturers		
	Auditor's Information	
Auditor Details	Name of Auditor	
	Location of Auditor	
Educational Qualification	Bachelor's Degree (Yes/No and specify the type of degree)	
	Master's Degree (Yes/No and specify the type of degree)	
Language Proficiency	Proficient in local language (specify languages)	
	Proficient in English (written and spoken)	
Trainings/ Certifications	ISO-19011 training (Yes/No)	
	SA8000 basic training (Yes/No)	*Have attended basic and advanced SA8000 training (or equivalent, e.g. amfori BSCI)*
	SA8000 advanced training (Yes/No)	
	amfori BSCI certification (Yes/No)	
	Any other equivalent certification (please specify)	
Professional experience	Total no. of years of Industrial Experience	
	No. of years of experience in Pharmaceutical Industry (if any)	
	No. of years of experience in Chemical Industry (if any)	
	No. of years of experience in other Industry (Please specify which Industry)	
	Total no. of years of social auditing experience	
	No. of years of experience in Auditing Pharma Companies (if any)	
	Total no. of social audits conducted in last 2 years	*Minimum 12 social audits every two years (Exception may apply on a case by case basis)*
Other requirements	Knowledgeable in local regulations related to labor/ethics (please explain)	*2 years social auditing experience in the country of concern*

	Demonstrated Proficiency against the requirements of SA8000 and labor standards of the country - Please explain	
Any Additional Comments by Auditing Company		
Review by PSCI Audit Committee		