



Pharmaceutical Supply Chain Initiative

PSCI Audit Program Guidance

November 2025

www.pscinitiative.org

About This Document

THE PSCI AUDIT PROGRAM GUIDANCE

The **PSCI Audit Program Guidance** has been developed by the [PSCI Audit Committee](#) as an information source for 3rd Party Audit Firms, suppliers, PSCI members and other interested stakeholders.

Along with the [PSCI Principles](#) and the [PSCI SAQ / Audit Report templates](#), the Audit Program Guidance explains and specifies the requirements and procedures for a credible, transparent, and consistent audit approach. Following the methodology described in the PSCI Audit Program Guidance ensures that PSCI Audits are carried out in accordance with the PSCI Standards, thereby providing the foundation for a shared audit program.

Any deviation from the methodology described in this document must be noted and recorded in the PSCI Audit Report in the appropriate place.

DOCUMENT HISTORY

Version	Date	Status/Changes
1	2012	First version.
2	April 2013	Light refresh.
3	September 2015	Re-arrangement of content to better reflect the audit process. Change of focus from joint audit to shared audits, also considering the different type of PSCI Audits (e.g. full Audit, PSCI HSE Audit, PSCI Social/Ethical Audit, PSCI audit conducted by 3 rd parties and PSCI audits conducted by members). PSCI Pre-Audit Document checklist as Annex 1.
4	June 2017	Included supplier self-audit model.
5	April 2020	Included revised SAQ/Audit Protocols, replaced the term “PSCI Shared Audit Program” against “PSCI Audit Program”, updated understanding of PSCI Audit Scheme (chapter 3, removal of “no certification scheme”), provided more guidance and details on audit duration and audit process activities, added new external reference (AMR Alliance), added reference to pre-audit information resources (OSHA and IPE), updated qualification for social auditors; added language on option of suppliers to share PSCI SAQs/Audit Reports digitally and it being the preferred sharing method, revised audit findings classification (addition of “others/major”, “others/minor”), addition/update of links
6	October 2020	Updated to reflect option for Fully Remote or Partly Remote audits, alongside Onsite Audits.
7	December 2021	Updated to reflect changes to Supplier Categorisation, classification of findings only as critical/major/minor (and added link to finding classification guidance document) and remove reference to the now withdrawn OHSAS 18001.

8	November 2025	Updated to align with the updated PSCI Principles and Strategy, inclusion of the digital Data Sharing via the PSCI Audit Platform, updated audit uploading requirements for full members, introduced online SAQ and removed reference of word version template, referenced the Audit Checklist as a separate resource in Chapter 10 and added section on Managing Audit Related Issues in the appendix.
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Chapter 1: Introduction and Purpose

The [Pharmaceutical Supply Chain Initiative \(PSCI\)](#) is the leading association for pharmaceutical and healthcare companies. Through our three modes of impact – Audit, Capability and Projects – we work as one voice to deliver responsible value chains. This includes improved conditions for workers, safe processes and facilities, economic development and a cleaner environment for local communities.

The PSCI created the [Pharmaceutical Industry Principles for Responsible Supply Chain Management](#) ("PSCI Principles") which address the five key areas of responsible business practices throughout the pharmaceutical and healthcare industry's supply chain:

- Governance and Management Systems;
- Ethics;
- Human Rights;
- Health and Safety;
- Environment.

The **PSCI Principles** are consistent with industry and international expectations and are applicable both in developed and emerging economies for all suppliers in the pharmaceutical and healthcare supply chain, ranging from service providers to chemical and pharmaceutical manufacturing companies and to contract manufacturers.

The PSCI recognizes that its members have large and diverse supply bases, and there will be advantages to both PSCI members and suppliers in the adoption of a shared audit approach. Supply to patients is expected to improve via a more robust supply chain risk management approach, including compliance with regulatory requirements and the PSCI Principles.

This document describes the PSCI Audit Program which is based on:

- Defined PSCI audit objectives and scope;
- A defined methodology for the audit process from initiation, through execution to reporting;
- A defined methodology for responding to audit findings/observations and corrective action tracking;
- A defined mechanism for uploading and sharing of audit reports;
- Clear requirements and defined minimum qualifications and experience for auditors conducting PSCI audits.

Chapter 2: Documents and References

All documents relevant for the **PSCI Audit Program Guidance** are available on the [PSCI Resource Library](#) or appended to this document:

- The PSCI Principles
- PSCI Audit Program Brochure
- PSCI Introductory Training for Auditors - webinar
- Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers - excel
- Abbreviated PSCI SAQ & Audit Report Template for Service Providers & General Manufacturers - excel
- Introduction presentation for PSCI audit opening meeting
- Audit Document Checklist
- Corrective Action Plan Template – excel
- PSCI Audit Program Supplier FAQ (for suppliers)
- PSCI Audit Completion & Redaction Guidance (for member users)
- PSCI Auditor Evaluation Tool
- PSCI Supplier Self Initiative Audit Brochure
- Audit Finding Classification Examples
- PSCI audit firm application process

The following external references have been used to develop the **PSCI Audit Program**, amongst others:

- International Labor Organization (ILO) Declaration on Fundamental Principles and Rights at Work;
- ILO Convention No 155 “Occupational Health & Safety”;
- ILO Core Conventions on Labor Standards;
 - Conventions No. 87 & No. 98 on “Freedom of association and the effective recognition of the right to collective bargaining”;
 - Conventions No. 29 & No. 105 on “The elimination of all forms of forced and compulsory labor”;
 - Conventions No. 138 & No. 182 on “The effective abolition of child labor”;
 - Conventions No. 100 & No. 111 on “The elimination of discrimination in respect of employment and occupation”.
- UNGC: United Nations Global Compact;
- International Organization for Standardization (ISO);
- ISO 14001: Standard for Environmental Management Systems;
- ISO 19011: Guidelines for Auditing Management Systems;
- ISO 26000: Guidance on Social Responsibility;

- ISO 45001: Standard for Occupational Health and Safety Management Systems;
- SA 8000: Social Accountability International Standard;
- United Nations, Guiding Principles for Business and Human Rights;
- United Nations, UN Convention against Corruption;
- OECD Guidelines (Organization for Economic Co-operation and Development for Multinational Enterprises);
- Responsible Care Global Charter;
- Antimicrobial Resistance Alliance (AMR Alliance) Manufacturing Framework
- Science Based Targets Initiative
- ISO 50001 for energy management systems

Chapter 3: PSCI Audit Program Fundamentals

AUDIT OBJECTIVES

PSCI Audits as described in this Guidance are designed to assess a supplier's performance against the PSCI Principles as well as against international standards and agreements and local regulatory requirements in the areas of:

- Governance and Management Systems;
- Ethics;
- Human Rights;
- Health and Safety;
- Environment.

Suppliers are expected to follow the [PSCI Principles](#), to operate in full compliance with their local legal requirements as well as national and internationally recognized standards and agreements pertaining to the above listed areas, and to continuously improve their performance in these areas.

The objectives of the PSCI Audit Program are:

- To gain efficiency for both suppliers and PSCI member companies, by avoiding to the extent possible, multiple auditing of suppliers through structured sharing of audit information;
- To provide a consistent approach for the assessment of a supplier's performance against the PSCI Principles, international standards and agreements and local legal requirements;
- To obtain an Audit Report (including a Corrective Action Plan) which:
 - Is appropriate for the suppliers to understand their performance and improvement potentials;
 - Serves as an information source for PSCI member companies to evaluate their business relationship with a supplier, and to individually and independently decide on further actions to be taken as warranted.
- To collect and evaluate data to shape and further improve the PSCI Supplier Capability Building Program.

The PSCI Audit Program is **NOT** and **SHOULD NOT** be understood as:

- A compliance exercise with a “pass or fail” outcome;
- An endorsement or suggestion of preference for those suppliers that undergo a PSCI Audit.

AUDIT SCOPE

The [PSCI SAQ/Audit Report Templates](#) developed by the PSCI Audit Committee serve as tools for the documentation of the PSCI Audits. They are consistent with the PSCI Principles, industry practices and acknowledged international standards and conventions (see also Chapter 2: Documents and References).

There are two types of PSCI SAQ/Audit Report Templates:

1. The **Full PSCI SAQ/Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers** (“C” and “B” Suppliers, see Figure 1 below) which should be applied to chemical manufacturers [e.g. active pharmaceutical ingredients (APIs), intermediates, raw materials], pharmaceutical production for human and animal use (e.g. finished dosage forms, primary and secondary packaging of pharmaceutical/medicinal products), biological manufacture, contract research laboratories, warehouse distribution centers and logistic centers and waste facilities. The report template is available in [excel](#). Note: The format allows for the auditors to identify how the audit was performed (Fully Remote, Partly Remote or Onsite)
2. The **Abbreviated PSCI SAQ/Audit Report Template for Service Providers & General Manufacturers (“A” suppliers**, see Figure 1 below), – this template should be used for less complex operations (non-chemical/pharmaceutical), facility & engineering services, IT services & hardware suppliers, temporary labor agencies, travel & fleet services and other service or material suppliers (such as marketing, lab equipment etc.). The report template is available in [excel](#). Note: The format allows for the auditors to identify how the audit was performed (Fully Remote, Partly Remote or Onsite)

The respective PSCI SAQ/Audit Report Templates are applicable for all suppliers despite whether they are located in developed or emerging economies.

Online SAQ

In July 2023, PSCI introduced new format of the SAQ – online version available for all suppliers who wants to assess the maturity of their processes before the audit.

Filling out the SAQ online is not mandatory at the moment, but is highly recommended. As eventually the whole SAQ/Audit reporting process will move online, suppliers will benefit from making an early move to get familiar with the online functionalities.

The offline Excel template will be kept in use for the time being, for two main reasons: 1) some suppliers/ members might still choose to use the Excel template; 2) since the audit reporting still remains offline at this stage, the audit reports will still be in the Excel format. There’s a two-step copy and paste to import suppliers’ answers from the SAQ that is filled out online, to the offline SAQ/Audit Excel template. User may refer to the instructions and demo videos (resources pack can be found [here](#)) on how to do that.

Figure 1: Examples for “A”, “B” and “C” Suppliers



A PSCI audit typically covers a clearly defined supplier location (e.g. a chemical or pharmaceutical production site, a warehouse, a research & development site, or an office building).

In some circumstances (such as due to travel restrictions, pandemic outbreak etc), it may not be possible to complete an onsite assessment of a supplier location. In these circumstances, the use of a partly remote or fully remote audit using appropriate technology (such as MS Teams, Zoom, Skype etc.) may be possible, but the audit objectives remain the same i.e. assessment of a supplier’s performance against the PSCI Principles, International Standards and agreements and local legal requirements. Further guidance on the use of partly remote or fully remote audits is included later in this document.

The audit should cover all applicable internal and external areas of the facility (e.g. key production areas, laboratories, utilities, infrastructure areas, storage areas, waste handling and storage facilities, waste water treatment units, workshops, security and fire service arrangements, canteens, kitchens and dormitories, as well as the office areas - especially at service provider sites).

Permanent staff as well as temporary and contracted staff and migrant workers are to be included in the audit (e.g. interviews) as well as the human rights conditions on site. The audit furthermore includes management systems and key program elements (e.g. policies, standards, resources, competencies and capabilities). Confidentiality and intellectual property protection must be guaranteed. Where a PSCI member representative is present at an audit or conducts a PSCI Audit, careful controls are required to ensure discussions, disclosures and observations are restricted to only the individual PSCI member’s interests. This is absolutely necessary to maintain antitrust considerations.

A PSCI Audit may exclude parts of the supplier site or activities from the audit scope, however this must be clearly stated and explained in the PSCI Audit Report.

A PSCI audit generally covers both, social (ethical and human rights) and HSE (health, safety and environment) areas along with the related governance & management systems. While focus and depth of both social and HSE audits and the methodology for assessment may be different, both parts should be addressed during the same audit.

In case a PSCI member company decides to have one or more of the areas (e.g. Ethics, Human Rights, Health & Safety, Environment) excluded in an audit (“limited” PSCI Audit, e.g. PSCI Social/Ethical Audit or PSCI HSE Audit), this must be clearly stated in the resulting PSCI Audit Report.

Chapter 4: Auditor Qualification

TYPE OF AUDITORS

In general, PSCI Audits should be carried out either by professional and independent 3rd party audit firms or by PSCI member internal auditors.

In case of 3rd party auditors, it is essential that these companies have a system in place to assure the quality of their output, that is the quality of the audit and the quality of the documentation produced to record the audit. The 3rd party audit firm should align with the requirements of the PSCI Audit Firm Application Process.

All 3rd party audit firms that conduct PSCI audits are approved by the PSCI Audit Committee for certain categories. A standard agreement is signed by both the 3rd party audit firm and PSCI which outlines the expectations for an approved 3rd party audit firm. A list with approved 3rd party audit firms is available on the [PSCI website](#). Suppliers can access this list and select an audit firm to carry out a self-paid audit with appropriately qualified auditors from these 3rd party audit firms.

If a PSCI member decides to carry out a PSCI Audit with internal auditors, this should be documented on the audit report taking confidentiality into account (e.g. as “internal auditor of client”). Proper redacting of the PSCI Audit Report according to a four-eye principle (PSCI Member and PSCI audit report redaction team) prior to uploading is important to avoid any accidental disclosure of confidential member information (see also Chapter 8, section “Data sharing and uploading of audit information”).

QUALIFICATION OF AUDITORS

In order to ensure the integrity of the audit process, it is essential that all auditors carrying out PSCI Audits are appropriately qualified as outlined in the [PSCI Audit Firm Agreement](#).

If a 3rd party audit company selected auditor is chosen for carrying out an audit, it must ensure that all auditors (including 3rd party employed and sub-contracted):

- While performing PSCI Audits on behalf of the selected auditor, do not make any modifications to any of the PSCI Audit Program Documents.
- Carry out PSCI Audits have a proven audit record and applicable industry experience;
- Are fluent in the local language (as a minimum the social auditor due to interview of workforce) and in English, as well as familiar with the local culture and working conditions in the applicable industry;
- Need to have the proven ability to write reports in English that are clear and unambiguous;
- Demonstrate the competencies listed in ISO 19011;
- Social auditors have attended the [basic and advanced SA8000 auditor qualification course](#) (or equivalent training, e.g. from [amfori BSCI \[Business Social Compliance Initiative\]](#)) and are knowledgeable about key local and national laws as well as international standards pertaining to labor/ethics;
- Social auditors have sufficient experience (i.e. completed a minimum of 12 social audits every 2 years);
- Health, Safety & Environmental (HSE) auditors have the necessary experience and qualification relevant to the type of supplier being audited and are knowledgeable in key local and national HSE regulations as well as in International Standards (e.g. ISO

14001, ISO 45001);

- Health, Safety & Environmental (HSE) auditors have – especially when selected for an audit of complex manufacturing facilities (e.g. chemical /pharmaceutical production sites) – the necessary knowledge and experience in specific HSE topics (e.g. Industrial Hygiene, Process Safety Management, Hazardous Waste Management), and completed a minimum of 12 HSE audits every 2 years.

In case that a PSCI Member company carries out PSCI Audits with their own internal auditors, the member company should ensure that these auditors have similar qualification and experience, such as assuming an auditor’s function as their primary employment responsibility with the member company.

Table 1 summarizes the guidelines for minimum experience requirements for individual 3rd Party Social, HSE Auditors and sub-contractors:

Table 1: Minimum Experience Requirements for Individual 3rd Party Social and HSE Auditors

	Social Auditor	HSE Auditor	All Auditors
Office/service provider	<p>2 years social auditing experience in the country of concern.</p> <p>Minimum of 12 social audits every 2 years.</p> <p>SA8000 basic and advanced course (or equivalent e.g. in terms of training content, training days and exam).</p>	<p>2 years HSE auditing experience</p> <p>Minimum of 12 HSE audits every 2 years</p>	<p>Proficient in English (written and spoken) and the local language.</p> <p>Knowledge in local and national regulations (HSE or human rights regulations depending on role).</p> <p>Familiar with local culture.</p>
Simple manufacturing/ assembly (component & materials)	<p>2 years social auditing experience in the country of concern.</p> <p>Minimum of 12 social audits every 2 years.</p> <p>SA8000 basic and advanced course (or equivalent, see above).</p>	<p>2 years HSE auditing experience, in case of manufacturing companies at least 1 year of experience in the country of concern is recommended.</p> <p>Minimum of 12 HSE audits every 2 years.</p>	<p>Audit firms must be able to demonstrate the proficiency of their auditors to audit against the requirements of SA8000, ISO 14001, ISO 45001 and Health, Safety and Environmental regulations and standards as applicable.</p>
Complex manufacturing/ API/CMO/ Chemical/ Pharmaceutical	<p>2 years social auditing experience in the country of concern.</p> <p>Minimum of 12 social audits every 2 years.</p> <p>SA8000 basic and advanced course (or equivalent, see above).</p>	<p>Technical degree in chemical engineering, chemistry or similar qualification.</p> <p>3 years HSE auditing experience, at least 2 years of international experience and 1-year experience in the country of concern is recommended.</p> <p>Minimum of 12 audits every 2 years, preferably of similar facilities.</p> <p>Knowledge of specific HSE topics like Industrial Hygiene, Process Safety Management and Hazardous Waste Management.</p>	

	If possible, certified Professional Auditor (CPA) or Certified Safety Professional (CSP), Certified Environmental Professional (CEP) or equivalent.	
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As part of their continuous professional development, all 3rd Party auditors are subject to a review and appraisal of their performance. This includes:

- Social auditors should attend an SA 8000 full refresher course (or equivalent) every two years and demonstrate completion of a minimum of 12 social audits every 2 years;
- HSE auditors must take appropriate refresher training every 2 years and should demonstrate completion of a minimum of 12 HSE audits every 2 years;
- All auditors' performance may be monitored on an ongoing basis by a combination of audit report review, audited supplier feedback and observed audits;
- Provisions within the 3rd party audit company to ensure continual development of auditors.

The PSCI, as well as the PSCI Member Companies, or suppliers carrying out a supplier paid audits, reserve the right to verify the qualification of auditors by checking their CVs and credentials, by assessing audit reports written by them and by collecting feedback on the auditors' performance.

For PSCI members and suppliers who plan to nominate themselves for a self-paid PSCI audit, the PSCI maintains a list of pre-approved 3rd party audit firms. The list and their contacts are available on the [PSCI website](#).

Chapter 5: Audit Process

OVERVIEW

PSCI Members will individually identify suppliers subject to an audit in the areas of Governance & Management Systems, Ethics, Human Rights, Environment and Health & Safety. PSCI Members will decide individually and independently which of their suppliers will be invited for a PSCI Audit, and what kind of an audit will be carried out (e.g. with 3rd party audit firms or with own internal auditors, onsite or partly/fully remote, “full” PSCI Audit or “abbreviated” PSCI Audit (Governance & Management Systems alongside HSE only or Human Rights & Ethics only).

The overall process comprises the following steps:



Suppliers executing a supplier paid audit follow the same overall process. Additionally securing that the audit is performed by independent auditor via the [pre-approved list](#).

Chapter 6: Pre-Audit Activities

AUDIT INITIATION AND PREPARATION

In general, a PSCI member will initiate contact with the proposed auditee supplier, announce the audit and provide information about the purpose and benefits of the PSCI Audit Program. Alternatively, in case of a supplier self-paid audit, the supplier will contact a PSCI-approved 3rd party audit firm and ask to be audited under the PSCI protocol.

There are three ways to carry out an audit (Fully Remote, Partly Remote or Onsite):

- Fully Remote audit: the entire audit, including the verification of responses to questions within the SAQ, are all verified via remote methods, such as livestreaming video, telephone/video call, etc.
- Partly Remote audit: part of the audit was conducted remotely and part of the audit was conducted on-site.
- Onsite audit: the audit and verification of responses to questions on the SAQ were carried out via onsite visit(s).

If there are restrictions on accessing the supplier site, the PSCI member agrees with the supplier whether a partly or fully remote audit would be appropriate. In case of a supplier-self paid audit, the supplier agrees with the PSCI-approved 3rd party audit firm whether a partly or fully remote audit would be appropriate. The contracted 3rd Party audit firm will then:

- Contact the supplier, introduce the audit team and agree on the audit date;
- Request the supplier to select the sharing type of the audit on the PSCI platform digitally and ensure that the sharing option is determined as soon as possible;
- Supplier must be made aware of the PSCI Audit Process which includes that the audit report will be uploaded to the PSCI Audit Platform (but will only be visible to the sponsor and the PSCI Secretariat until a data sharing decision is made by the supplier).

- Request the supplier to fill out and submit an online Self-Assessment Questionnaire (SAQ) using [the PSCI platform](#) or provide the **applicable PSCI SAQ/Audit Report Template** to the supplier;
- If requested by the supplier: sign a confidentiality / data protection agreement between the audit firm and supplier before any exchange of information takes place;
- Check the **completed PSCI Self-Assessment Questionnaire** at least two weeks in advance to the audit;
- Check **publicly available data** about companies regarding regulatory compliance such as [OSHA](#) in USA or [IPE](#) in China;
- Prior to the audit, provide the supplier with **an agenda** and an indication of the documentation required to be available during the audit, see e.g. [PSCI Audit Document Checklist](#) which comprises documents/information which should be available during the audit; If the audit is to be partly or fully remote, assess technology requirements, data sharing platforms and any limitations such as ability to perform virtual site tour etc.
- Consider the need to request pre-recorded video(s) of key areas of the site, as an alternative to a 'live' streamed site tour;
- Inform the supplier that the auditors will ask for access to confidential information, including pay and overtime information of workers. Inform the supplier that data privacy will be respected. In case they do not want to disclose pay information linked with employees' private data, it will be acceptable if such information is either only viewed by auditors, or shown in semi-blinded format so that the auditors cannot see private data;
- Announce that **employee interviews** will be carried out on a random basis to cross-check, in particular, the prevalent working conditions; interviews shall be conducted without supplier management present (see Chapter 7)
- Ask the supplier to confirm which key staff members will be available during the audit (e.g. management staff, payroll and human resources representatives, health & safety staff, operations managers, union or worker committee representatives);
- For an onsite audit, confirm logistics for the audit team, including travel, accommodation, parking, arrival time and any additional necessary documents needed for the visit;
- For a partly or fully remote audit, consider the need to check and test technology and sharing platforms ahead of the audit, to identify and resolve any issues;
- For an onsite audit, confirm safety requirements prior to the site visit. This pre-work will include identifying necessary personal protective equipment (PPE) and any other special requirements.

Also, suppliers may request to be audited according to the PSCI Audit standard (supplier self-initiated audit). The supplier can contact a PSCI member company who the supplier is in business with and ask them to sponsor an audit. Alternatively, the supplier may initiate to be audited under the self-paid model, please refer to the [Supplier Self-Initiated Audit Brochure](#).

The supplier then decides whether it agrees to share the final PSCI Audit Report and Corrective Action Plan with **selected members of the PSCI and PSCI supplier partners** (a list of the current PSCI members and PSCI supplier partners can be found on the **PSCI website**). This is completed through the digital Data Sharing Agreement function on the PSCI

platform. Only audits that have been formally endorsed by the supplier by selecting of the digital **Data Sharing Agreement** will be shared and visible on the **PSCI Audit Platform**.

AUDIT DURATION

Guidance on the Auditor Equivalent Days required on-site is provided below as a benchmark for a PSCI audit. For the social audit component, this is based on the number of employees on site and includes the recommended number of individual and group employee interviews. The HSE audit components are based mainly on site size and the nature of site operations.

The on-site time required for the social auditors and the HSE auditors may vary from site to site. For example, at a complex chemical manufacturing plant, the HSE component of the audit may take longer to complete than the Human Rights and ethical audit component. At a very large office complex with several thousand employees, the HSE component of the audit may take less time than the social component.

For any partly or fully remote audit, it is likely that similar or even more time will be required to complete the full scope of the audit.

The suggested Auditor Equivalent Days are **only** guidelines. Auditors must use their experience and knowledge and consider the industry, location, size of the site, workforce size and individual knowledge of the site when defining the length of time required on-site for both the HSE and social elements of the audit – as well as the number of employees to interview.

In case of time constraints, auditors should apply a risk-based audit approach (i.e. they should preferably cover those questions for which additional auditor guidance notes have been added to the SAQ/Audit Report template or a sponsor may have recommended).

The ratio of individual and group interviews provided in the table below is for guidance only and may be modified depending on circumstances. Where it is not possible to follow this guidance, a clear explanation for a lower number of interviews should be given in the report.

If a site has more than 2,000 workers, the number of interviews is determined on a case by case basis depending on the circumstances of the site.

The table does not take into account the physical size of sites. If sites are very large or very small, different Auditor Equivalent Days per site than shown in the table may be required.

The time spent on interviews is based on an estimation of 15 minutes for an individual interview with no issues, and 30 minutes for an individual interview where issues are raised. Group interviews are estimated at 45 minutes, taking into account the additional time to get workers to attend and to give everyone an opportunity to speak.

This length is only a guideline/suggested minimum. Auditors will rely on their training and experience to determine the length of actual interviews with individual employees. If issues are uncovered with a particular worker, the interview will be extended to fully explore the issue. Alternatively, if workers are consistently providing the same information, interviews can be shortened to adjust to the individual situation.

Table 2: Guidance for Auditor Equivalent Days on Site for PSCI HSE Audit Component

Site Type	Site Size ¹	Auditor Equivalent Days on Site
Office	Small	1
	Medium/large	1-2
Light manufacturing /assembly	Small	1
	Medium/large	1-2
Medium to Heavy Manufacturing (not chemical or pharmaceutical)	Small	1-2
	Medium	1-2
	Large	2
Complex manufacturing e.g. chemical plants or pharmaceutical plants	Small	1-2
	Medium	2-3
	Large	2-4

¹E.g. small sites: 1-100 employees, medium sites: 101-1000 employees, large sites: more than 1000 employees.

Table 3: Guidance for Auditor Equivalent Days on Site for PSCI Social Audit Component

Auditor Equivalent Days on site	Number of Workers (excluding managers)	Individuals interviewed	Group interviews	Total Employees interviewed	Effective Time spent on Interviewing
1	1-100	ca. 5 (or total number of workers if <5)	1 group of 4	max. 10	1.5-2.5 hours
1-2	101-500	5-7	1-3 groups of 5	10-20	2-3 hours
1-3	501-1000	5-10	2-5 groups of 5	10-30	2-4 hours
2-4	>1000	10-20	4-8 groups of 4	20-40	3-6 hours

AUDIT AGENDA

The audit team (3rd party or PSCI member internal team) will forward an agenda to the supplier site outlining the planned activities during the audit minimum two weeks prior to the audit. The typical agenda shall include, but is not limited to:

- **Opening meeting:** suggested participants: management team including health, safety and environmental (HSE) representatives, manufacturing/technical operations representatives, union and HR representatives; a link for the opening meeting is available [here](#) or on the PSCI Resource library.
- **A site tour (may be performed virtually via 'live' video links or using pre-recorded videos from the supplier for any partly or fully remote audit)** of all key production and infrastructure areas (e.g. storage areas, laboratories, waste and wastewater treatment areas, offices, canteen, medical facilities, sanitary facilities, dormitories, if necessary also outside area (e.g. perimeter of the facility, water outlets, waste disposal areas) in scope of the audit including informal, impromptu interviews with operators;
- **Employee interviews** (individual and group interviews, including union representative interviews and interviews of temporary and part-time employees and contractors);
- **Interviews with Management** (e.g., HR, HSE and site representative, engineering or maintenance staff);
- **Documents review** (for reference please find the list of documents that may be checked during the audit)
- **Pre-closing meeting:** Preparation of a draft **Corrective Action Plan** for closing meeting;
- **Closing meeting** with management team: auditors to thank the site for collaboration during the audit, to mention good practices seen during the audit, to share findings, get sign-off from site management that findings were communicated and understood; discussion about corrective actions and timelines for implementation.

RECOMMENDATIONS FOR SUPPLIER SITES TO PREPARE FOR A PSCI AUDIT

After receiving the audit announcement and above information from the 3rd party audit firm or the PSCI member audit team, the supplier site should ensure that they prepare for the audit. This may include, but not be limited to:

- Site management should be briefed by the lead auditor prior to the audit, to ensure they understand the scope of the audit and what is required from each department;
- If an audit is to be partly or fully remote, ensure that appropriate technology and data sharing platforms are agreed with the auditors, along with ways of working;
- Applicable site management should be instructed on the importance of having the correct key personnel and documentation available on the day(s) of the audit and understand the importance of making personnel available for interviews on time;
- Two meeting rooms free from interruptions and with appropriate technology, one of which must be large enough to accommodate group interviews for the social audit, should be reserved for the auditors use throughout the audit. The larger room should be a place where workers will feel comfortable, near a canteen or a workers' area is preferred;
- Union or other worker representatives should be briefed about the audit, in particular the human rights aspects, to ensure their availability and understanding;
- The workforce should be informed about the audit including the code to which the audit is conducted (e.g. PSCI Principles);
- The employees should be informed that the auditors will randomly pick employees for individual and group interviews relating to their human rights situation, and that they have the right to refuse being interviewed without reason or consequence;
- Employees should be informed about their right for data privacy in this context;
- There should be a contact within the site for the workforce if they have any questions or worries about the audit (e.g. HR Manager, worker representatives);
- Any labor providers (agencies) the site uses should be informed about the audit and ensure they understand the importance of having the correct key personnel and documentation available on the day of the audit(s);
- Any questions or points the site may have about the audit should be referred to the audit team leader for clarification;
- In advance of the site visit, the site should provide all documents requested by the auditors. This includes the completed PSCI Self-Assessment Questionnaire (SAQ) along with the documents /links requested there;
- PSCI provides [a list of documents](#) that are likely to be checked during the audit.

Chapter 7: Audit Execution

The overall audit execution process consists of the following steps:



OPENING MEETING

The opening meeting aims at achieving a common understanding between the management and the audit team about the purpose of the PSCI audit, the underlying audit requirements, the audit process and the audit agenda including timelines and activities.

During the opening meeting the lead auditor should address the following topics:

- Introduce the audit team;
- Briefly introduce the PSCI, the PSCI Audit Program and the benefits they offer to the supplier;
- Confirm purpose and scope of the audit; clearly state that this audit is not a pass or fail exercise, but directed at promoting continuous improvement;
- Explain the audit process and importance of the corrective action plan and corresponding follow-up activities;
- Assure the confidentiality of the interviews and audit findings;
- Confirm the key contact persons for the audit;
- If not yet received, ask management for any prior requested information that has not yet been provided;
- Check whether any non-routine activities are planned during the audit duration (e.g. evacuation drills, alarm testing, etc.);
- Remind management team of the closing meeting and agree on a tentative time. Ensure that enough time is allowed to re-investigate non-compliances if challenged;
- Explain that the auditors, when onsite, should be accompanied and allowed to move freely and that the auditor is granted access to all areas of interest. Ask permission to take pictures for documentation and explanatory purposes. If this permission is not granted, request if the supplier can take and manage requested pictures instead. Note: photos should not contain product information or other proprietary information;
- Ask the management team if they have any questions.

SITE TOUR

The site tour allows the auditors to observe and inspect key production and infrastructure areas and to gather evidence if activities are carried out in accordance with the suppliers' internal policies, stated practice, legal requirements and standards as well as the PSCI Principles. The duration of the site tour depends on the size and complexity of the facility. The site tour needs to be performed efficiently and will cover all relevant site areas to ensure effectiveness and efficiency of the audit.

Where the audit is partly or fully remote, the site tour may be performed using either 'live' or pre-recorded video(s), as agreed ahead of the audit. Any pre-recorded video(s) should be recorded without sound. All shared information is to be treated confidential and under consideration of data privacy regulation.

During the site tour the audit team should, as far as possible:

- Understand the main activities and types of work carried out;
- Assess the surroundings of the site (e.g. neighbouring facilities, companies, hospitals, schools, shops), adjacent natural habitats;
- Observe the working environment (e.g. space, temperature, housekeeping, noise);
- Get a view on the overall health, safety and environmental systems and practices at the site.
- Observe any display of information (e.g. Codes of Conduct, national law, information released by union, awareness raising posters);
- Observe the atmosphere among workers as well as between workers and managers
- Initiate first interviews of individual workers and identify workers for possible subsequent interview;
- Inform supplier management in a timely manner if a finding could be considered critical, so that further information can be made available and/or immediate corrective actions can be initiated.

If there is more than one auditor, and especially if there are a social and an HSE auditor conducting the audit, the audit team may choose to split up. The social auditor may want to spend more time talking to employees and focus on human rights-related topics. The HSE auditor may need to spend more time and focus on HSE-related topics. The site management is expected to allow for the split-up.

During the site tour, the audit team seeks to meet site staff/workers including production managers and support staff, warehousing managers and support staff, engineering staff, site cleaning and maintenance staff, health and safety managers, dormitory supervisors, clinic/first aid staff, kitchen and security staff. The auditors should not be purely guided by management on areas to visit, but should be allowed to freely investigate all areas that they feel applicable.

It is the responsibility of the supplier to inform the auditors prior to any onsite tour about the safety rules and requirements pertaining to the site [e.g. personal protective equipment (PPE)] and to provide the auditors with the necessary PPE, if required.

The auditors should NOT disturb or disrupt the production processes while carrying out the facility tour.

MANAGEMENT AND WORKER INTERVIEWS

The purpose of worker interviews is to cross-check information provided in documents ahead of the audit or collected during the site tour. The audit team should randomly choose a sample of workers (e.g. from the site tour or the daily attendance list). The management should not interfere when the auditor selects the interview sample.

To obtain a representative sample of the workforce, the following aspects should be taken into account:

- Different departments / areas (e.g. personnel from production and warehousing, engineering and maintenance, health and safety, dormitories, clinic/first aid staff, kitchen and security, cleaning), including shift pattern where applicable;
- Different ranks and salary grades (e.g. apprentices, regular workers, temporary workers, supervisors, managers, department heads);
- Different contract types (e.g. permanent, temporary, agency workers);
- Union and / or worker representatives (to learn about their assessment of the working conditions and their specific role);
- Diversity of the workforce (e.g. gender composition; different ages; physically disabled persons; different nationalities; different cultural /ethnic background).

The interviews must account for production/ work requirements and must be planned to minimize disruptions to work flows.

Where possible, the first round of interviews should take place in the earlier part of the audit to give the maximum time to investigate the points raised prior to the closing meeting. All comments raised at the interviews need to be thoroughly investigated before the closing meeting.

All interviews will be conducted in a separate room (in case of remote/partially remote audits with appropriate technology), preferably away from the work stations and in an area where workers are comfortable to speak.

In contrast to individual interviews, questions raised in group interviews should be of a more general nature and do not require workers to disclose any personal details such as their wage or union membership. Group interviews should rather be directed at general working conditions in the company and points for improvements. Employee interviews are strictly confidential, especially regarding human rights issues, and thus must be managed with discretion and conducted in the absence of management or supervisors. Participation of employees in interviews shall always be voluntary from an employee's side. Also, identities of workers (e.g. names or ID numbers) should never be included in the audit report.

Good communication and personal skills of the auditors and a sense for the local culture are important for the success of the interviews:

- The auditors should make the interviewed individuals/groups feel comfortable [e.g. considering the way they dress (a very formal business suit may not be suitable), in the approach the interviews are carried out (e.g. with friendliness, empathy and discretion) or in the way the interview room is arranged (e.g. not creating artificial barriers by sitting behind a desk/laptop)];
- The auditor must introduce himself/herself and explain the audit purpose and emphasize the confidential nature of the interviews and assure the interviewee(s) that individual worker's identity will not be communicated nor any part of the interview

recorded (if performed via live video stream);

- The auditor should conduct the interview in an informal conversational style rather than a check list approach;
- Open-ended questions should be raised to encourage dialogue with the interview partners.

Only approved information (e.g. confirmed by document review) may be shared with the supplier's management. Not approved or sensitive information should not be disclosed to the management in order to protect workers. However, such information may be reported confidentially and separately to the PSCI Secretariat and/or the respective PSCI member.

Finally, auditors should always provide a business card and/or a local phone number for workers to get in contact after the interview, e.g. in case they have a question.

DOCUMENT REVIEW

Documents build the basis of the audit by providing support for the procedures implemented, evidence obtained, and conclusions. The objective of the document review is to obtain further evidence and check the availability and status of key documents, such as guidelines, handbooks, files and certificates as summarized in the [PSCI Pre Audit Document List](#) and as listed in the PSCI SAQ/Audit Report Templates. The duration of the document review will depend on the preparation of the supplier and the size of the company.

If waivers are presented during the audit, they need to be verified. For example, if a waiver is presented by the supplier which allows workers to work in excess of the legal maximum, the auditor must verify that the workers have agreed to such practice and that they are suitably compensated at the correct rates with the application of overtime premiums as required. Details should be documented in the PSCI Audit Report and copies attached (e.g., an endorsement or certification by local government). It should be noted that even if a valid waiver is in place which overrides local law, there could still be non-compliance against the PSCI Principles.

A waiver is a voluntary agreement to give up a right, claim, or privilege, often used in contracts, business, finance, and law. This could mean giving up the right to sue, skipping a required fee, or allowing an exception to a rule (e.g. deviations from working hour rules). While they protect businesses from liability and offer flexibility, they can also limit individual rights, making it crucial to read and understand them before signing.

PRE-CLOSING MEETING

Prior to the official closing meeting, the audit team members should review the overall audit results:

- Review and discuss the evidence found/presented;
- Examine and reach consensus on the findings/observations to be shared with the supplier's management;
- Examine specific documentation or evidence to verify audit findings;
- Prepare a finding list or presentation using pictures (if feasible) to explain the findings. Discuss first ideas for mitigating the audit findings;
- Enter the findings into the Corrective Action Plan section of the Audit report template.

CLOSING MEETING AND SUMMARY OF THE AUDIT

The aim of the closing meeting is to inform the site management about the audit findings and to reach a common understanding about the corrective actions with timelines. The lead auditor will explain the classifications of the audit findings (critical/major/minor, see Chapter 8) and may discuss first ideas for mitigating the audit findings during the closing meeting. The audit findings need to be added into the **Draft Corrective Action Plan (CAP)** section and agreed between the auditor and the supplier during the closing meeting. It is crucial that all issues are clearly described and understood by the end of the meeting.

During the closing meeting the team leader should:

- Thank the management for their time, patience and openness and indicate how this contributes to fostering the mutual relationship and building trust;
- Re-confirm the purpose of the audit;
- Mention good working practices that have been observed during the audit;
- Explain that the audit was based on a sample examination of their site and that it is the site's responsibility to conduct a deeper investigation into their programs;
- Explain which findings and improvement potentials have been observed during the audit, and may discuss first ideas for possible corrective actions;
- Remind the supplier that they may challenge/discuss findings (or provide factual evidence that a finding was incorrect) in this meeting, but any issues they have agreed to will not be changed later;
- Besides listing the findings, ensure that any agreements or disagreements are clearly recorded on the **Draft Corrective Action Plan template**;
- If possible, obtain the signature of the site management on this **Draft Corrective Action Plan template**;
- Explain the next steps;
 - Drafting of **PSCI Audit Report** and **PSCI Corrective Action Plan** template by 3rd party audit firm or PSCI member internal auditors including an internal quality check (see Chapter 8);
 - Finalization of the PSCI Audit Report and Corrective Action Plan template and distribution to supplier and to the respective PSCI member;
 - Inform the supplier that they are encouraged to upload the PSCI Audit Report and Corrective Action Plan to the PSCI platform (a secure database), and the audit will not be shared with other PSCI member companies without the supplier's consent.
 - Encourage the management of the site to allow for **PSCI Audit Report** and **Corrective Action Plan Sharing** with other PSCI member companies by sharing the audit digitally via the PSCI.

If management does not agree with a certain finding, the auditor should state that if they can provide factual evidence that shows the finding is incorrect, the audit team will review it. In case the evidence can be verified and accepted by the audit team, the finding will be deleted from the preliminary corrective action plan template.

In case an audit finding has been corrected immediately during the audit (e.g. clearance of a

blocked gangway), it should still be recorded as an audit finding with the corresponding classification of the finding (critical/major/minor) in the CAP template and the PSCI Audit Report along with the information that this finding has been corrected during the audit. Nevertheless, it is expected for the supplier to determine a root cause and provide a Corrective Action Plan.

Chapter 8: Audit Report and Outputs

DOCUMENTATION OF PSCI AUDITS AND PSCI CORRECTIVE ACTION PLANS

The following steps describe the drafting, checking, distribution and follow-up of the PSCI Audit Report and Corrective Action Plan template:



1. The PSCI Audit Report including the corresponding Corrective Action Plan template should be drafted as soon as possible after the audit and provided to the 3rd party audit firm and/or the responsible PSCI member internal function (maximum 10 working days);
2. A quality check of these drafts by the 3rd party audit firm and/or the PSCI member internal function will take place to ensure that the audit has been documented according to requirements described in the current version of the PSCI audit guidance. The quality check covers as a minimum a completeness check, acceptable language, classification of findings and anti-trust considerations (see also [service level agreement](#) between 3rd party auditor and PSCI) More guidelines for an audit completion and redaction of the final audit report might be found [here](#);
3. The final PSCI Audit Report including the Corrective Action Plan template is then provided to the audited supplier;
4. The supplier completes the Corrective Action Plan section with the required information on measures, responsibilities and timelines and provides a regular update on the closure of the agreed on corrective actions.

As already mentioned under Chapter 4, **the PSCI SAQ & Audit Report Templates** must be used for the documentation of PSCI Audits. If not indicated otherwise (e.g. by the audit sponsor) it is recommended to complete the online Self-Assessments Questionnaires (SAQs) on the PSCI platform in order to support overall data evaluation by the Audit Workstream. The PSCI [provides guidance](#) for auditors to import data from the PSCI Audit Platform into the PSCI Audit Template. Embedded in these Audit Report Templates are the completed **SAQs** of the supplier.

Links to PSCI Audit report templates

[Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers \(excel\)](#)

[Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers \(excel\) with import sheet – for online SAQ only](#)

[Abbreviated PSCI SAQ & Audit Report Template for Service Providers & General Manufacturers \(excel\)](#)

[Abbreviated PSCI SAQ & Audit Report Template for Service Providers & General Manufacturers \(excel\) with import sheet – for online SAQ only](#)

The audit team should use this document to:

- Compare the Self-Assessment provided by the supplier against the evidence found during the audit;
- Clearly describe **how** the supplier is complying with its internal policies, stated practice, legal requirements and standards as well as the PSCI Principles, including the evidence gathered during the audit. The audit evidence includes visual observations (e.g. during the site tour), information received at the interviews and/or document review;
- Identify on the PSCI Audit Report whether the audit has been performed onsite, partly remote or fully remote and specify the corresponding verification method. For the excel versions this information is to be provided on the Overview & Guidance tab.
- Make use of the embedded auditor guidance notes as support for interviews and evaluation of received information and documents;
- Document all findings made during the audit in the PSCI Audit Report along with their classification and reference to local law and/or PSCI Principles;
- Document also examples of good practice (e.g. additional benefits such as free meals, free transport, private health schemes) in the respective sections of the PSCI Audit Report.
- The 3rd Party Auditors should furthermore be clear about the report owner (the party who pays for the audit) and the reviewers of the report and ensure that they conduct the audit in the best interest of all stakeholders in the process.

AUDIT FINDINGS

It is good practice to state all audit findings in simple language, stating the issues or observations clearly so that they can also be understood by someone who was not present at the audit.

PSCI audit findings are generally classified into “critical”, “major” or “minor” findings.

Critical Findings:

- Are **very** high risk findings that require immediate action to protect human life, the health of employees or the environment;
- May result in loss of license to operate or serious damage to reputation;
- Require immediate corrective action by the supplier;
 - Need to be communicated to the audit sponsor prior to audit report finalization. Examples for critical findings:
- Severe violations of human rights or labor rights (e.g. presence of child labor in a facility or forced labor, over-excessive working hours);
- Health and safety issues that can cause immediate life-threatening situation or serious injuries to employees and other individuals on site;
- Environmental or safety issues that could result in serious and immediate harm to the community.

The following [guidance](#) should be used as basis for deciding whether a finding should be classified as a “major” or “minor”:

Major findings:

- Are audit findings that may pose major impacts to workers, community or the environment
- Are findings that may pose major regulatory non-compliances
 - Illustrate systematic program gaps

Minor findings:

- Are findings that may pose minor impacts to workers, community or the environment
- Are findings that may pose minor regulatory non-compliances

All findings need to be summarized in a PSCI Corrective Action Plan template as illustrated in Table 4. The Corrective Action Plan template (available as separate [word](#) or [excel](#) version, or embedded in the excel version of the [PSCI SAQ/Audit Report template](#)) should also be used by the supplier for documentation of agreed corrective actions, time period for close-out of the corrective action, the type of verification (e.g. desk top review of documents or follow up visit), responsible individual at the supplier for the individual corrective actions, details on the implemented corrective action and a status assignment (open/closed).

Table 4: PSCI Corrective Action Plan template

PSCI Supplier Corrective Action Plan								
Findings, Corrective Actions and Follow-up								
Finding Number <i>The reference number of the Finding from the Audit Report, for example, Discrimination No.7</i>	Finding Type C= Critical O= Other <i>Please state whether Critical, Other Finding</i>	Description of Finding <i>Please describe the finding (as done in the PSCI Audit Report)</i>	Agreed Corrective Actions <i>Details of actions to be taken to follow up on the Finding</i>	Recommended Completion Timescale <i>Timescale (Immediate, 30, 60, 90, 180,365 days)</i>	Verification Method <i>Desktop / Follow-Up Visit</i>	Agreed by Management and Name of Responsible Person: <i>Note if management agree to the Finding, and document name of responsible person</i>	Verification Evidence and Comments <i>Details on corrective action evidence</i>	Status <i>Open/Closed or comment</i>

DATA SHARING AND SHARING OF AUDIT INFORMATION

PSCI SAQs, Audit Reports and other relevant audit related information are uploaded to the PSCI Audit platform as part of the regular audit process. If a supplier wishes to share the audit information, this can be done via the PSCI platform.

Prior to the upload of audit information, especially SAQ and the Audit Report, the sponsor or supplier must check the documents with regard to the following:

- Check/ensure that there is no mentioning of sponsor name in any of the documents;
- Ensure that no data privacy violation takes place (e.g., no mentioning of supplier employee names);
- Ensure that no Intellectual Property-protected information is mentioned in the documents.
- Then the sponsor (or, in case no sponsor exists, the 3rd Party Auditors) should upload the completed documents to the PSCI platform.
- See [the PSCI Audit Completion & Redaction Guidance](#) for more information.



PSCI SAQs and Audit Reports may be submitted and shared electronically via the PSCI Audit Platform. Instructions for PSCI Members ([PSCI Audit Sharing Platform Member User Guide](#)) as well as instructions for suppliers ([PSCI Audit Sharing Platform User Guide](#)) are available on the PSCI Resource Library. Digital sharing via the PSCI Audit platform is the best and preferred way of sharing PSCI SAQs and Audit Reports as it also facilitates future sharing with new PSCI members and allows suppliers to better manage their sharing preferences.

The PSCI Secretariat will carry out a final check prior to releasing the documents on the platform to avoid any accidental disclosure of confidential member information.

Chapter 9: Follow Up Audit Process

After receiving the PSCI Audit Report and the Corrective Action Plan (CAP) template, the supplier should provide an updated version of the CAP (ideally within 30 working days),

- Confirming or adjusting the proposed corrective actions;
- Confirming or adjusting the time scales;
- Indicating the individuals/functions responsible for the implementation of the corrective actions;
- Providing a short description regarding the evidence of the corrective actions;
- Providing a status definition (open/closed) of the individual findings.

A regular status report (e.g. every 3 months) should be shared by the supplier for review by the sponsor of the audit (PSCI member) and/or the PSCI Secretariat (in case of self-paid audits), until all audit findings are closed. The reviewed status report should ideally also be shared on the PSCI platform, so that it can be requested by other PSCI member companies.

In case the verification methods were defined as “follow up visit” or the corrective action evidence cannot be effectively verified by a desk top review, a follow up audit needs to be scheduled. This follow-up audit is not a full audit, but a shorter visit to verify if adequate corrective actions have been taken in response to an audit finding. The follow-up audit may be conducted by a 3rd Party Auditors (ideally with the same auditors who carried out the initial audit) or by PSCI Member auditors.

For a follow up on social audit findings, employee interviews, hours of work and payroll review should still be undertaken, however, the sampling numbers will usually be lower than for a full audit. A follow-up report is issued as an updated version of the original report with all new elements highlighted so as to be clearly seen. For all findings previously raised there should be a clear explanation of the evidence reviewed, comments on applicability and effectiveness of corrective actions and whether the issue is now considered closed or remains open. Any new findings must be included in the report. A new corrective action plan must be generated which addresses open and new audit findings.

Chapter 10: The PSCI Audit Document Checklist

The [PSCI Audit Document checklist](#) summarizes important documents which the audit team may want to see in advance for audit preparation or want to review during the onsite audit visit. Depending on the type of supplier or the information provided as per SAQ, the list may be shortened (e.g. for service providers) or extended (e.g. for complex chemical or pharmaceutical manufacturers).

Chapter 11: Contact Details

In case of any questions related to the PSCI Audit Processes, please contact the PSCI Secretariat by using the following email address:

info@PSCIinitiative.org.

Appendix: Managing Audit Related Issues

In the event of any incidents occurring during the audit process or related to cooperation with the selected auditor, please refer to the applicable escalation and incident reporting guidance that can be found below.

Guidance on audit related issues

Goal of this guidance:

- Define and present the steps and responsibilities within the audit related issue reporting process.

Parties involved in the process

- PSCI member / supplier
- Audit company
- PSCI Secretariat
- Audit committee

Definitions

- Audit related issue – any kind of issue that is related to audit execution that might be observed by the PSCI member company, supplier or the audit service provider. E.g. audit report delivery time, audit classification categorization, poor quality of the final audit report, non-ethical behaviour of the auditor, inappropriate behavior of supplier.
- SLA – Service Level Agreement – defined in the PSCI – Auditor agreement level of the service that should be delivered while executing the PSCI audits.
- Auditor – audit service provider company approved by the PSCI to perform PSCI audits.
- Sponsor – PSCI member company or the Supplier who order and covers the audit costs.

Escalation process description

1. Identification of the audit related issue

- The audit related issue might be identified by
- either PSCI member company
- a Supplier (who could also be the sponsor of the audit)
- Auditor

If an audit related issue is identified it needs to be discussed between the involved parties (e.g. Sponsor and the Auditor) first with the goal to resolve the issue without further involvement of other parties.

If no improvement or consensus is achieved between the Sponsor and the Auditor – this audit related issue may need to be reported to PSCI Secretariat who will support in resolving the issue or taking further steps..

An information about the audit related issue should be sent to PSCI secretariat in a written form (email) and should contain at least:

- Name of the Sponsor and the Auditor (and if necessary the supplier involved)
- Description of the issue with annotation what kind of corrective actions were taken and their result
- Frequency of the issue observed