



Pharmaceutical Supply Chain Initiative

PSCI Audit Guidance

November 2018

About This Document

THE PSCI AUDIT PROGRAM GUIDANCE

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

Along with the **PSCI Principles**, the **PSCI Implementation Guidance** and the **PSCI 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 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 3rd parties and PSCI audits conducted by members). PSCI Pre-Audit Document checklist as Annex 1.
4	June 2017	Included supplier self-audit model

ABOUT THE PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

The Pharmaceutical Supply Chain Initiative (PSCI) is a group of major pharmaceutical and healthcare companies who share a vision of better social, economic, and environmental outcomes for all those involved in the pharmaceutical supply chain. This includes improved conditions for workers, economic development, and a cleaner environment for local communities.

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Chapter 1: Introduction and Purpose

The Pharmaceutical Supply Chain Initiative (PSCI) is a group of pharmaceutical and healthcare supply chain companies that share a vision of better social, economic and environmental outcomes for all those involved in the pharmaceutical supply chain. 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:

- Ethics;
- Labor;
- Environmental Protection;
- Health & Safety;
- Management Systems.

The **PSCI Principles** are consistent with industry and international expectations and are applicable both in developed and developing countries 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 Shared 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 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 Shared Audit Program Guidance** are available on the PSCI website (<http://pscinitiative.org/resources>) or amended in this document:

- PSCI Principles;
- PSCI Implementation Guidance;
- Data Sharing Agreement;
- Self-Assessment Questionnaires (SAQ);
- PSCI Audit Report Templates;
- Corrective Action Plan Template;
- Sample PSCI Pre-Audit Document checklist.

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;
- OHSAS 18001: Occupational Health and Safety Assessment Series;
- SA 8000: Social Accountability International Standard;
- United Nations, Universal Declaration of Human Rights and 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.

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:

- Ethics;
- Labor;
- Health & Safety;
- Environmental Protection;
- Management Systems.

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 Shared 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 Plan.

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

- A certification scheme;
- A compliance exercise with a "pass or fail" outcome;
- An endorsement or suggestion of preference for those suppliers that undergo a PSCI shared audit.

AUDIT SCOPE

The **PSCI Audit Report Templates** developed by the PSCI Audit Working Committee serve as tools for the documentation of the PSCI Shared 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 Audit Report Templates**:

1. The **full PSCI Audit Report Template** for Core Suppliers, External Manufacturers, Component and Material Suppliers (“C” and “B” Suppliers, see Figure 1 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.
2. The **abbreviated PSCI 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, marketing service providers, travel & fleet services, construction services.

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

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



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).

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 labor 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 labor) and HSE (health, safety and environmental) areas along with the related 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 visit.

In case a PSCI member company decides to have one or more of the areas (e.g. Ethics, Labor, Health & Safety, Environmental Protection) 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 Shared 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, as a minimum, be certified against a recognized quality management system, such as ISO9001:2000 and should ideally be accredited to the requirements of ISO/IEC Guide 62, 65 or ISO17020, ISO17021, ISO 17065.

All 3rd party audit firms that conduct PSCI audits should be approved by the PSCI Audit Working Committee. A list with approved 3rd party auditors will be made available on the PSCI website. Suppliers can access this list and select an audit firm to carry out a self-paid audit with PSCI approved auditors from these firms.

If a PSCI member decides to carry out a PSCI Shared 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 prior to sharing is important to avoid any accidental disclosure of confidential member 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.

If a 3rd party audit company is selected for carrying out an audit, it must ensure that:

- All auditors carrying out PSCI Shared Audits have a proven audit record and applicable industry experience;
- All auditors 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;
- Auditors need to have the proven ability to write reports in English that are clear and unambiguous;
- Auditors demonstrate the competencies listed in ISO 19011;
- Social auditors have attended the basic and advanced SA8000 auditor qualification course, 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, OHSAS 18001);
- 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 Shared 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 social and HSE Auditors:

Table 1: Minimum Experience Requirements for Individual 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).</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 labor 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).</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, OHSAS 18001 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).</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> <p>If possible, certified Professional Auditor (CPA) or Certified Safety Professional (CSP) or equivalent.</p>	

As part of their continuous professional development, all auditors are subject to a review and appraisal of their performance. This includes:

- Social auditors should attend an SA8000 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 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 third 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 assessment, 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.

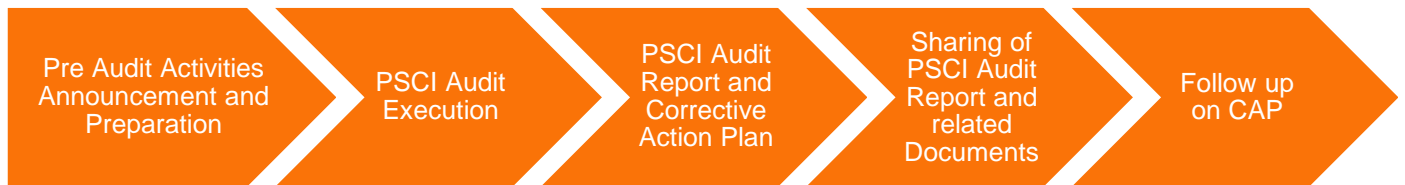
For PSCI members and suppliers who plan to nominate themselves for a self-paid PSCI audit, the PSCI maintains a list of pre-approved 3rd party auditors and audit firms. The list and their contacts are available on the PSCI website.

Chapter 5: Audit Process

OVERVIEW

PSCI Members will individually identify suppliers subject to an audit in the areas of Ethics, Labor, Health/Safety, Environmental Protection and the underlying Management Systems. PSCI Members will decide individually and independently which of their suppliers will be invited for a PSCI Shared Audit, and what kind of an audit will be carried out (e.g. with 3rd party audit firms or with own internal auditors, “full” PSCI Audit or “limited” PSCI Audit (HSE or social/ethical)). Suppliers executing a supplier paid audit follow the same overall process.

The overall process comprises the following steps:



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 Shared 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. The contracted 3rd Party audit firm will then:

- Contact the supplier, introduce the audit team and agree on the audit date;
- Provide the **PSCI Data Sharing Agreement** to the supplier and ensure that the form is signed as soon as possible and returned to the client or the PSCI secretariat;
- Provide the **applicable PSCI Audit Report Template** to the supplier, so that they can fill out the **embedded Self-Assessment Questionnaire**;
- 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;
- Prior to the audit, provide the supplier with **an agenda** and a tailored **PSCI Pre-Audit Document checklist** which comprises documents/information which should be available during the audit (a sample is provided in Annex 1);
- 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;
- 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);
- Confirm logistics for the audit team, including travel, accommodation, parking, arrival time;
- Confirm with the supplier the key site personnel to be available during the audit (e.g. management personnel, HSE staff, operations managers, union or worker committee representatives, health and safety representative);
- 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. 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 nominate themselves to the PSCI Secretary requesting that they be audited under the self-paid model.

The PSCI Secretary will then inform the supplier about general PSCI Shared Audit process and provide a list of PSCI approved 3rd party audit companies and corresponding approved auditors. The supplier can choose an audit company from this list and contact the audit firm to work out the details including the cost to have an audit completed. The 3rd party audit firm will then plan and execute the audit and provide the final PSCI Audit Report and Corrective Action Plan to the supplier.

The supplier then decides whether it agrees to share the final PSCI Audit Report and Corrective Action Plan with **all current and future PSCI members (recommended) or parts of the PSCI Membership** (a list of the current PSCI members can be found on the **PSCI website**). This is completed by providing the **signed Data Sharing Agreement** to the PSCI Secretary. Only audits that have been formally endorsed by the supplier (and the sponsor, if applicable) by signing of the **Data Sharing Agreement** will be shared 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 labor 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.

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.

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
	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

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

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

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 on-site assessment. The typical agenda shall include, but is not limited to:

- **Opening meeting** [management team including health, safety and environmental (HSE) representatives, manufacturing/technical operations representatives, union and HR representatives];
- A **site tour** of all key production and infrastructure areas (e.g. storage areas, laboratories, waste and wastewater treatment areas, offices, canteen, medical facilities, sanitary facilities, dormitories) 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** (HR, HSE and site representative, engineering or maintenance staff);
- **Document review sections** covering;
 - HR documentation including documents and records (if authorized) of those individuals interviewed;
 - Labor / Ethics related documentation;
 - HSE related documentation.
- Pre-closing meeting: Preparation of a draft **Corrective Action Plan** for closing meeting;
- **Closing meeting** with management team: auditors 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 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;
- 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, 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 labor aspects, to ensure their availability and understanding;

- The workforce should be informed about the audit including the code to which the audit is conducted (PSCI Principles);
- The employees should be informed that the auditors will randomly pick employees for individual and group interviews relating to their labor 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);
- 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 for review. This includes the completed PSCI Self-Assessment Questionnaire (SAQ);
- The site should ensure that all documents requested by the auditor (via the Pre-Audit Document Request) are available during the site visit.

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 Shared 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 should be accompanied and allowed to move freely on-site 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.

During the site tour the audit team should:

- Understand the main activities and types of work carried out;
- Assess the surroundings of the site (e.g. neighboring 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 labor-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 the site tour about the safety rules and requirements pertaining 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

Interviews have the obligation to cross-check information collected during the site tour and the document review. 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 /ethical 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, 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 with regard to labor issues, and thus must be managed with discretion and conducted in the absence of management or supervisors. 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;
- 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 Secretary and/or the respective PSCI member.

Finally, auditors should always leave 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** (see Annex 1). 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.

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 presentation using pictures (if feasible) to explain the findings. Discuss possible solutions;
- Enter the findings into the Corrective Action Plan 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 and others, see Chapter 8) and discuss/propose options for mitigating the audit findings during the closing meeting. A **preliminary Corrective Action Plan (CAP)** needs to be established for the audit findings 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 discuss 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 **Preliminary Corrective Action Plan**;
- Obtain the signature of the site management on this **Preliminary Corrective Action Plan Report**;
- Explain the next steps;
- Drafting of **PSCI Audit Report** and **PSCI Corrective Action Plan** by 3rd party audit team or PSCI member internal auditors including an internal quality check (see Chapter 8);
- Finalization of the **PSCI Audit Report and Corrective Action Plan Report and distribution to supplier and to the respective PSCI member**;
- Encourage the management of the site to allow for **PSCI Audit Report and Corrective Action Plan Report Sharing** with other PSCI member companies by signing the PSCI Data Sharing Agreement.

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.

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 or others) in the CAP and the PSCI Audit Report along with the information that this finding has been corrected during the audit.

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:



1. The PSCI Audit Report as well as the corresponding Corrective Action Plan 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 (after maximum 10 calendar 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 (e.g. completeness, acceptable language, classification of findings, anti-trust considerations);
3. The final PSCI Audit Report and the Corrective Action Plan is then provided to the audited supplier;
4. The supplier completes the Corrective Action Plan 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 Audit Report Templates** must be used for the documentation of PSCI Audits. Embedded in these Audit Report Templates are the completed **Self-Assessments Questionnaires** (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 (<http://pscinitiative.org/resource?resource=32>)

Abbreviated PSCI SAQ & Audit Report Template for Service Providers & General Manufacturers (<http://pscinitiative.org/resource?resource=31>)

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;

- 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.

Due to the different audit finding classification systems applied by the individual PSCI members, PSCI audit findings are only classified into “critical” and “other” 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.

Other findings:

- Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time

All findings need to be summarized in the PSCI Corrective Action Plan as illustrated in

Table 4. This document 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 (<http://pscinitiative.org/resource?resource=285>)

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 AGREEMENT (DSA) AND SHARING OF AUDIT INFORMATION

A completed and signed **PSCI Data Sharing Agreement (DSA)** is mandatory for sharing any supplier audit-related information among the PSCI member companies.

Figure 2: PSCI Data Sharing Agreement (<http://pscinitiative.org/resource?resource=283>)

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

DATA SHARING AGREEMENT

The Pharmaceutical Supply Chain Initiative (PSCI) is a group of pharmaceutical companies who share a vision of better social, economic and environmental outcomes for all those involved in the pharmaceutical supply chain. This vision is detailed in the [PSCI Principles](#) and includes improved conditions for workers, economic development and a cleaner environment for local communities. Please go to the PSCI website to find out more about the initiative: <http://www.pscinitiative.org>

The members of the PSCI recognize the burden that multiple information requests and audits create for your company. To reduce this burden, we have created standard protocols and tools to assess suppliers' alignment with our Principles and we have set up a platform for sharing completed questionnaires, audit reports and corrective action plans.

Therefore, we ask for your permission to share the following documents with members of the PSCI via our platform. Please select the document(s) that you agree to share with our members:

- Completed PSCI Self-Assessment Questionnaire (SAQ)
- PSCI Audit Report
- Corrective Action Plans

You can share these documents with all existing and future PSCI members, or you can select specific members.

- All existing and future PSCI members (**we strongly RECOMMEND this option as it adds the biggest value for all parties involved**)



The supplier (and if applicable also the sponsor, i.e. the company who paid for the audit) agrees on the sharing of a PSCI Audit Report, the Corrective Action Plan and other audit related documents (e.g. updates to the Corrective Action Plan) by signing the DSA. The supplier provides the signed DSA to the PSCI Secretary by email or post. Upon receiving the above audit documents from the 3rd party auditor or his internal auditors, the sponsor must properly redact all documents intended to be shared and:

- 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 auditor) should submit the completed documents to the PSCI Secretariat.

The PSCI Secretariat or designee will carry out a final check prior to uploading the documents to avoid any accidental disclosure of confidential member information. In the case a supplier performs a supplier paid audit, the PSCI Secretariat or designee will also complete a quality check prior to posting to ensure only robustly executed audits are shared.

IMPORTANT: PSCI Audit Reports and related documents can only be uploaded to the PSCI Audit Platform and thus shared with PSCI members only after the supplier has completed and signed the Data Sharing Agreement and sent it to the PSCI Secretariat info@PSCIInitiative.org.

The DSA provides different options for a supplier to share audit results. However, **sharing with all existing and future PSCI Members is strongly recommended** to realize the highest benefit from the PSCI Shared Audit approach.

Chapter 9: Follow Up Audit Process

After receiving the PSCI Audit Report and the Corrective Action Plan (CAP), the supplier should provide an updated version of the CAP within 30 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 submitted by the supplier to the PSCI Secretariat and/or the sponsor of the audit (PSCI member), until all audit findings are closed.

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 audit firm (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: 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.

Annex 1: PSCI Pre-Audit Document Checklist

The below 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).

PSCI Pre-Audit Document checklist

1 GENERAL MANAGEMENT SYSTEMS

Organization chart

Site drawings showing:

- property borders;
- above ground tanks;
- detailed building layouts;
- hazardous chemicals, solvents, oils and wastes storage;
- stacks and vents;
- buried services (pipes, drains, sewers);
- buried tanks;
- sumps, pits, oil separators;
- lagoons and any points of discharge to local watercourses;
- on site waste disposal areas (used and abandoned and disused).

Site HSE policies and programs

Management of change documentation

Inspection and follow-up records

Compliance self-assessment reports

HSE training records

Incident and Emergency Response Plans.

Roles and responsibilities matrix

Regulatory agency correspondence

Previous social and HSE audits/review reports

Details and outcome of complaints if any (plus correspondence).

Government Inspection reports, e.g. sanitation, fire safety, structural safety, environmental compliance

2 ENVIRONMENT – General

Correspondence with authorities relating to any environmental violations and pollution incidents (air, water, effluent, wastes, odor and noise).

Emission Reduction Plan

Waste reduction plan

Spill, incident and upset reports

Documented procedures and operating manuals relating to environmental matters (e.g. emergency response, spill containment, waste handling and disposal).

3 AIR EMISSIONS

PSCI Pre-Audit Document checklist

All current air permits

Air monitoring data for the past 36 months

Air emissions inventory

Air emissions reports submitted to regulatory agencies

Copies of any violation notices received in the past three years

Copies of any federal/national, state/provincial and/or local emissions standards

CFC equipment maintenance records

Air pollution abatement equipment maintenance records

4 WATER SUPPLY, STORM WATER, AND WASTEWATER

Wastewater discharge permits

Wastewater discharge inventory

Wastewater sewer drawings

Wastewater treatment permits

Wastewater discharge monitoring data/reports for flow and permit parameters for last 36 months

Wastewater treatment plant maintenance records and as-built drawings

Site's water balance

Water abstraction permits

Storm water discharge permits.

Water supply drawings.

Storm water sewer drawings.

Copies of violation notices received in the past three years.

Well construction diagrams for on-site water supply or groundwater monitoring wells.

Water quality analyses from water supply or groundwater monitoring wells for the past 36 months.

List of active pharmaceutical ingredients (API) being discharged in the waste water and a list of known Predicted No Effects Concentration Levels for these APIs.

Copies of waste water risk assessment studies detailing the Predicted Exposure Concentration of API discharges.

5 WASTE MANAGEMENT

Waste inventory

Waste transport and disposal documentation (manifests, receipts, invoices)

Waste generation, storage, treatment or disposal permits or registrations

Disposal records of halones, refrigerants, PCBs and asbestos including costs.

Any waste-related reports to regulatory authorities

Copies of violation notices received in the past three years

Waste storage area Inspection records

Waste analyses and classification determinations

PSCI Pre-Audit Document checklist

6 HAZARDOUS MATERIALS CONTROL AND REPORTING

Tank inventory (e.g. number, location, age, construction, volume, content, alarms, vent pumps and cathodic protection fitted to bulk tanks).

Documented procedures for filling and unloading bulk storage tanks.

Procedures and records for tank maintenance - integrity testing (bulk tanks and pipework) etc.

Hazardous material inventory.

Tank and containment inspection records.

Tank integrity and tightness test records.

Drum management plan.

Spill response plans.

Hazardous materials reports.

Copies of spill and release notifications or reports and remediation.

Hazard communication training records.

7 ASBESTOS, PCBs AND OZONE-DEPLETING SUBSTANCES

Asbestos survey.

Inventory of asbestos-containing materials.

Records of asbestos abatement and disposal.

PCB-containing equipment inventory.

PCB test results from analysis on electrical equipment.

Pesticide inventory.

8 HEALTH & SAFETY DOCUMENTATION

Summary of occupational injuries and illnesses for the past 3 years.

Permit to Work program.

Lock-out/tag-out program.

Hazard communication program.

Respiratory protection program.

Industrial hygiene monitoring results.

Personal protective equipment program.

Hot Work Program.

Noise, chemical, or indoor air quality monitoring data.

Hearing Conservation Program and Test Records.

Biohazard Safety Program.

Blood-borne Pathogens Program and Records.

Confined Space Entry Program and Permits.

Fire protection plan.

Piping & Instrumentation Diagrams.

List of pressure vessels.

PSCI Pre-Audit Document checklist

Hazard Area Classification.

Process Safety Analyses (PHAs).

Health and Safety training records.

Radioactive material inventory and licenses.

Safety Inspection Reports.

Safety Manual.

Records of baseline physical examinations and periodic examinations.

Medical Surveillance program.

Risk assessment reports demonstrating characterization of the toxicity of Active Pharmaceutical Ingredients and the protection requirements for employee exposure to APIs.

9 LABOR DOCUMENTATION

Labor contracts.

Labor standards policies/Codes of Conduct including:

- Non discrimination;
- Fair compensation;
- Working hours;
- Freedom of association;
- Child Labor.

Employee handbook (terms and conditions of employment).

Collective Bargaining Agreements (CBA).

Child labor policies.

Wages and hours of work.

Disciplinary policies and practices.

Benefits and allowances.

Discrimination and harassment policies.

Homeworkers, outworkers and Sub-contractors policies.

Time records for the past 36 months.

Payroll records for past 36 months.

Piece rate records for the past 36 months (if applicable).

Insurance, tax and other required receipts.

Minutes of joint committees on HS and disciplinary matters.

10 ETHICS

Policy/Codes of Conduct covering.

- Business integrity & fair competition
- Anti-corruption
- Investigation of employee concerns

Policy on Animal Welfare (if applicable)