THE PSCI AUDIT PROGRAM

Understanding how you can benefit from participating in the PSCI Audit program

Why do we audit?

PSCI Audits 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, and Environment.

The PSCI Audit Program provides a framework and methodology to ensure PSCI Audits are carried out in accordance with PSCI Standards, thereby following a credible, transparent, and consistent audit approach.

The PSCI auditing model has developed into a widely accepted standard for our industry.

Who benefits from the Audit program?

Audits cost time and money. Sharing audits means *fewer audits for each supplier* and that brings efficiency gains for suppliers and members alike. Common auditing guidelines and a *consistent industry approach* for auditing gives suppliers a clearer understanding of what's expected of them.

Shared Audits also provide greater visibility within the supply chain. They allow us to see trends and patterns in the supply chain and to better understand where improvements are needed. The data we collect gives us invaluable insights into the issues our suppliers struggle with and feeds directly into our supplier capability building program.

"Uploaded" and "Shared" Audits

As part of the PSCI Audit Program, supplier audits are uploaded to the PSCI platform. Once an audit is uploaded to the platform, suppliers can choose to share the audit with specific member companies or with all existing and future PSCI members by using the Sharing function on the platform.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

What is the PSCI?

The 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. The PSCI was formed as an initiative between the six founding members in 2006 and was legally established in the United States as a non-profit membership organization in 2013. **Our membership** has grown substantially.

Our vision is for excellence in safety, environmental, and social outcomes, across the global pharmaceutical and healthcare value chain.

Our purpose is sector collaboration, using one voice to define, instil and drive responsible value chain practices.

We achieve our vision and purpose through the PSCI Principles for Responsible Supply Chain Management. They are the blueprint for responsible practice in the pharmaceutical and healthcare industry, setting our members' expectations for five relevant topics.

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Who can be audited?

The PSCI Audit approach can be applied to all suppliers in the supply chain of pharma and healthcare companies, located in either developed or emerging economies.

How to get started?

PSCI Audits may be initiated by PSCI members or suppliers.

Members may invite a supplier to participate in an audit and provide them with the information they need to get started.

Alternatively, suppliers can make their own request to be audited according to the PSCI Audit Guidance by contacting one of the PSCI approved audit firms to conduct a self-paid audit.

Who carries out the audit?

To ensure the integrity of the audit process, PSCI Audits are carried out either by professional and independent 3rd party audit firms or by qualified PSCI member internal auditors.

What's in scope?

PSCI Audits generally consider all, or part of, the pillars described in the PSCI Principles (i.e. Governance and Management Systems, Ethics, Human Rights, Health and Safety, and Environment) and in the PSCI Audit Guidance.

The audit will typically cover a clearly defined supplier location (e.g. a pharmaceutical or chemical production site, a warehouse, an R&D site, or an office building).

It covers all applicable internal and external areas of the facility, such as key production areas, laboratories, storage areas, utilities, infrastructure areas, waste handling and storage facilities, wastewater treatment units, workshops, security and fire service arrangements, canteens, kitchens, dormitories, and office areas.

As the audit scope also covers Human Rights topics, permanent, temporary, and contracted staff, as well as migrant workers are included in the audit. Selected interviews will be carried out to better understand the prevailing working conditions.The audit also includes management systems and key program elements (e.g. policies, standards, resources, competencies and capabilities).

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Understanding the PSCI Audit Process

Supplier categories

For auditing purposes, suppliers are categorized according to their activities:

- "A" - service providers and suppliers of non-supply chain goods
- "B" - component & material suppliers
- "C" - core suppliers & contract manufacturers

For "A" suppliers, the abbreviated *PSCI Self-Assessment Questionnaire (SAQ) and Audit Report Template* are used, as these suppliers operations and requirements are less complex, especially in health, safety, and environment. For "B" and "C" suppliers, the full *PSCI SAQ* and *Audit Report Template* should be used due to the complexity of their operations and requirements in all areas.

5-step audit process

I. Preparing for the PSCI Audit

To prepare for an audit, the supplier is given key information, such as purpose, duration (usually 1-3 days on-site with 1-2 auditors), agenda proposal, and a list of documents needed for the audit. The supplier is also asked to complete the Self-Assessment Questionnaire (SAQ) within an offline document or online.

II. Carrying out the Audit

The audit itself will include the following stages:

- Opening meeting
- Site tour
- Interviews with management and employees
- Review of documents and records
- Pre-closing meeting
- Closing meeting, including final wrap-up

III. Audit Report and Corrective Action Plan

After the on-site audit, the audit will be documented in a standardized PSCI Audit Report Template, which includes: an overview of the audited facility, the completed questionnaire and a summary of findings.

The Corrective Action Plan (CAP) contains all findings and their proposed corrective actions (including timeframes for completion), agreed upon by the auditor and the supplier.

IV. Uploading and Sharing the Audit

The audit documents may be uploaded to the PSCI platform after completion. *ONLY the member company who sponsored the audit can access the uploaded audit documents at this stage*.

We encourage suppliers to further share the audit with other members companies by editing the sharing preferences on the Audit page. Suppliers may choose to share with either all current and future PSCI members, or just with selected PSCI members. The first option is recommended, as it maximizes the benefits both for suppliers and PSCI member companies.

V. CAP follow-up

The supplier is responsible for correcting any findings listed in the CAP and must provide appropriate supporting documentation on the implementation of any corrective action.

Depending on the type of findings, a follow-up audit may be required to verify if adequate corrective actions have been to address the audit finding.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

PSCI Growing membership*

Full Members

Associate Members

*By end of 2024

Supplier Partners

In January 2024, PSCI launched our new Supplier Partnership category to formally recognize and acknowledge suppliers' commitment to responsible business practices.

Supplier partners have access to the PSCI audit platform, and access to the PSCI audit & environment survey reports of other supplier sites (once sharing permission is granted by the supplier).

Supplier partners are required to share audits of their own sites to the PSCI platform.

For more information about the PSCI please contact:

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