THE PSCI SHARED AUDIT PROGRAM

UNDERSTANDING HOW YOU CAN BENEFIT FROM PARTICIPATING IN A PSCI SHARED AUDIT

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: Ethics, Labor, Health & Safety, Environmental Protection and Management Systems.

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

Our goal is to ensure that the PSCI auditing model and tools become the norm for our industry.

What are "Shared" Audits?

The *PSCI Shared Audit Program* allows supplier audits to be shared among PSCI members via a web-based platform.

Once the audit is complete, it can then be shared with other PSCI members, provided that the supplier agrees and signs a *PSCI Data Sharing Agreement (DSA).* The DSA protects the rights of all parties and is mandatory for sharing any supplier audit-related information.

Who benefits from Shared Audits?

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.

Initiating a PSCI shared Audit

For the most part, PSCI Shared Audits are initiated by PSCI members, who will invite one of their suppliers to participate in an audit and provide them with all the information they need to get started.

- *Supplier Self-initiated Audit*

Suppliers may also make their own request to be audited according to the PSCI Audit standard, either by asking a member to sponsor their audit or by nominating themselves to the PSCI Secretary under the self-paid mode.

What happens in a PSCI Audit?

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

A PSCI audit typically covers 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.

Permanent, temporary and contracted staff, as well as migrant workers are included in the audit, as are the labor conditions onsite. The audit also includes management systems and key program elements (e.g. policies, standards, resources, competencies and capabilities).

Who carries out the audit?

In order 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.

PSCI

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

What is the PSCI?

The Pharmaceutical Supply Chain Initiative is a group of major pharmaceutical and healthcare companies whose members share a vision for responsible supply chain management. We believe that by joining forces, we are able to use our collective influence to drive complex global change more effectively than one organization alone.

PSCI Vision

Our vision is for excellence in safety, environmental, and social outcomes for the whole of the global pharmaceutical and healthcare supply chain. Our purpose is to bring together members to define, establish, and promote responsible supply chain practices, human rights, environmental sustainability, and responsible business.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

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 supplier have less complex operations and requirements, 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 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)*.

II. Carrying out the audit

- 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 (CAP)

After the onsite 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 positive and negative 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. Sharing the PSCI Audit

As outlined in the *PSCI Data Sharing Agreement*, the supplier may choose to share the audit documents with either all current and future PSCI members, or just with selected PSCI members. The first option is strongly 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 implemenation of any corrective action.

Depending on the type of audit findings, a follow-up audit might be necessary to verify if adequate corrective actions have been taken in response to an audit finding.

PSCI MEMBERS

For more information about the PSCI please contact:

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