

## PSCI Audit Program Supplier FAQ

This document addresses the common questions suppliers have around the PSCI audit program, the key points include:

- **Benefits for suppliers:** Suppliers benefit from sharing a PSCI audit as member companies are likely to wave / postpone / reduce the scope of a planned audit after gaining access to a shared audit previously conducted at the supplier site.
- **Information security:** Suppliers have full control regarding who can access an audit report. Besides the audit sponsor (this is the PSCI Member who initiated and financed the PSCI Audit at your site), only the member companies a supplier chooses to share the audit with and the PSCI admin can access the shared audit. **A share audit will NOT be viewed by any peer suppliers** unless the peer supplier is also a PSCI member AND the sharing supplier chooses to share the audit with the peer supplier in their capacity as a PSCI member. Any audit uploaded to the PSCI will go through a **rigorous redaction process** to remove confidential information.
- **Use of Audit results:** PSCI members hope to access shared audits in order to establish or continue a partnership. The audit results are NOT used as a pass/fail exercise but to identify areas for improvement at the supplier sites. The audit reports form the basis for understanding the sustainability side of your facilities which is integral to the responsible sourcing practices of a PSCI Member. Besides sharing an audit report, a supplier is also highly recommended to share updates of the corrective and preventive action plans of the respective audits (especially if the audit result was not very good, i.e., in case of many findings) to clearly demonstrate continuous improvement.
- **Key audit resources:** A comprehensive overview on the PSCI Program is provided by the [PSCI Audit Program Guidance](#). This document and a lot of helpful audit related documents can be found on the PSCI website under [“What we do – taking part in a PSCI Audit”](#)

To help you navigate the document:

Q1. Who is the PSCI? What is the PSCI Audit program? (p1-2)

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Q3. Who can access my audit and is my information secure? (p2-4)

Q4. How do members use the audit reports? Will I be ‘punished’ for a bad audit?

Q5. Can you take me through the PSCI audit steps? How to use the Audit platform

## Q1. Who is the PSCI? What is the PSCI Audit program?

The PSCI is a non-profit business membership organization, consisting of [57 member companies](#)<sup>1</sup> operating in the pharmaceutical or healthcare industries. The PSCI brings together member companies to define, establish, and promote responsible supply chain practices, human rights, environmental sustainability, and responsible business.

The PSCI member companies developed PSCI Audits to assess suppliers' performance in the areas of Ethics, Labor, Health & Safety, Environmental Protection and Management Systems. The questions asked in the audit questionnaire adhere to the PSCI Principles and reflect local regulatory requirements, international standards and agreements specific to the pharmaceutical and healthcare supply chain.

An overview on the PSCI Audit Program is also illustrated in the [PSCI Audit program Brochure](#). Further details are also described in the [PSCI Audit Program Guidance](#), which provides a detailed overview of the audit process and corresponding roles and responsibilities at each stage of the process.

**Any PSCI member company may request a PSCI audit to be conducted at your facility for pre-evaluation and periodically as part of the procurement / supplier evaluation process.** Once you agree to a PSCI audit, the audit will be arranged and carried out either by independent 3rd party audit firms or by qualified PSCI member internal auditors, in order to ensure the integrity of the audit process. After the audit, the member company that sponsored the audit (sponsor) will work with you to develop a plan to implement corrective actions if there are findings from the audit.

While the majority of PSCI audits are initiated by PSCI members, suppliers may also make their own requests, either by speaking to one of the [PSCI approved audit firms](#) and proactively arranging a self-paid PSCI audit, or by nominating themselves to the [PSCI Secretariat](#) (the PSCI Audit program may be able sponsor a small number of supplier self-initiated audits each year).

## Q2. Why should I share a PSCI audit conducted at my site?

If your audit is sponsored by a PSCI member company, the audit will be automatically shared with the sponsor company when it is uploaded to the PSCI platform, but NO ONE ELSE (other than the sponsor and the PSCI admin) can access your audit without obtaining your permission.

If you are supplying to multiple pharmaceutical companies, it will help **reduce your burden of receiving duplicate audit requests** if you grant access to the previously conducted PSCI audit to more PSCI member companies (you can choose to share the audit with specific member companies or All PSCI member companies on the platform). **Upon gaining access to your audit report, other PSCI member companies may choose to wave / postpone / reduce the scope of an audit previously planned for your site.**

According to our member survey where we ask whether / how a specific audit has been useful for to members: 44.5% of the responses are **“Yes, it has waived an audit”**; 33.3% responded **“Yes, it has postponed an audit”**; 22.2% **“Yes, for another reason”**.

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<sup>1</sup> as of 1<sup>st</sup> March 2022

In cases where you had an event with a negative impact on HSE (especially if they have appeared in media / screening alerts). Sharing your audit or corrective actions would be a **good opportunity to communicate that the event has been systematically investigated with root caused identified and addressed**. This would enable member companies to make informed evaluation instead of flagging risks only based on the negative event.

### Q3. Who can access my audit and is my information secure?

Suppliers have **full control** over who can access your audit. Your audit **will NOT be seen by any other member companies** than the sponsor company WITHOUT your permission.

*Any audits shared on the PSCI platform are meant to be viewed by PSCI members (pharmaceutical and healthcare companies), not the suppliers. Therefore, **your audit will NOT be seen by your peer suppliers** unless 1) the peer supplier is also a PSCI member and 2) you have chosen to share your audit with that supplier in their capacity as a PSCI member.*

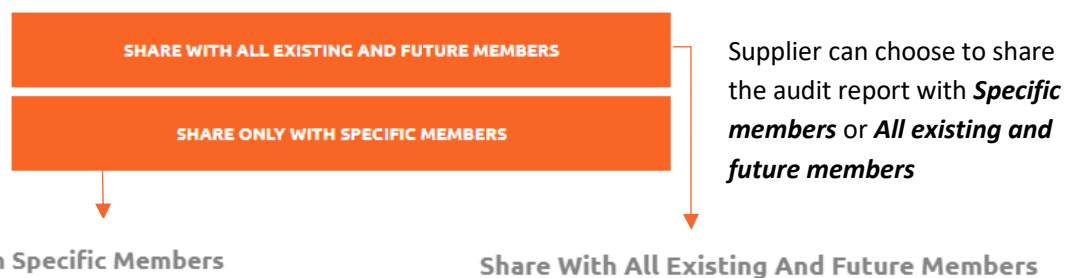
Below is how you will be able to administer the sharing of your audit report on the PSCI platform:

#### SHARING

This audit has automatically been shared with the sponsor, Pharma Co ✨.

You can share this audit with all existing and future PSCI members or you can select specific members. We **strongly recommend sharing with all existing and future members** as it adds the biggest value for all parties involved.

The PSCI will keep the linked SAQ, report, CAP, supplier correspondence, and other supplier facility records confidential. These will only be accessible by the member companies you have selected, and solely for the purpose of supplier evaluation in relation to the PSCI Principles.



You will need to add specific members to the sharing list for this audit in order to grant them permission to view it. By doing this, you are giving these member companies access to the linked SAQ, report, and CAP for this audit. **only** users from these companies and the PSCI admin staff will have access to the documents. The PSCI will keep the documents including the supplier correspondence, and other supplier facility records confidential.

By choosing this option, you are giving all existing and future PSCI members access to the linked SAQ, report, and CAP for this audit. **only** users from member companies and the PSCI admin staff will have access to the documents. The PSCI will keep the documents including the supplier correspondence, and other supplier facility records confidential.

Below is the member interface to show that without your permission to access, any member will only be able to see the *supplier name*, the *date*, *type* and *sharing status of the uploaded report*.

**AUDITS** [642] FILTER DOWNLOAD

Once you upload the audit to the PSCI platform, it will be saved in the PSCI Audit database together with other 600+ audit reports (as of Feb, 2022) 1 2 3 4 5 6 7 all

Audited	Supplier	Type	SAQ	Redacted	Shared		
6 Jan 2022	Supplier name A	PSCI Member Internal Audit Protocol		Pending	9 Feb 2022 Everyone	✕	
29 Dec 2021	Supplier name B	Full HSE, Labour & Ethics Remote		Pending	Not Shared	✕	
21 Dec 2021	Supplier name C	Full HSE, Labour & Ethics Remote		Pending	12 Jan 2022 Everyone	✕	
14 Dec 2021	Supplier name E	Full HSE		Pending	9 Feb 2022 Specific	✕	
14 Dec 2021	Supplier name F	Full HSE Remote				✕	
10 Dec 2021	Supplier name G	PSCI Member Internal Audit Protocol				✕	
10 Dec 2021	Supplier name H	PSCI Member Internal Audit Protocol				✕	
9 Dec 2021	Supplier name I	Full HSE Partially Remote		Pending	Not Shared	✕	
26 Nov 2021	Supplier name K	Full HSE Remote		5 Jan 2022	Not Shared	✕	

This means the audit is not accessible to the member and they can click on it to 'request sharing', you will then receive a sharing request.

Once you've received a sharing request from any PSCI member, you can choose to **approve** or **deny** the request

**REQUESTS** ?

Date	Organisation	User	
24 Apr 2020	Pharma inc *	Sally Black * ⚠	✓ ✕

**Approve Request** ✕

By approving this request, you are giving this member company access to the linked SAQ, report, and CAP for this audit. ONLY users from the member companies you select, and the PSCI admin staff, will have access to the documents. The PSCI will keep the documents including the supplier correspondence, and other supplier facility records confidential.

OK CANCEL

The member confirmation dialog below is to show you that even when a member has been granted access to an audit report, they need to agree to the PSCI requirements to use your audit only for the purpose of evaluating your site and not share your information with other companies.

13 Jun 2018



By viewing this audit, you are agreeing to the PSCI requirement that the linked SAQ, report, CAP, and other supplier correspondence/records will only be used for the purpose of evaluating the supplier site in relation to the PSCI Principles, and you will not share the information with other companies.

OK

CANCEL

The PSCI and its members are also bounded by the PSCI [Antitrust policy](#) in their activities around the PSCI including the use of shared audits and supplier information.

#### Q4. How do members use the audit reports? Will I be 'punished' for a bad audit?

PSCI member companies wish to access your audit **in order to work with you**. The audit results are **not seen as a pass or fail exercise**, but used by PSCI Members to understand the EHS risk level of your facilities and identify areas for improvement, which is integral to the responsible sourcing practices.

After findings have been identified in an audit, the auditor will work with you to agree on the specific corrective actions to be implemented. It is highly recommended to suppliers to provide a regular update on the status of your CAP on the PSCI Audit platform.

*"We highly appreciate it when our existing and potential suppliers share PSCI SAQ/Audit reports with us. Audit Information sharing should be done via the PSCI Audit Platform to ensure confidentiality for all involved parties. We will try to make use of this valuable information as far as possible, also to avoid multiple auditing in a short timeframe. We strongly encourage suppliers to allow sharing of PSCI Self assessments and audit reports with PSCI Members via the PSCI Audit Platform. This will ultimately lead to overall less audit burden, both from the suppliers and from the PSCI members perspective and enable all to allocate more resources towards correcting already identified deficiencies and thus contributing to continuous improvement in all areas of the PSCI Principles."*

**Dr. Birgit Skuballa**

Bayer AG, Head of HSE Audit & Supplier Management  
PSCI Audit Committee Co-Chair

**Note to suppliers: if you would like to share your experience with the PSCI audit program, for example, if you have benefited from sharing audits with member companies and working together on improving your practice, please share with us by emailing [info@PSCIinitiative.org](mailto:info@PSCIinitiative.org).**

### Q5. Can you take me through the PSCI audit steps? How to use the Audit platform?

An overview on the PSCI Audit process is illustrated in the [PSCI Audit program brochure](#), and covers the following steps:

#### *Initiate a PSCI audit*

As a supplier, you can either respond to the audit request made by any PSCI member company or initiate an audit yourself by making request to the PSCI approved audit firms or to the PSCI Secretariat (see Q1 for relevant links).

- If the audit is initiated by a PSCI member, the member will discuss with you about the audit date, whether it will be a remote / on-site / hybrid audit and whether the audit will be carried out by 3rd party audit firms or by qualified PSCI member internal auditors. Usually the sponsor company will cover the audit fees.
- In cases of supplier self-initiated audit, the supplier will have more flexibility and decide on the audit date, which audit firm to carry out the audit and whether the audit will be remote / on-site / hybrid. The supplier will pay for the audit. Please note that the PSCI may sponsor a small number of supplier self-initiated audits (please contact the PSCI Secretariat for more information)

#### *Pre-audit preparations*

The auditor will inform you on what to prepare for an audit and what to expect on the day. The supplier will be required to fill in the Self-Assessment Questionnaire (SAQ) before the audit.

**Depending on the type of your services, either the Full or Abbreviated PSCI SAQ / Audit template will apply<sup>2</sup>**

"A" suppliers are **service providers** with less complex operations and requirements, especially in health, safety and environment. The [Abbreviated PSCI Self-Assessment Questionnaire \(SAQ\) and Audit Report Template](#) is used for type A suppliers.

"B" suppliers are **component & material suppliers** and "C" suppliers are **core suppliers & contract manufacturers**. For B and C suppliers, the [Full PSCI SAQ / Audit template](#) should be used due to the complexity of their operations and requirements in all areas.

#### *During an audit*

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.

A PSCI audit usually consist of Opening meeting > Site tour > Interviews with management and employees > Review of documents and records > Pre-closing meeting > Closing meeting, including final wrap-up.

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

#### *Upload and share the audit through the PSCI*

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<sup>2</sup> For auditing purposes, suppliers are categorized into A/B/C suppliers



***You can either have your sponsor upload and share the audit FOR you, or upload and share the audit by yourself.***

- **If you choose to have your sponsor upload and share the audit FOR you:**

**Please communicate with you sponsor that you are willing to upload the audit to the PSCI platform ([The Link](#)<sup>3</sup>) and which PSCI member companies you would like to share the audit with.**

The sponsor will create a 'site' on the PSCI platform for your facility, upload the audit report to the 'site' and grant access to the member companies that you both agree to share the audit with.

**Please also ask your sponsor to add you as a 'site' user. That will effectively create a PSCI user account for you, and the login details will be automatically sent to the registered email address.**

You will then be able to use the login details to access The Link to administer your site (see instructions below from step 7 onwards) and audit sharing (see Q3 above for illustrations).

- **If you would like to upload and share the audit by yourself, here are the simple steps to follow:**

1) Register with the [PSCI Link](#) (cost free)

*Before starting the registration, please check with the relevant functions at your company whether they have already registered with the PSCI and can add you to any 'site' that has already been created. This will help avoid any duplication of efforts from your end in term of administering your audits and coordinating with PSCI members.* If in doubt, please contact the [PSCI Secretariat](#) to find out if your company/site has already been registered, and which of your colleagues have oversight and can set you up on the platform.

2) If you have confirmed that your company has not registered with the PSCI before. Please go to [Supplier Registration - PSCI \(pscinitiative.org\)](#) and proceed with the registration.

3) Fill in the 'Site details' including:

- a. Site name: (format: Company name\_XXX site) a company may have multiple sites at different locations. Please enter the specific site that's being audited.
- b. Company name: if the audited site is part of a larger company/group, this should be the group company name; if the audited site is not part of a larger group, then the company name may be the same as the site name.
- c. Country: this is the country where the audited site is located, not where the group is headquartered
- d. PSCI Member Referral: If a PSCI member company requested that you register, please select the company here

4) Fill in 'My details' including your **valid work email** address, password (please set a password of at least 8 characters), name.

5) Submit your application by clicking  (Register)

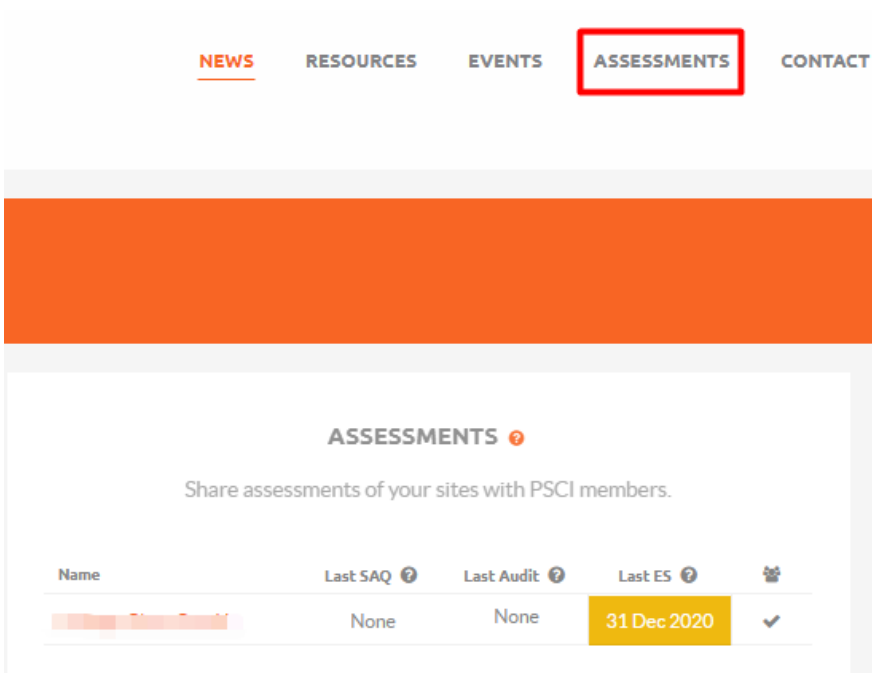
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<sup>3</sup> The Link is a platform for PSCI members and suppliers to interact and share resources, events and other information. On this platform, you will also be able to share audits, access the useful resources and webinars prepared by PSCI and its members, as well as to complete the environmental surveys as per member requests.

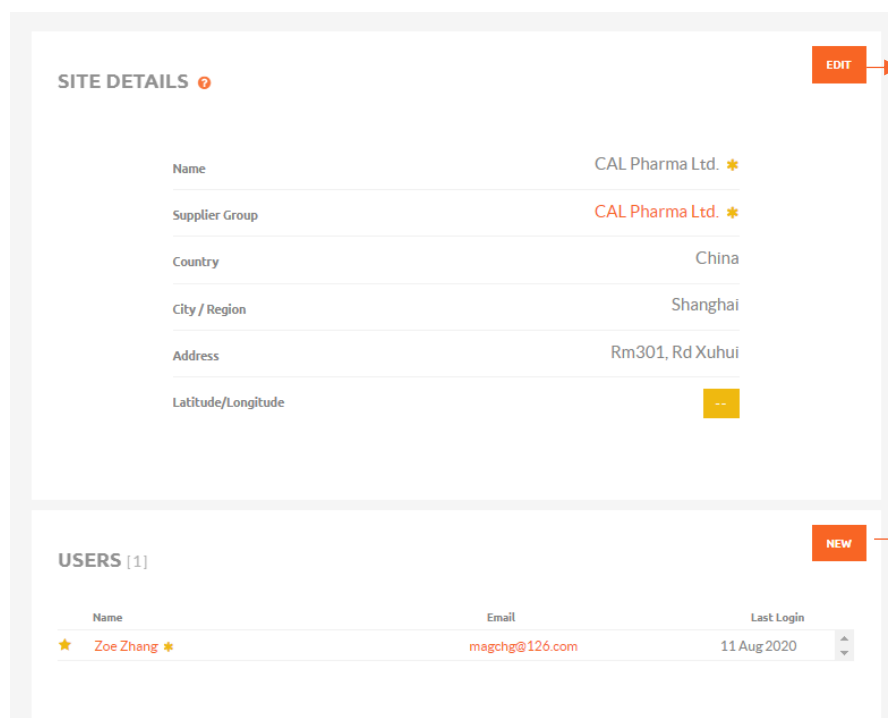
6) With your access to the Link created, head back to <https://pscinitiative.org/home> and use your email and password to log in.

You will have access to the audit platform immediately after registering, but will need to wait for your application being approved by the PSCI Secretariat before you can start interacting with PSCI members, or them with you).

7) To access the audit sharing module within the Link, click on the 'Assessments' on the top right



8) click into the site you would like to administer



Click '**Edit**' to edit your site details.

Click '**New**' to add users for your site.

*Please note that only Lead users at your site can add users for the site*



SAQs [1] Click 'New' to add new SAQs NEW

Date	Type	Audits	Redacted	Shared		
21 Jan 2022	Online Type		Pending	Not Shared	0	0

AUDITS [4] Click 'New' to add new audits NEW

Audited	Type	Company	SAQ	Redacted	Shared	
1 Jan 2021	Full HSE, Labour & Ethics	BSI Group		No Report	Not Shared	0
5 Feb 2020	Full HSE, Labour & Ethics <span style="background-color: #f4a460; font-size: small;">Partially Remote</span>	Intertek		29 Apr 2020	28 Sep 2021 Everyone	62
21 Nov 2019	Full HSE, Labour & Ethics	TÜV-Rheinland		24 Apr 2020	Not Shared	0
5 Nov 2019	Full HSE, Labour & Ethics	PSCI Member Company		Pending	Not Shared	0

9) Fill in the audit information:

**AUDIT**

The details and report for this audit will not be shared with any members until you complete a sharing agreement after submission.

Please check with your auditor / Sponsor regarding the Type, Template Scope of the audit if you are unsure.

**Sponsor** ? This is member company that sponsored (= paid or resourced) your audit

**Date Audited** Choose the date when the audit is conducted (choose the first day in case of multiple days)

**Type** PSCI

**SAQ** ? Choose whether the SAQ of the audit has been uploaded

**Template** Choose...

**Scope** You will be able to find the scope of the audit in the first page of your audit report. If in doubt, please check with the auditor / sponsor.

**Audit Company** Choose...

**Identification No.**

**Remote** ? Choose...

**Audit Report** ? 📄 AUDIT REPORT... Upload the audit here  
Files must be no more than 30MB.

**Corrective Action Plan (CAP)** ? 📄 CORRECTIVE ACTION PLAN (CAP)... If there is a separate CAPR document (not mandatory), upload here  
Files must be no more than 30MB.

SUBMIT TO PSCI

Before submitting the audit to the PSCI, you need to work with the auditor to make sure that:

- The uploaded document is clear to read. For PDF documents, please check whether the cells are properly displayed, especially if it's converted from an excel document;
- **Proper redaction has been performed.** The auditors are required by the PSCI to remove sensitive commercial/personal information such as proprietary product name, interviewee names. **Please also check the File > Info/Properties in the Excel or PDF documents and remove any sponsor company contact**
- The CAP section in the audit report has been completed including the **Completion timescale** and **Verification method** unless a separate CAP document containing such information has been uploaded.

Normally, it takes another two weeks for the PSCI Secretariat to check the uploaded documents before the audit becomes accessible to the members who have been granted access. But failing to meet the above requirements will delay the process.

If you have any questions, please email [info@PSCIinitiative.org](mailto:info@PSCIinitiative.org) for more information.