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PHARMACEUTICAL
SUPPLY CHAIN
INITIATIVE

Pharmaceutical Supply Chain Initiative

PSCI Audit Sharing Platform Supplier User Guide

January 2016

About This Document

THE PSCI AUDIT SHARING PLATFORM USER GUIDE

This **PSCI Audit Sharing User Guide** explains how to use the Audit Sharing Platform for suppliers.

The platform underpins the PSCI Audit Sharing Program. It is the platform for sharing audits with the PSCI membership.

Please refer to the **PSCI Shared Audit Program Guidance** available on the PSCI website (http://pscinitiative.org/resources) for more information about the PSCI Audit Sharing Program.

DOCUMENT HISTORY

Version	Date	Status/Changes
1	2016	First version

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. Find out more on the PSCI website: http://pscinitiative.org/home

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Chapter 1: Introduction

The PSCI Audit Sharing Platform has been developed as the platform for sharing audits with the PSCI membership. The platform underpins the PSCI Audit Sharing Program. Please refer to the **PSCI Shared Audit Program Guidance** available on the PSCI website (http://pscinitiative.org/resources) for more information about the PSCI Audit Sharing Program and process.

PLATFORM OVERVIEW

This guide gives an introduction to the basic functions of the PSCI Audit Sharing Platform for suppliers.

It includes how to handle the following processes:

- How to upload an audit document
- How to upload supporting documents
- How to share an audit document
- How to record actions taken to address audit findings

REMINDER OF THE AUDIT SHARING PROCESS

SHARING AUDIT DOCUMENTS

Completed Self-Assessment Questionnaires (SAQs), Audit Reports and Correct Action Plan Reports (CAPRs) can be uploaded to the system and shared with PSCI members. The audit should be uploaded by the party who paid for the audit ("audit sponsor"), or with their permission.

More detail on how to share an audit can be found in **Chapter 3.**

REDACTION

The audit sponsor must ensure that all audit related documents are redacted before upload. For details on how to carry out a proper redaction, please refer to the PSCI Audit Guidance. A redaction check is built into the system. When a document is uploaded an alert is sent to the PSCI. The PSCI downloads the document, checks the redaction, and then uploads the approved document. Any PSCI member linked to the supplier is then able to view the document.

RECORDING THE MAIN FINDINGS

As part of the approval process the PSCI will capture the main findings of the audit and put them into the system against the supplier. Suppliers can then log in and update the status of their corrective actions and provide the required evidence (e.g. descriptions, documents, pictures).
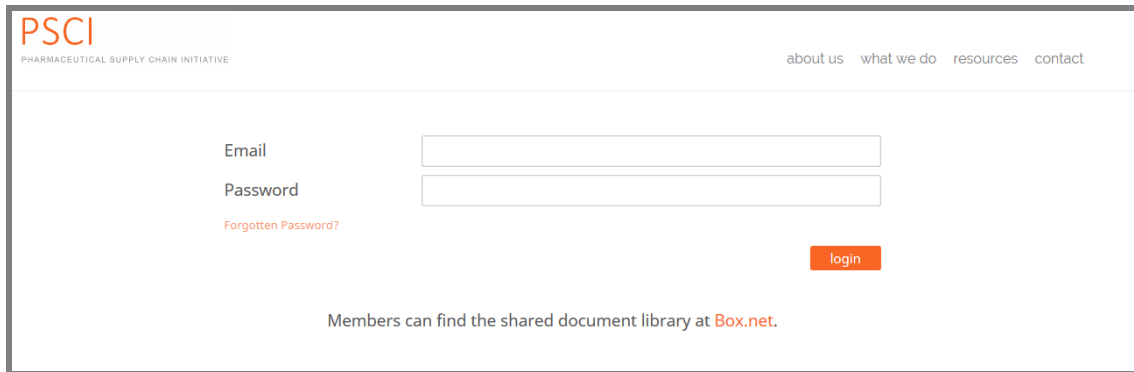
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Chapter 2: How to log-in

Open a browser and type the URL link into the address field and click the Enter key. The URL link is:

http://pscinitiative.org/login

Add the URL to your 'Favourites' for ease of access later.

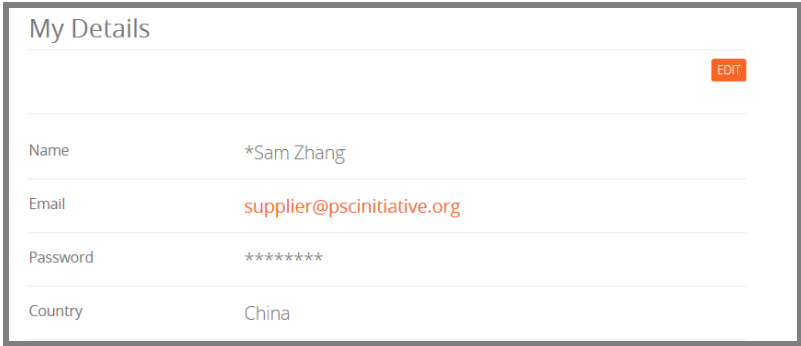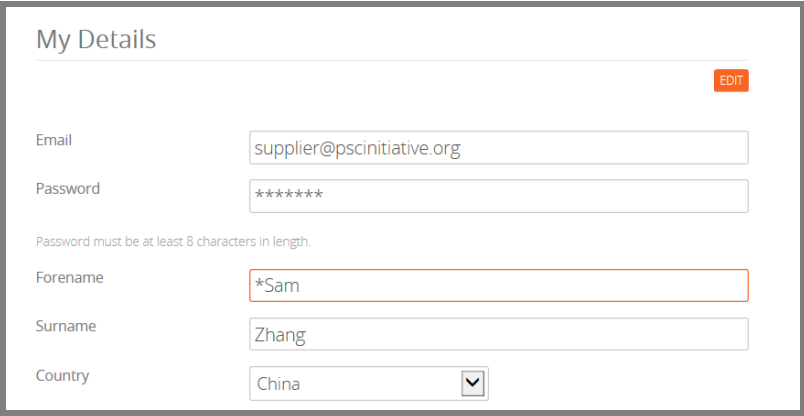Once you have entered the URL successfully the login screen appears.

Step	Action
1	Enter your email address into the **Email** field
2	Enter your password into the **Password** field
3	Click the **Login** button

If you do not have login details, contact the secretariat: info@pscinitiative.org

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Chapter 3: How to operate the system

CHANGE YOUR USER DETAILS

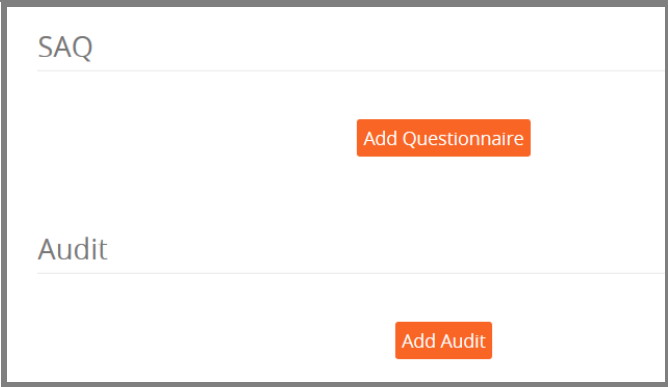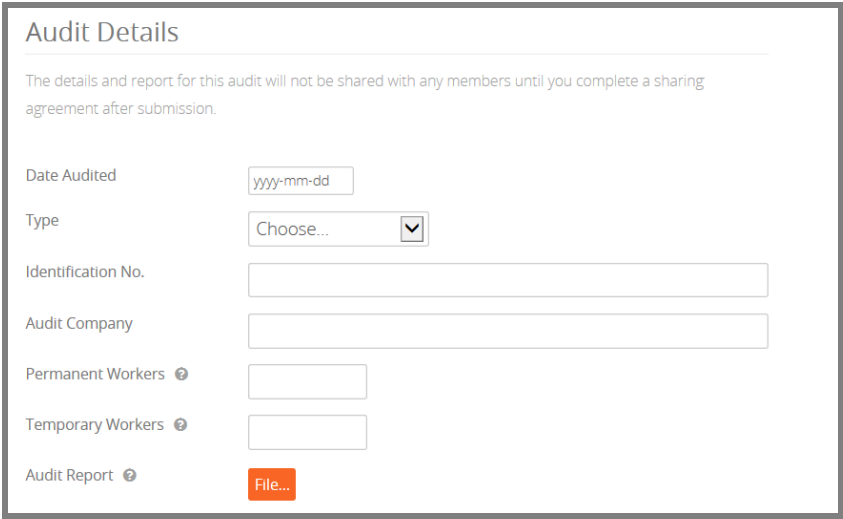When you log in (see Chapter 2), you will be on the **My Details** page. To edit your details:

Step	Action
1	Click on the orange **Edit** button. You will be presented with user detail fields.

My Details

EDIT

Name   *Sam Zhang

Email   supplier@pscinitiative.org

Password   ********

Country   China

| 2 | Click into the field box that you wish to edit and edit as appropriate. |

My Details

EDIT

Email   supplier@pscinitiative.org

Password   *******

Password must be at least 8 characters in length.

Forename   *Sam

Surname   Zhang

Country   China

| 3 | Click **Save**. |

UPLOAD AN AUDIT AND/OR SAQ
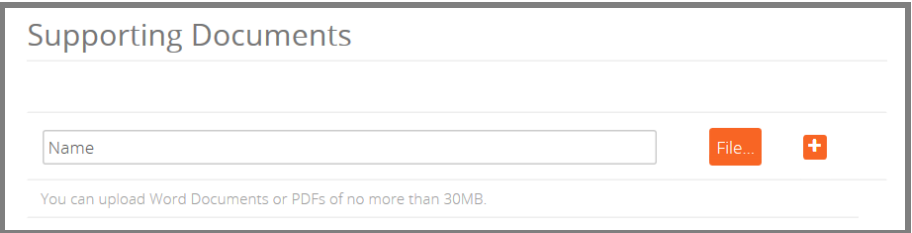
When a supplier is ready to share an audit document (SAQ and/or audit) they can do so by following this procedure:

Step	Action
1	Log on to the platform.
2	Scroll down to the **Suppliers** section and click on your site name. This will take you to the **Supplier Details** page

	Supplier Details EDIT Name *Finished Formulations Supplier Shenzhen Type Finished Formulations Pseudonym FFS China Supplier Group *FFS China Country China
3	Scroll down to the **Assessments** section. **Assessments** ❷ ADD Type Sponsor SAQ Audit PSCI *Pharma inc 1 Oct 2015 1 Sep 2015 HSE 🔍 PSCI *Pharma inc 16 Oct 2014 2 Jun 2014 Full Audit 🔍 PSCI *Pharma inc 16 Oct 2013 12 Oct 2013 Labour Rights 🔍
4	Click on the orange **Add** button to add an assessment. This will take you to the **Assessment Details** page. **Assessment Details** Type ❷ Choose... ▾ Sponsor Choose... ▾ Create
5	Choose the **Type** and click **Create**
6	If you want to add a Self-Assessment Questionnaire (SAQ), click on the orange **Add Questionnaire** button. If you want to add an audit, click on the orange **Add Audit** button.

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SAQ

Add Questionnaire

Audit

Add Audit

7	Complete the **Questionnaire/Audit Details** page, upload the file by clicking on the orange **File** button.

Audit Details

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

Date Audited	yyyy-mm-dd
Type	Choose...
Identification No.	
Audit Company	
Permanent Workers ?	
Temporary Workers ?	
Audit Report ?	File...

8	When you are ready to submit, click on **Submit to PSCI**

UPLOAD SUPPORTING DOCUMENTS

Step	Action
1	On the **Audit Details** page, scroll down to the **Supporting Documents**
2	Type the name of the document into the **Name** free text box and upload the document by clicking on the orange **File** button, then click on the orange **+** to add the document.

Supporting Documents

| Name | File... | + |

You can upload Word Documents or PDFs of no more than 30MB.

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SHARE AN AUDIT DOCUMENT

Step	Action
1	On the **Assessment Details** page, scroll down to the **Audit** section
2	Open the audit that you want to share by clicking on the orange magnifying glass.
3	On the **Audit Details** page, scroll down to the **Sharing** section, where you will see two options – to **share with all existing and future members of the PSCI** and alternatively to **share only with specific members**. Select your preferred option. If you chose to share only with specific members when you click on that option you will be taken back to the **Audit Details** page. Scroll down to the **Sharing** section and use the drop down list to add the member companies that you want to share the audit with. Select the member company name, and click on the orange **+** button to add that company.

PSCI members will only be able to view the documents that suppliers have shared with them.

ADD RESPONSE TO AN AUDIT FINDING

Suppliers are able to record progress on resolving audit findings.

If a CAPR report is uploaded the audit, the PSCI will record the CAPR findings on the audit details page.

Step	Action
1	On the **Audit Details** page, scroll down to the CAPR section
2	Click on the orange speech bubble button to record a written response against an individual action. There is also the option to upload supporting evidence. Click on the orange **File** button to upload a file. Then click on the orange **+** button to complete the response. CAPR Area — Risk Status — Follow Up — Timescale Health & Safety Compliance & Risk Management - Worker Protection — -- — Desk Based — 1 Jan 2016 File... — +

Audit documents

Audit Program Guidance (http://pscinitiative.org/resource?resource=3)

PSCI Audit Report and Self-Assessment Questionnaire (SAQ)

- SAQ and Audit Report Template: API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers (http://pscinitiative.org/resource?resource=32)

- SAQ and Audit Report Template: Service Providers and Suppliers of Non-Supply Chain Goods (http://pscinitiative.org/resource?resource=31)

Data Sharing Agreement (DSA) (http://pscinitiative.org/resource?resource=283)

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Chapter 4: Glossary of system terminology

Assessments	Each PSCI Assessment consists of a completed SAQ and an Audit.
Assessment Details	The **Assessment Details** section shows the sponsor and type of the assessment
Audit Details	The **Audit Details** page shows the details of the audit including auditing company, sponsor, and date.
Audit Status	On the **Supplier Details** page, **Audit Status** section, the colours in the **Last Audit** column represent how recently the audits have taken place:

- Green (Current) - an audit of this type has been conducted within the past 12 months.

- Yellow (Due) - an audit of this type has not been conducted within the past 12 months.

- None (Historic) - the last audit of this type took place more than 24 months ago (or has never been conducted).Questions related to the PSCI Audit Sharing Platform should be directed to the PSCI Secretariat at the following email address: info@PSCInitiative.org

CAPR	CAPR stands for Corrective Action Plan Report and is the report issued by the auditing company which records findings and suggests actions and timescales for completion.
SAQ	SAQ stands for Self-Assessment Questionnaire. PSCI member companies ask suppliers to complete an SAQ to give them more information on the supplier and their management practices.
Update History	The **Update History** section shows when the Audit or SAQ was created in the system, and whether it is pending redaction or redacted.

Chapter 5: Contact Details

Questions related to the PSCI Audit Sharing Platform should be directed to the PSCI Secretariat at the following email address: info@PSCInitiative.org**.**

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