

Pharmaceutical Supply Chain Initiative

PSCI Audit Sharing Platform Member User Guide

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About This Document

THE PSCI AUDIT SHARING PLATFORM USER GUIDE

This **PSCI Audit Sharing User Guide** explains how to use the Audit Sharing Platform <u>for</u> <u>members</u>.

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 (<u>http://pscinitiative.org/resources</u>) for more information about the PSCI Audit Sharing Program.

DOCUMENT HISTORY

Version	Date	Status/Changes
1	2016	First version
2	2017	Second version in compliance with the 2017 platform updates and training video

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 (<u>http://pscinitiative.org/resources</u>) 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 members.

It includes how to handle the following processes:

- How to upload an audit document
- How to share an audit document
- How to find and download an audit document
- How to view supplier progress in addressing 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. When the audit is uploaded, if the supplier has already linked to members then the audit will be automatically shared with those members. If that supplier has not yet registered then the system will send a message to the supplier asking them to register, and begin the process of linking to members. The system includes an inbuilt Data Sharing Agreement.

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 <u>PSCI Audit Guidance</u>. 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).



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.

PHARMACEUTICAL SUPPLY CHAIN INITIATIVE	about us	what we do resources	contact
Email Password Forgotten Password?	login		
Members ca	n find the shared document library at Box.net.	-	

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



Chapter 3: How to operate the system

CHANGE YOUR USER DETAILS

When you log in (see Chapter 2), you will be on the **Organisation Details** page. To edit your personal details, use the following procedure:

Step	Action					
1	-	ame in the Users section, half way down the page or on your t hand corner of the page. You will be taken to your My Details				
2	Click on the orange	Click on the orange Edit button. You will be presented with user detail fields.				
	My Details					
		то				
	Name	*Sally Black				
	Email	member@pscinitiative.org				
	Password	*****				
	Country	USA				
	Organisation	*Pharma inc				
3	Click into the field bo	ox that you wish to edit and edit as appropriate.				
	My Details					
		EDIT				
	Email	member@pscinitiative.org				
	Password	*****				
	Password must be at least 8	3 characters in length.				
	Forename	*Sally ×				
	Surname	Black				
4	Click Save.					



ADD A NEW SUPPLIER

Members are able to add a new supplier to the system, giving basic information including email contact details. The system then automatically sends an email to that contact asking them to register on the system. Use the following procedure:

Action				
		top of the page. This w	ill bring u	o a list of the
Click on the ora	nge New button. Yo	u will be on the Supplie	er Details	page.
Suppliers (2) 📀				
				FILTER DOWNLOAD NEW
Name *Finished Formulations	Supplier Shenzhen	Туре	Country	Last PSCI Audit 18 Jan 2016
*FFS China		Finished Formulations	China	Full Audit
*API Worldwide		API	Malaysia	NONE
Fill out the Supp	blier Details form.			
Supplier Detai	ls			
Name				
Other Names				
Service 🕝	Choose			
Supplier Group	Choose			
Country	Choose			
City / Region				
Address				
	Suppliers on the Click on the ora Suppliers (2) @ Name *Finished Formulations *FFS China *Malaysia API *API Worldwide Fill out the Supplier Supplier Detai Name Other Names Service @ Supplier Group Country City / Region	suppliers on the platform. Click on the orange New button. Yo Suppliers (2) Name *Finished Formulations Supplier Shenzhen *FFS China *Malaysia API *API Worldwide Fill out the Supplier Details form. Supplier Details Name Other Names Service @ Choose Supplier Group Choose Country Choose City / Region	suppliers on the platform. Click on the orange New button. You will be on the Supplier Suppliers (2) @ Name *Finished Formulations Supplier Shenzhen *Finished Formulations Supplier Shenzhen *Fis China *Malaysia API *API Fill out the Supplier Details form. Supplier Details Name Other Names Service @ Choose Supplier Group Choose City / Region	Click on the orange New button. You will be on the Supplier Details Suppliers (2) Name Type Country *Finished Formulations Supplier Shenzhen *Finished Formulations China *Alaysia API *Arit Wondowde Fill out the Supplier Details form. Supplier Details Name Other Names Service @ Choose Supplier Group Choose Country Choose City / Region

FIND A SUPPLIER

This feature is used to search by supplier name, service, country and your list of suppliers. Use the following procedure:

Step	Action
1	Click on the Suppliers tab. This will bring up a list of the suppliers on the platform.
2	Click on the orange Filter button.
3	Type in the name of the supplier you are looking for and/or search by service, country location and your suppliers.



		Filter Suppliers
	Name	
	Service	All
	Country	All
	My Suppliers	All Suppliers
		Reset View→
Click on	the orange View bu	itton to see the search results.

FIND AND DOWNLOAD AN AUDIT AND/OR SAQ

Step	Action		
1	Log on to the platform.		
2	Click on the Suppliers tab.		
3	Select the supplier from the Suppliers list and click on its name.		
4	On the Supplier Details page, scroll down to Assessments. Click on the type of the assessment that you want to view. This will take you to the Assessment Details page.		
5	Scroll down to the SAQ or Audit section. Click on the download icon for the document you want to download (SAQ or Audit). You will see a pop up box which alerts you to the fact that this audit is the property of the supplier and they have given your organisation permission to view it. You are asked to seek permission from the supplier if you want to share the audit with other parties, for example with your customers. Click Ok to confirm		
	Confirm		
	This audit is the property of the supplier. They have given your organisation permission to view it. Please get permission from the supplier if you want to share the audit with other parties, for example with your customers. Ok Cancel		



Audit Details	
Supplier	Finished Formulations Supplier Shenzhen 🔺
Date Audited	1 Sep 2015
Туре	PSCI HSE Audit
Identification No.	002
Audit Company	SGS
Audit Report	Download 📥

UPLOAD AN AUDIT AND/OR SAQ

For a PSCI member owned audit the PSCI member will either upload it themselves or ask the secretariat to upload the audit. To upload the audit document use the following procedure:

Step	Action			
1	Log on to the platform.			
2	Click on the Suppliers tab.			
3	Select the supplier from the Su	uppliers list. Alte	ernatively create a n	ew supplier.
4	On the Supplier Details page	, scroll down to a	Assessments.	
	Assessments o			
	Last upload on 19 Oct 2015.			ADD
	Туре	SAQ	Audit	
	PSCI	1 Oct 2015	✓ 1 Sep 2015 HSE Audit	× .
	PSCI	16 Oct 2014	× 2 Jun 2014 Full Audit	~
	PSCI	16 Oct 2013	12 Oct 2013 Labour Rights Audit	•
5	Click on the orange Add butto	n. This will take	you to the Assessn	nent Details page.
	Assessment Details			_
	Туре	100Se		
			Creat	e



6	Choose the Type and click Create
7	If you want to add a SAQ, click on the orange Add SAQ button. If you want to add an audit, click on the orange Add Audit button.
	SAQ Add SAQ
	Audit Add Audit
8	Complete the SAQ/Audit Details page, upload the file by clicking on the orange File button.
	Audit Details
	Date Audited yyyy-mm-dd
	Type Choose
	Identification No.
	Audit Company 🐵
	Audit Report @
	Files must be no more than 30MB.
	CAPR Ø
	Files must be no more than 30MB. Submit To PSCI
9	When you are ready to submit, click on Submit to PSCI

If the supplier has already linked to members then this will be automatically shared with those members. If that supplier has not yet registered then the system will send a message to the supplier asking them to register, and begin the process of linking to members.

VIEW THE CAPR AND SUPPLIER RESPONSE FOR AN AUDIT

Step	Action
1	Log on to the platform.
2	Click on the Suppliers tab.
3	Select the supplier from the Suppliers list and click on its name.



Scroll do	wn to the Auc	dit section.	Click on the d	ate of the a	udit.		
Aud	dit ø						
	Audited	Туре	Audit Company	Created	Redacted		
	16 Jan 2016	PSCI Full Audit	SGS 11	27 Jan 2016	27 Jan 2016	*	
the supp asked to parties, f	lier and they h	nave given sion from th	alerts you to th your organisat e supplier if yo stomers.	ion permiss	sion to viev	w it. You	are
			Confirm		×		
		They ha permiss permiss to share	lit is the property of ve given your orga ion to view it. Pleas ion from the supp the audit with oth with your custom	nisation se get lier if you want ner parties, for			
				Ok Ca	incel		
	ext page, Auc		scroll down to gested type of	follow-up a			
finding, t	he area, risk s	sponses ar	e displayed be	elow.			
finding, t Any writt	he area, risk s	sponses ar	e displayed be	90W.	Risk Status	Follow Up	Timescal
finding, t Any writt CAPR Area Health &	he area, risk s en supplier re	<u> </u>	e displayed be		Risk Status Other	Follow Up Audit	
finding, t Any writt CAPR Area Health & Detailed Health &	he area, risk s en supplier re	Management - Emerget	ncy Preparedness & Respon:				30 days
finding, t Any writt CAPR Area Health & Detailed Health & Detailed	he area, risk s een supplier re Safety Compliance & Risk M description of the Issue Safety Compliance & Risk M	Aanagement - Emerger Aanagement - Hazard I	ncy Preparedness & Respons		Other	Audit	Timescal 30 days 30 days 30 days
finding, t Any writt CAPR Area Health & Detailed Health & Detailed Health &	he area, risk s ten supplier re Safety Compliance & Risk M description of the Issue Safety Compliance & Risk M description of the Issue	Aanagement - Emerger Aanagement - Hazard I	ncy Preparedness & Respons		Other Other	Audit Desk Based	30 days 30 days



Audit documents

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

PSCI Audit Report and Self-Assessment Questionnaire (SAQ)

- <u>SAQ and Audit Report Template: API, Dosage Formulation, Chemicals and</u>
 <u>Intermediate Chemical Manufacturers</u> (http://pscinitiative.org/resource=32)
- <u>SAQ and Audit Report Template: Service Providers and Suppliers of Non-Supply Chain</u> <u>Goods</u> (http://pscinitiative.org/resource?resource=31)

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

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: <u>info@PSCInitiative.org</u> 				
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: <u>info@PSCInitiative.org</u>

