PSCI
PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

The PSCI Link 2.0 Platform will have a fully integrated online audit

Each section of the Audit is easy to complete, and the user can view progress through the report

The different stages of the audit can be completed by the necessary individual, e.g. Auditor/Supplier

From selecting the audit firm, to the supplier SAQ, to conducting the audit, to writing and finalising the CAPA

Auditors with approved audit firms now have a profile on the PSCI platform, to organize and complete audits

ALL PSCI AUDITS will be captured on the platform

A fully online audit approach
What this means for auditors

Attend the training session for the new online audit platform on Wednesday 18 February

10:00 – 11:30 CET

16:00 – 17:30 CET

How will members be planning their audits?

For 2026 audits, from Monday 2 March, the online audit in Link 2.0 is LIVE and is the **_only audit option_** (no excel file option).

Members will schedule audits later in the first quarter (after Switch-over) to utilize the online audit.

> The online audit | How it looks

Does this mean the new "online" audit will be remote?

No, documenting the audit will now be done online. The only change is the format of the audit report, and the audit process remains the same as before.

How do we initiate a PSCI audit on Link 2.0?

The audit initiation process is simple and easy to do. We recommend that you attend the trainings scheduled on 18 February to learn the process. *Recordings will be made available.*

What will the new audit process be?

The audit process itself is unchanged.

- Member sponsor initiates the audit and notifies the supplier (and third-party audit company if applicable).
- The supplier will complete the SAQ in the online form.
- The auditor performs the audit, verifying the supplier's answers.
- When the audit is complete, the onsite CAPA is prepared for the closing meeting, and the report undergoes technical verification.
- The report is approved by the Member sponsor and the supplier.
- The supplier may share this information with any other Member.

Will the onsite CAPA also be generated online in 2026?

Yes, the onsite CAPA will be available in the platform.

Is there an offline audit report template if there are internet connection issues during the audit?

The PSCI platform will enable you to prepare the audit report when you have internet connection. If there is no internet connection during the audit, the report will need to be finalized after the audit has been completed onsite.

Is it mandatory to have a supplier profile with supplier ID prior to initiating an audit?

Yes, because the supplier will need to complete the SAQ section.

Who will be the responsible person to set up the supplier data?

The supplier or member sponsor will be responsible.