

Do you supply a PSCI  
Member?

And has the Member  
scheduled to have a PSCI  
audit of your site?

Then this information is for  
**YOU**

From Monday 16 February,  
the PSCI will have a fully  
integrated online audit

Note: PSCI audits will remain  
**SITE AUDITS**

Each section of the Audit is  
easy to complete

You will complete each  
section that requires your  
input: SAQ, onsite CAPA and  
closing actions in the final  
CAPA

You will still be able to  
decide how you share your  
audit information

A fully online audit approach

What this means for you

|                      |                      |             |                   |                        |                        |                       |                        |
|----------------------|----------------------|-------------|-------------------|------------------------|------------------------|-----------------------|------------------------|
| Abbott               | acino                | AstraZeneca | GRUNENTHAL        | CSK                    | Piramal Pharma Limited | Roche                 | SANDOZ                 |
| AUROBINDO            | BASF                 | BAYER       | Johnson & Johnson | Kenvue                 | Lilly                  | sanofi                | SARTORIUS              |
| Boehringer Ingelheim | Bristol Myers Squibb | Catalent    | Mallinckrodt      | MERCK                  | NOVARTIS               | teva                  | ucb                    |
| CONCENTRA            | Coloplast            | Elanco      | novo nordisk      | ORION                  | Pfizer                 | West                  | zoetis                 |
| abbvie               | ALKEM                | almirall    | Fagron            | FOSUN PHARMA           | Perrigo                | Sai                   | SHIONOGI               |
| AMGEN                | aragen               | aspen       | FRESENIUS KABI    | GILEAD                 | hameln                 | SK BioPharmaceuticals | sobi                   |
| BAUHAUS NORDGOLD     | Baxter               | BD          | Immedica          | IOI OLEOCHEMICAL       | karo                   | Sterling              | ten 23                 |
| Biogen               | charles river        | Chiesi      | SYOWA KIRIN       | MALLAX PHARMACEUTICALS | VERTEX                 | Vetquinol             | xellia PHARMACEUTICALS |
| Cipla                | CSL                  | moderna     | NORDIC            | ZENTIVA                |                        |                       |                        |
| Eisai                | ESTEVE               | BOLAN       | ONO PHARMA        | ORGANON                | ORIFARM                |                       |                        |

Attend the training session for the new online audit  
platform on **Friday 20 February**

10:00 – 11:30 CET

16:00 – 17:30 CET

The online audit | How it looks

The screenshot displays the PSCI online audit platform interface. At the top, there is a navigation bar with links: About us, What we do, Get involved, News, Events, Tools, and a search icon. Below the navigation bar, the breadcrumb trail shows: Home > Browse > Latest > General Pharma > Audit 1252.

The main content area is titled "Audit #1252" with a status of "In progress". It is divided into two main sections:

- Audit metadata:** This section contains fields for ID (1252), Date (01/01/2021), Type (Full HSE, Labour & Ethics), Sponsor (AstraZeneca), and Audit company (TDV Rheinland).
- Audit sharing:** This section includes a "Share" button and text indicating that the audit has been automatically shared with its sponsor, AstraZeneca, and has not been shared with any supplier partners.

Below these sections is a list of audit sections with progress bars and status indicators:

- 1 Overview & guidance:** 70% complete, In progress.
- 2 Facility background information:** 25% complete, In progress.
- 3 Governance & management systems:** 100% complete, Completed.
- 4 Ethics:** 0% complete, Not started.
- 5 Human rights:** 0% complete, Not started.
- 6 Environment:** 25% complete, In progress.
- 7 Health & safety:** 0% complete, Not started.
- 8 Company specific questions:** 25% complete, In progress.
- 9 Photos:** 50% complete, In progress.

### When will the new audit platform launch?

The new online audit will be available from Monday 2 March 2026.

### 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.

### What will the new audit process be?

The audit process itself is unchanged.

- Member sponsor initiates the audit and notifies you as the supplier that they require an audit of your site.
- You will be directed to complete the SAQ in the online form.
- When complete, the auditor will perform the audit, verifying your 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 you, as the supplier.
- You may choose to share this information with any other Member, to help reduce the audit burden on your site.

### 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?

No, the SAQ and audit are now fully online.

### Is it mandatory to have a profile for my company and sites prior to being audited?

Yes, because you will need to complete the SAQ section in the audit. A profile with the PSCI is completely free to use, and provides many benefits to you:

- Share data – share SAQ and audit reports with PSCI member companies
- Attend events – the PSCI hosts webinars, conferences, and workshops. These are online or in person, and registered suppliers can attend for free.
- Take trainings and use expert tools – the PSCI has a range of interactive trainings and expert tools that you may use, for free, to support your journey on responsible business practices.