



# Pharmaceutical Supply Chain Initiative Audit Program

In the pharmaceutical and healthcare industry, the PSCI Principles for Responsible Supply Chain Management have become a widely recognized standard for defining industry expectations. These principles focus on five key areas: ethics, human rights, health & safety, environment, and governance & management systems. Demonstrating compliance with these principles can significantly enhance your company's reputation and position within the sector.

## 1. WHAT DOES PSCI STAND FOR?

The Pharmaceutical Supply Chain Initiative (PSCI) is a non-profit membership organization formed by a group of major pharmaceutical companies that share a vision of better social, economic, and environmental outcomes for all those involved in this industry.

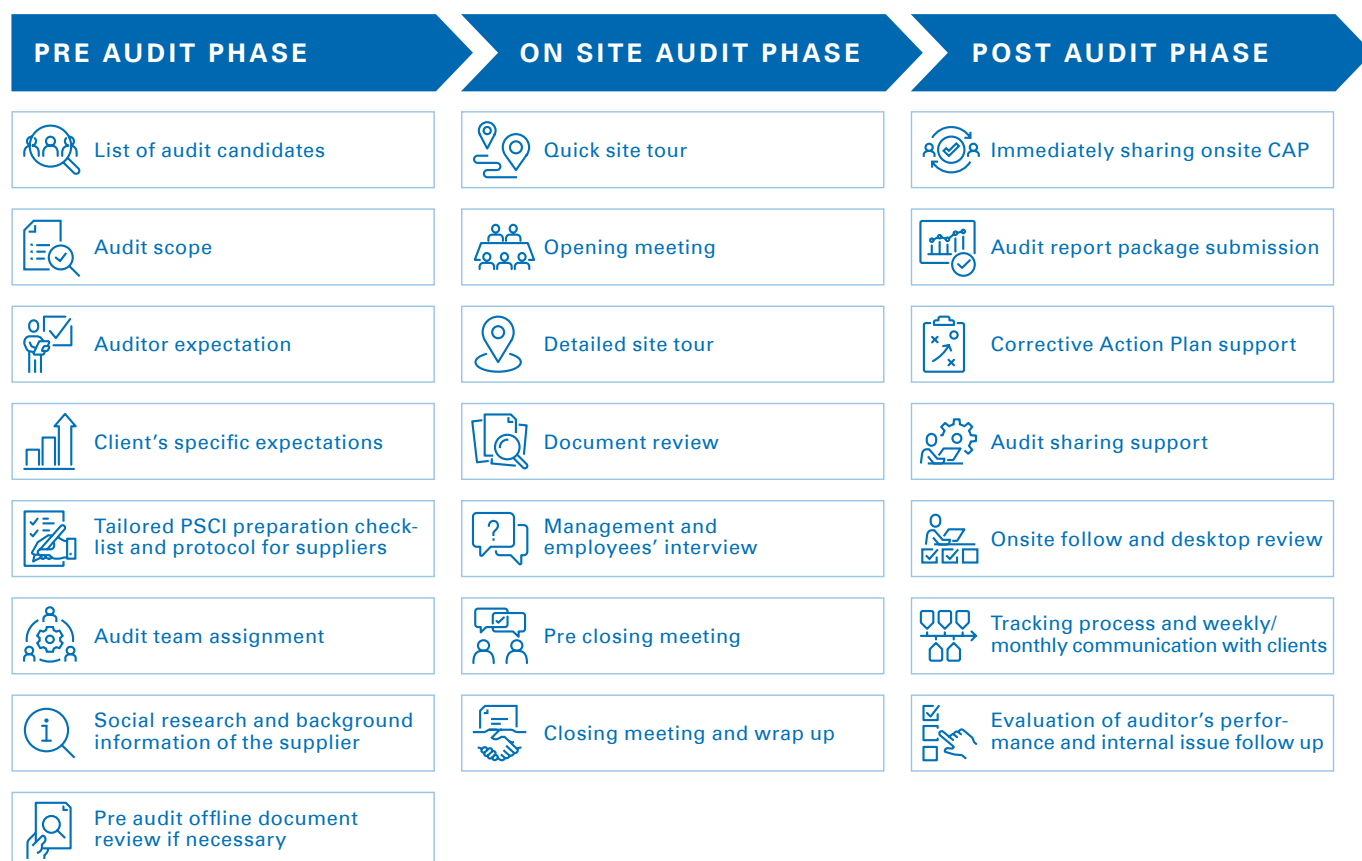
## 2. WHAT IS THE PSCI AUDIT PROGRAM?

The PSCI audit program is a unique opportunity for suppliers to demonstrate conformity with sustainability standards in the pharmaceutical and healthcare industry. The PSCI principles are an increasingly important criterion for the selection of suppliers. TÜV Rheinland is globally approved as an audit service provider of the PSCI, and so our audit reports are recognized by more than 80 large international pharmaceutical producers including PSCI full members and associate members.

## 3. WHAT ARE PSCI PRINCIPLES?

The PSCI audit program is designed to assess a supplier's performance against the PSCI principles as well as against international standards and agreements, and local regulatory requirements in the areas of ethics, human right, health and safety, environmental protection, and governance & management systems. The PSCI principles are consistent with industry expectations and applicable both in developed and developing countries for all suppliers in the pharmaceutical and healthcare supply chain.

#### 4. WHAT DOES A PSCI AUDIT INCLUDE?



Central project management and local scheduling are focused on under the initiative. The audit process consists of three phases: the pre-audit, the on-site audit and the post-audit. Audit status tracking for PSCI members is an essential part of a transparent and holistic reporting process. Periodically sent tracking-lists give clients a better overview and more efficient control of the audit process. Additionally, periodic status-calls ensure close and clear communication between client and global project management.

#### 5. WHO BENEFITS FROM THE PSCI AUDIT PROGRAM?

The PSCI audit program is especially important for three specific groups. Firstly, global supply chain audits carried out by experienced and qualified auditor teams can benefit pharmaceutical and healthcare producers and companies. Regular project communication and reports ensure maximum transparency on progress.

Secondly, pharmaceutical and healthcare suppliers that undergo an audit can demonstrate conformance with the PSCI principles. Audits give suppliers the opportunity to develop their expertise, identify and solve social, environmental and ethical issues, and thus meet industry expectations.

Thirdly, audits strengthen credibility, integrity and drive leadership practices at PSCI member companies by enabling continuous improvement throughout the supply chain. Member access to a supplier database and shared audits help reduce audit costs and efforts.

#### 6. HOW DOES A PSCI AUDIT BENEFIT CLIENTS?

Auditing facilitates decision-making regarding supplier acceptability. Companies can actively qualify as suppliers and distinguish themselves from competitors. Risks connected with the way on site operations can be identified and prioritized.

Furthermore, supplier companies are educated about requirements and regulatory expectations. As a result of auditing, trust with customers and business partners is built through access to information, transparency and accountability.

#### 7. CAN A SUPPLIER VOLUNTARILY REQUEST TO BE AUDITED ACCORDING TO THE PSCI AUDIT STANDARD?

Yes. As a PSCI approved third party audit company, suppliers can contact us to initiate an audit. We will submit a quotation, and subsequently plan and execute the audit and provide the final PSCI audit report and corrective action plan to the supplier. The audited company can share the PSCI Audit Report with all PSCI members by providing a signed Data Sharing Agreement.

It is also possible to contact any PSCI member company and ask them to sponsor an audit. Alternatively, a company may nominate themselves to the PSCI Secretary requesting that they be audited under the self-paid model. The PSCI Secretary will then inform them about PSCI Shared Audit processes and provide a list of PSCI approved third party audit companies.

#### 8. WHAT IS A SHE OR HSE AUDIT?

The label Safety, Health and Environment (SHE) is often interchangeably used for Health, Safety and Environmental (HSE) audits. SHE management systems and HSE audits aim to protect employees, the public, and the environment by complying with applicable laws and guidelines, which in turn build customer trust in the company. Such programs seek to prevent incidents resulting from abnormal operating conditions and reduce risk posed by normal operating conditions in industrial contexts.

#### 9. WHAT IS A CSR OR SOCIAL AUDIT?

Corporate social responsibility, or CSR is a form of corporate self-regulation integrated into a business model. CSR includes ethics, human rights, environmental, health and safety guidelines to advise companies on the best way and practices to treat stakeholders such as customers, employees or business partners. A CSR or social PSCI audit helps assess a company's performance on ethics and human rights objectives through scalable and measurable criteria.

#### 10. WHAT DO THE PSCI AUDIT, HSE AUDIT AND CSR AUDIT HAVE IN COMMON?

A PSCI full-scope audit typically covers both EHS (Environmental, Health, and Safety) and social aspects. During a PSCI audit, EHS auditors possess the necessary experience and qualifications relevant to the type of supplier being assessed. They are well-versed in key local and national HSE regulations, as well as international standards, such as ISO 14001 and ISO 45001.

Additionally, a PSCI audit involves an inspection by a Corporate Social Responsibility (CSR) auditor. The CSR auditor engages in detailed conversations with employees and focuses on ethics, labor conditions, and management system-related issues to verify sustainable development practices that go beyond basic compliance requirements.

While EHS auditors specifically concentrate on health, safety, and environmental standards established by the pharmaceutical and healthcare industry, PSCI also allows clients and suppliers the flexibility to initiate either an EHS or social audit based on actual needs.

Do you have additional question on our PSCI audit program?  
Our experts are here to assist you. Please contact us now!

ONLINE KONTAKT 