

PSCI

Pharmaceutical Supply Chain Initiative



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What is Pharmaceutical Supply Chain Initiative (PSCI)?

The Pharmaceutical Supply Chain Initiative (PSCI) is a non-profit business membership organisation that was founded in 2006 to address concerns such as supply chain issues, bonded labour, pollution, bribery, and corruption. Its mission is to build and support ethical practises in the pharmaceutical supply chain that will continuously enhance ethics, labour, health, safety, and environmental sustainability. Within the last five years, the PSCI has grown from 19 to 40 members.

The Pharmaceutical Supply Chain Initiative (PSCI) is a consortium of pharmaceutical and healthcare supply chain firms that share a goal of better social, economic, and environmental results for all people participating in the pharmaceutical supply chain. Improved working conditions, safer processes and facilities, economic development, and a cleaner environment for local people are all part of this.

The memberships are divided into two classes. There are two types of membership: "Full Membership," which is geared for corporations that want to actively participate and display leadership, and "Associate Membership," which allows companies to take a less active position. The latter is intended for businesses who are just getting started with responsible sourcing or do not have the time to fully participate. The members of PSCI agree with and support the vision, but more importantly, they are dedicated to continuous supply chain improvement.

What are the focus points of Pharmaceutical Supply Chain Initiative (PSCI)?

- Ethical business practices.
- Compliance to Human & Labour rights.
- Employees Health & Safety.
- Environment sustainability.
- Implemented Management Systems.

What are the document requirements for Pharmaceutical Supply Chain Initiative (PSCI)?

The organization must demonstrate the compliance to the requirements as per the principles of Pharmaceutical Supply Chain Initiative (PSCI), the compliance can be in form of documented information, which will be reviewed during the Audit.

The documented information required for Pharmaceutical Supply Chain Initiative (PSCI):

1. Organization Chart with roles & responsibilities.
2. HSE training records.
3. Emergency Response Plan.
4. Documented procedures related to environment matters.
5. Air permits.
6. Air monitoring data.
7. Wastewater discharge permits.
8. Wastewater discharge monitoring records.
9. WTP maintenance records.
10. Water quality analysis records.
11. Waste storage area inspection records.
12. Tank & containment inspection records.
13. Tank integrity & Fitness records.
14. Hazardous materials report.
15. Hazard communication training records.
16. Permit to work.
17. LOTO
18. Noise, chemical, or indoor air quality monitoring data.
19. Health and Safety training records.
20. Policy on Animal Testing.

Who all are eligible for Pharmaceutical Supply Chain Initiative (PSCI)?

- All the organizations which deals in manufacturing of the medical products or provide materials to pharmaceutical, medical device industries are eligible for the Pharmaceutical Supply Chain Initiative (PSCI).

How will Pharmaceutical Supply Chain Initiative (PSCI) Benefits your Organization?

- Reduce Multiple Audit Fatigue.
- No Duplication of Audits.
- Better use of resources used for multiple audits.
- Greater data visibility of supply chain.
- Improvement areas identified.
- More focus on continuous improvement due to fewer audits.
- One common guidelines facilitating improvement

How did Pharmaceutical Supply Chain Initiative (PSCI) evolve throughout the year?

- The Pharmaceutical Supply Chain Initiative (PSCI) was established in year 2006 as a non-profit business membership organization & is located in United states.

Who are considered as the stakeholders in pharmaceutical supply chain?

- A stakeholder could be defined as a group of individuals without whose provision the organization would cease to exist. There are multiple stakeholders in a pharmaceutical supply chain which includes raw material suppliers, manufacturers, distributors, regulatory authorities, pharmacies, hospitals, and patients.

What is a Pharmaceutical Supply Chain Initiative audit?

- In the areas of ethics, labour, health and safety, environmental protection, and management systems, the PSCI audit programme is meant to evaluate a supplier's performance against the PSCI principles, as well as international standards and agreements and local regulatory requirements.

What are the main objectives of PSCI?

Their three main objectives are to:

- Drive leadership practices at member companies
- Enable suppliers to continuously improve
- Improve engagement across the industry and with key stakeholders

What does a supply chain audit entail?

- Using more advanced data collection technology and software.
- Managing risk sources.
- Data is being double-checked.
- Data change records are kept and reviewed.
- Measuring the performance of vendors.

PQSmitra help you how have PSCI audit benefits?

- Auditing makes it easier to decide whether or not a provider is acceptable. Companies can actively qualify as suppliers and set themselves apart from the competition by doing so. Risks associated with how on-site activities are carried out can be identified and prioritized. Supplier companies are also trained on regulatory needs and expectations. As a result of the audit, customers and business partners have more faith in you.

What are the similarities between the PSCI and HSE audits?

- During a PSCI audit, an HSE auditor is present. He possesses the essential expertise and qualifications for the type of supplier being inspected, as well as a thorough understanding of critical local and national HSE legislation as well as worldwide standards (e.g. ISO 14001, OHSAS 18001). A PSCI audit also necessitates the presence of a Corporate Social Responsibility (CSR) auditor, who ensures long-term growth

How PQSmitra help you with a hassle – free Implementation Process for PSCI Audit?

PQSmitra Team helps organizations to implement the requirements of Pharmaceutical Supply Chain Initiative (PSCI) in the simplest and systematic manner. The methodology of system implementation covers Initial review, planning followed by implementation, and documentation. PQSmitra Team offers active support and hand-holding to organizations to achieve successful system implementation and positive audit results. 100% documentation support is offered to expedite the implementation process. The implementation process is described below:

- Initial visit and Review of the existing system with respect to List of documents needed for Audit & Self-assessment questionnaire (SAQ).
- Gap analysis and planning for compliance.
- Documentation including procedures, work instructions, etc.
- Updating of the Self-Assessment Questionnaire (SAQ) checklist.
- Inviting the 3rd party Auditor for Audit.
- Support for the closure of the CAP.
- Uploading of the Audit documents as per PSCI Data Sharing Agreement (DSA).



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