

# PSCI

Pharmaceutical Supply Chain Initiative

**VISION** Through the application of the PSCI Principles, better social, economic and environmental outcomes will result for all those involved in the pharmaceutical supply chain. As an industry, we will focus our efforts on positive social and environmental changes, and building supply chain capacity.

**OBJECTIVES** Shared industry expectations and objectives for responsible supply chain management

Use of common supplier assessment evaluation tools and audits

Listening and working with suppliers to improve supply chain management

**PSCI MEMBERS**

AstraZeneca	Johnson & Johnson
Bayer	Merck & Co.
Biogen Idec	Novartis
Bristol-Myers Squibb	Novo Nordisk
Covidien	Pfizer
Eli Lilly	Roche
GlaxoSmithKline	Sanofi

## PSCI JOINT AUDIT

Deliver shared industry expectations and high quality standards through the application of PSCI Principles

Utilize PSCI Audits in order to:

Reduce individual company audits.

Enable better utilization of limited company resources.

Drive improvements through industry collaboration on expectations.

Benefit suppliers due to fewer audits, allowing more time to focus on improvements.

Identify and prioritize areas for further pharmaceutical supply chain improvement

### 3 STEPS:

PRE-AUDIT

ON-SITE AUDIT

POST AUDIT

### PSCI PRINCIPLES

## ETHICS, LABOR, HEALTH & SAFETY, ENVIRONMENT, MANAGEMENT SYSTEMS

Business integrity & fair competition  
Worker concerns  
Privacy

Young workers / Child labor  
Non-discrimination, fair treatment  
Wages, benefits & working out

Worker protection  
Process safety  
Emergency preparedness & response

Environmental authorizations  
Waste & Emissions  
Spills & Releases

Commitment & Accountability  
Risk management  
Continual Improvement

## PSCI JOINT AUDIT PROCESS

### PRE-AUDIT

- MEMBER** checks with Secretary (via on-line tools) to see if PSCI audit report already exists, and whether report can be shared with Member
  - YES** Secretary releases audit report to Member
  - NO** Go to 2.
- SECRETARY\*** assesses whether other Members support launching new PSCI audit for this supplier
  - YES** Go to 3.
  - NO** PSCI member can initiate self-funded PSCI audit and share this
- MEMBER** who has been designated 'communications sponsor' for selected supplier initiates contact with supplier to explain PSCI concept and recruit them for the joint audit program
- SECRETARY** emails supplier with formal background to the PSCI audit program (including PSCI Principles and benefits), and includes Data Sharing Agreement (DSA) and Self Assessment Questionnaire (SAQ) for completion by Supplier
- SUPPLIER** returns completed DSA and Supplier Audit Questionnaire (SAQ) to Secretary within 30 days
- SECRETARY** reviews completed DSA and applies Audit Launch Criteria (ALC) to determine whether to proceed with audit
  - YES** Go to 6.
  - NO** Secretary advises Member and Supplier that audit does not meet criteria to proceed
- SECRETARY** confirms with Member and Supplier that audit will proceed
- SECRETARY** contacts PSCI approved Auditor to confirm launch of PSCI audit, and to provide PSCI documents (PSCI Audit Guidance, Checklists, PSCI Audit Report)
- AUDITOR\*\*** contacts supplier to schedule audit
- SECRETARY** sends auditor key documents (PSCI Audit Guidance, Checklists, PSCI Audit Report, PSCI Corrective Action Plan Report).
- SECRETARY** provides completed SAQ and DSA to Auditor (no later than 2 weeks before audit)
- SECRETARY** verifies auditor/supplier confidentiality agreement and confirms date of audit

### ON-SITE AUDIT

- SUPPLIER** opens meeting with Auditor with short company presentation
- SUPPLIER** provides site tour for Auditor
- AUDITOR** conducts management interviews
- AUDITOR** conducts employee interviews
- AUDITOR** conducts document reviews
- AUDITOR** conducts a pre-closing meeting (includes Auditors only) to prepare presentation of findings (as summarized in Audit Report)
- AUDITOR** conducts closing meeting with Supplier to share findings from Audit Report, get sign-off from site management that findings were communicated and understood, and to open discussion of corrective actions and timelines

### POST AUDIT

- AUDITOR** returns the completed Audit Report to Secretary within 7 days
- SUPPLIER** and **AUDITOR** sign the Corrective Action Plan Report (CAPR) (Critical findings must immediately reported)
- SUPPLIER** returns the completed Corrective Action Plan Report (CAPR) to the Auditor within 30 days
- AUDITOR** delivers the final signed CAPR to Secretary
- SECRETARY** provides the Audit Report, CAPR and SAQ to Members in PDF form as permitted by the Data Sharing Agreement
- SUPPLIER** independently informs Secretary of any updates that should be reflected in the PSCI supplier database
- MEMBERS** exercise independent business judgment in deciding path forward for closing action items with supplier. Members should not report back to other Members or Secretary on follow-up discussions with the audited Supplier

### RESOURCES

Complete details on the PSCI Audit Program can be found at: [www.pharmaceuticalsupplychain.org/downloads/PSCI\\_Audit\\_Program\\_Guidance.pdf](http://www.pharmaceuticalsupplychain.org/downloads/PSCI_Audit_Program_Guidance.pdf)

PSCI  
<http://www.pharmaceuticalsupplychain.org/>

BSR (PSCI SECRETARY)  
<http://www.bsr.org/>

\*\* Facilitation and project management support is provided by PSCI Secretary, BSR (Business for Social Responsibility)

\*\* PSCI audits are conducted by qualified third-party auditors that are certified to recognized starts