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.
Blegen Idex       Novartis
Bristol-Myers Squibb  Novo Nordisk
Coviden          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 JOINT AUDIT PROCESS

PRE-AUDIT
1. MEMBER checks with Secretary (via online tools) to see if PSCI audit report already exists, and whether report can be shared with Member.
2. SECRETARY assesses whether other Members support launching new PSCI audit for this supplier
3. 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
4. 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
5. SUPPLIER returns completed DSA and Supplier Audit Questionnaire (SAQ) to Secretary within 30 days
6. SECRETARY reviews completed DSA and applies Audit Launch Criteria (ALC) to determine whether to proceed with audit
7. SECRETARY confirms with Member and Supplier that audit will proceed
8. SECRETARY contacts PSCI approved Auditor to confirm launch of PSCI audit, and to provide PSCI documents (PSCI Audit Guidance, Checklists, PSCI Audit Report)
9. AUDITOR contacts supplier to schedule audit
11. SECRETARY provides completed SAQ and DSA to Auditor (no later than 2 weeks before audit)
12. SECRETARY verifies auditor/supplier confidentiality agreement and confirms data of audit

ON-SITE AUDIT
1. SUPPLIER opens meeting with Auditor with short company presentation
2. SUPPLIER provides site tour for Auditor
3. AUDITOR conducts management interviews
4. AUDITOR conducts employee interviews
5. AUDITOR conducts document reviews
6. AUDITOR conducts a pre-closing meeting (includes Auditors only) to prepare presentation of findings (as summarized in Audit Report)
7. 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
1. AUDITOR returns the completed Audit Report to Secretary within 7 days
2. SUPPLIER and AUDITOR sign the Corrective Action Plan Report (CAPR) (Critical findings must immediately reported)
3. SUPPLIER returns the completed Corrective Action Plan Report (CAPR) to the Auditor within 30 days
4. AUDITOR delivers the final signed CAPR to Secretary
5. SECRETARY provides the Audit Report, CAPR and SAQ to Members in PDF form as permitted by the Data Sharing Agreement
6. SUPPLIER independently informs Secretary of any updates that should be reflected in the PSCI supplier database
7. 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:
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 standards