



Pharmaceutical Supply Chain Initiative (PSCI)

Industry landscape

Pharmaceutical companies are embracing the challenge of sustainability and responsible business, with heavy focus on how the industry can better engage, monitor, and improve their suppliers and contract manufacturers. It's realized and understood across the industry that environment, safety, and social outcomes are critical and involve strong engagement and monitoring of compliance from the supply chain.

The changing landscape of near-shoring supply to tackle the personalized, rare disease, cell and gene therapy medicines presents the requirement to qualify and monitor a new set of suppliers, while embracing the trend of supporting the Low-Middle-Income-Countries with greater access to medicines, and therefore, supplying from and to markets further afield.

Finally, the investor community has identified supply chain management as one of the top 12 principles for ESG communications and reporting*.

Each of these market shifts show the need to have greater control and oversight of the topics of environment, safety, and social throughout the supply chain – where PSCI can serve as great evidence of such responsible business and supply chain practices.

At BSI, we strive to support the pharmaceutical industry in driving best practice and supplier improvements.

* Biopharma Investor ESG Communications Guidance 4.0.

Client journey examples

Contract manufacturing organization client:

- European-based pharmaceutical company joined the PSCI program and sought a partner for delivery of PSCI initial pilot audits.
- First time engaging in EHS audits on suppliers – so sensitivities around engaging suppliers.
- After three trial audits in year one, BSI scaled the program to audits delivered in seven countries – with a focus on India and China.
- Now carrying out corrective and preventative actions (CAPA) management for the audit delivery.
- Client satisfied with BSI audit delivery and new master service agreement (MSA) developed for scaling delivery globally.

Generics organization client:

- Global pharmaceutical company joined the PSCI program and sought out a partner for delivery of PSCI initial pilot audits.
- Client was a supplier to the pharmaceutical sector as well as the retail pharmacy sector – so the client needed to comply to both Sedex SMETA and PSCI program.
- BSI took an approach for our client to combine both programs into one overarching audit exercise for CSR/EHS supplier assessments, with two different output audit reports – one for each program.
- Through an agile, flexible approach – BSI was able to accomplish this need to satisfy multiple program compliance requests from our client's clients.

Innovator pharma client:

- Global pharmaceutical who has been managing an EHS and labour audit program, based on PSCI principles, on their manufacturing suppliers for a number of years.
- Client has faced auditor resourcing challenges for key suppliers in specific regions. Its primary need, therefore, was to tap into the resources, expertise and independence of BSI.
- When it came to programme delivery and management, the initial mobilization period was key to understand and create operating procedures and training based on the client's requirements and program specifics.
- A central team of PSCI experts was set up for auditor training, technical post-audit report review, etc.
- BSI also put in place an agreed service level agreement (SLA) on communication to the establishment of a robust auditor CV review and client approval process.



BSI approach to delivering PSCI

Audit excellence

BSI is one of the originally qualified PSCI audit firms, and support the development of the PSCI requirements and the audit approach with the program itself.

PSCI audits are 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, labour, health and safety, environmental protection and management systems. BSI engages in a robust, 5-step audit process when delivering the PSCI audit program to ensure a holistic and partnership approach, rather than a transactional audit exercise.

Service delivery approach and methodology

BSI quality review process embedded throughout the project timeline

1 Project mobilization

- Project kick-off meeting with client and BSI project/program manager
- Transition and strategy workshop(s)
- Client manual creation
- Selection of auditors:
 - Based on competency model
 - Technical ability
 - Experience in MS auditing
 - Specific knowledge of process
 - Geographic proximity and local regulatory knowledge
- Auditor orientation:
- Auditor code allocation
- Auditor briefing

2 Pre-audit activities

- Schedule audit with appropriate BSI and client stakeholders
- Plan audit approach (on site or remote) and confirm audit scope
- Contact supplier and engage for scheduling
- Pre-visit PSCI SAQ response review
- Prepare introductory and opening meeting materials
- Undertake on-site and / or remote audit risk assessment
- Pre-audit briefing call with supplier (+tech check if remote)

3 Audit activities (on-site or remote capabilities)

- Opening meeting
- Gather data per appropriate audit protocols (site survey, interview, records review)
- Evaluate data
- Engage with relevant supplier stakeholders
- Enter appropriate data into client or BSI system
- Closing meeting

4 Post-audit activities - technical report and corrective actions

- Draft audit report
- Technical report review
- Client feedback
- Address one round of questions and comments
- Develop final report (sharing the audit results where/ as relevant)
- BSI will oversee and monitor the closure of any findings raised in the audit
- Supplier must provide appropriate supporting documentation on the implementation of any corrective action

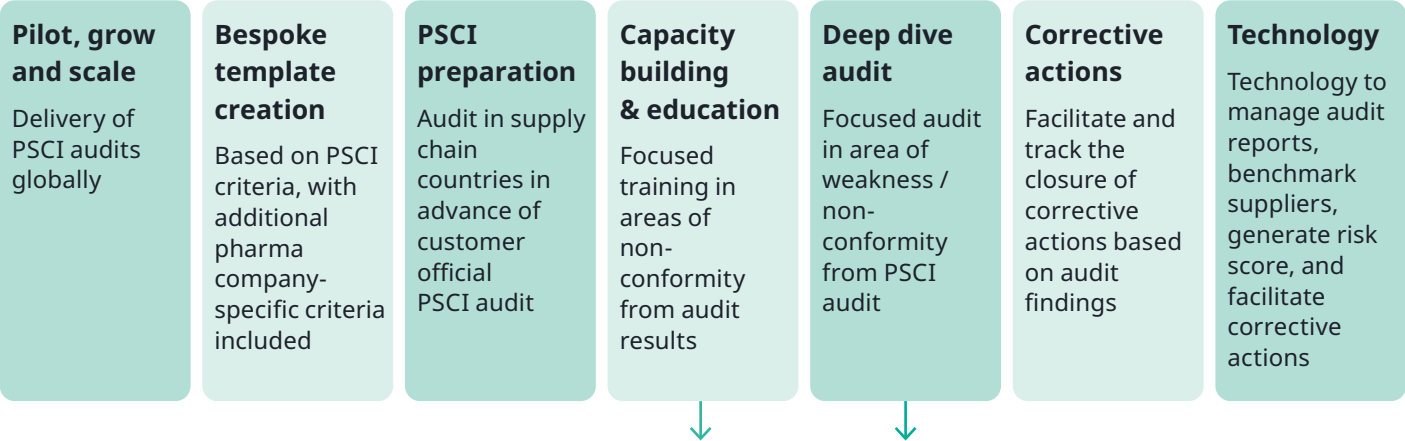
5 Monthly KPI review / improvement

- Between BSI project/program manager and client stakeholders
- Communication turn-around-time (TAT) – any bottlenecks
- Scheduling on time
- Report TAT
- Report accuracy/satisfaction

Positive impact through supplier engagement

Within the pharma industry, there's been a trend in the adoption of PSCI and its audit template, as the primary mechanism to assess and monitor environmental health and safety (EHS) and labour risks across their supplier base. Organizations are adopting the PSCI program in various guises and we're working with the industry to ensure the

adoption of the principles, while remaining agile and enabling a bespoke client-specific approach to deliver an EHS and labour audit on the supply chain. In addition to delivering the PSCI or client audit, BSI often engages in a more comprehensive delivery approach, to incorporate the offerings below:



Deep dive audit and education topics

Pharma industry priority focus areas

Sustainability	Labour / ethics	Environment, health and safety	Management systems	Training capabilities
- Sustainability basics - Client audit etiquette and preparations - Track utilities and energy use - Energy management - Greenhouse gas accounting and reporting - Carbon reduction forecast and management planning - How to conduct a life-cycle assessment (LCA) - Waste stream as a raw material – Reuse assessments	- Excessive working hours - Wages and benefits - Ethical recruitment of foreign migrant worker - Non-discrimination - Freedom of association - Antibribery / corruption - Data privacy / security - Conflicts of interest - Gender equality and inclusion	Occupational health: - Workplace safety - Incident investigation - Process safety assessment - Fire safety and emergency response - Industrial hygiene surveys Environmental management: - Air emissions - Storm and wastewater - Wastewater management – anti-microbial resistance - Hazardous material management: - Chemical labelling and inventory - Hazard communication - Waste disposal and oversight	- Business continuity - Legal and customer requirements - Training and competency - Communication practices - Governance programs	- Content development, languages, ADA, competency assessments, learning management systems - In person - Bootcamps - Train the trainer - Virtual - Computer based - VR



Why BSI?

1. Global team of experts and resources:

- 30+ years' experience of pharma health, safety and environment (HSE)
- Deep knowledge of labour / human rights in the supply chain
- Global reach with audits delivered in over 100 countries
- Long serving partner to pharma industry – over 50 years

2. Client-centric, responsive, professional program management and service design:

- Agreed service level agreements on communication; turn-around-time – 24/48 hours
- Auditor CV review and client approval process established
- Match program management structure to client program structure
- Central function set up of PSCI expert team for key program elements:
 - PSCI/client-specific auditor training
 - Auditor qualification, coding and approval
 - Technical post-audit report review

3. Flexible and agile to fit ways of working:

- Able to adopt client's report format or typical PSCI audit template
- Adaptive to client requirements of "management style" for engaging with suppliers

4. Scalable technology to support an efficient and effective program:

- BSI Connect integrated technology software for country intelligence and audit management
- Remote audit delivery technology, tried and tested since 2019 (pre-pandemic), can be deployed based on-site risk and pandemic situation

5. Deep dive in critical areas of PSCI audit requirements

6. Our heritage – trust and integrity at our core:

- Purpose-driven organization to work for the public good
- Not-for-profit distribution status – focus on profit for impact

7. Original author of OHSAS 18001 (now ISO 45001) and ISO 14001 standards:

- UK National Standards Body
- Founding member of International Standards Organization

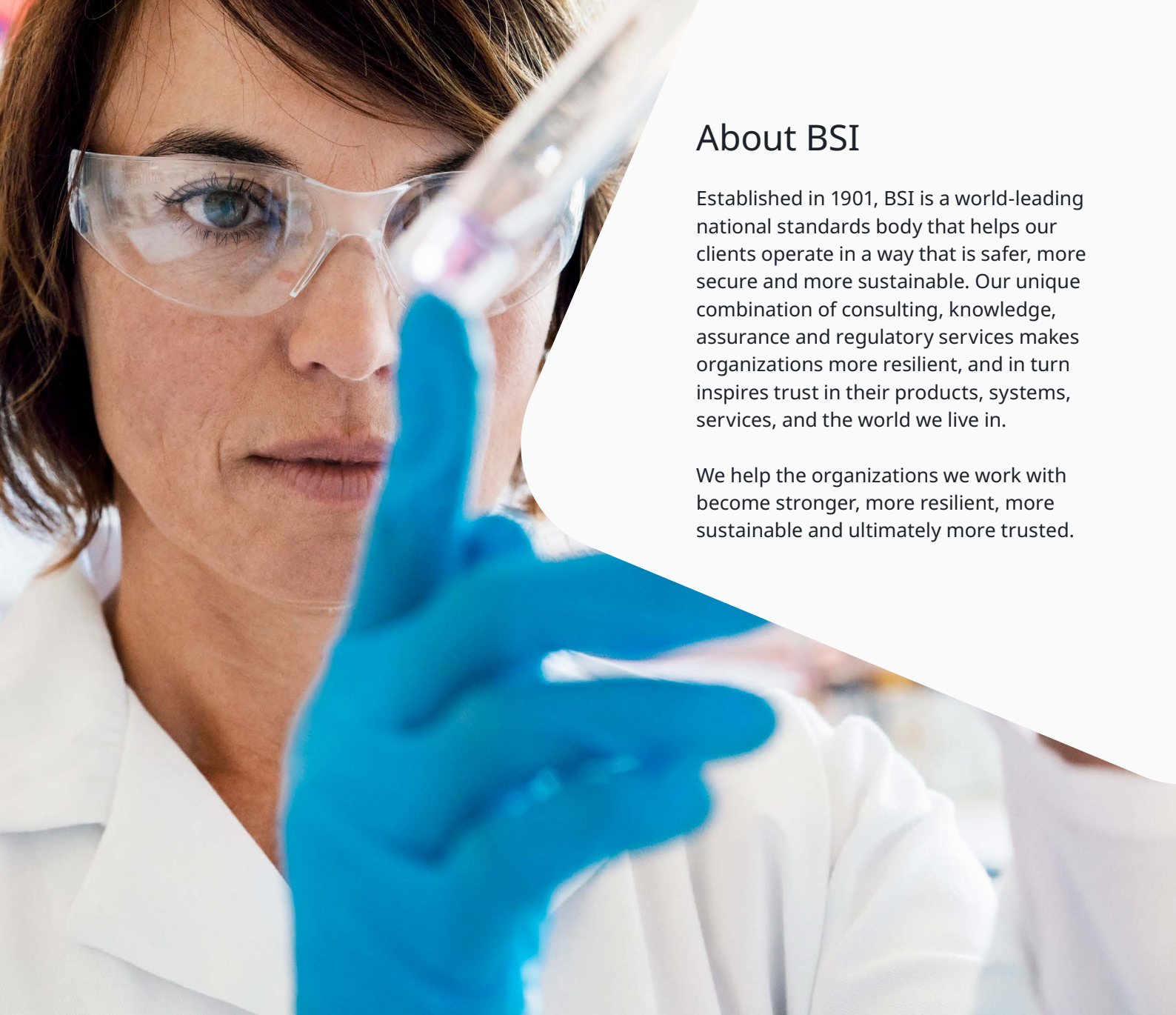
8. Board-level named priority sector – pharmaceutical and life sciences + BSI serves 90% of top 50 pharma companies:

- Investment in resources
- Co-innovation partnership

9. Expertise in pharma HSE management systems and labour/ethics risks:

- 400+ HSE consultant professionals
- 1300+ management systems auditors
- 200+ labour/ethics auditors





About BSI

Established in 1901, BSI is a world-leading national standards body that helps our clients operate in a way that is safer, more secure and more sustainable. Our unique combination of consulting, knowledge, assurance and regulatory services makes organizations more resilient, and in turn inspires trust in their products, systems, services, and the world we live in.

We help the organizations we work with become stronger, more resilient, more sustainable and ultimately more trusted.

For more information or to discuss your requirements, email: PSCI@bsigroup.com

