



2023
Annual Report



Contents

Chair's Welcome	03
2023 at a Glance	04
What We Stand for	05
The PSCI Principles	06
Our Members	07
Board & Governance	10
Strategy & Materiality	12
Our Modes of Impact	15
Audit	16
Capability Building	20
Projects	24
Financials	26
Collaborations & Partnerships	27
Vice Chair's Close	29
Contact	30

Vision

Our vision is for excellence in safety, environmental, and social outcomes across the global pharmaceutical and healthcare value chain.



Chair's Welcome

In 2013, 17 pharmaceutical and healthcare companies joined together to establish the PSCI.



Ingrid Vande Velde / 2023 PSCI Chair

DIRECTOR EH&S EXTERNAL SUPPLY & DELIVER, JOHNSON & JOHNSON

We had a vision of crystallizing our collective knowledge and influence to create a truly transparent, efficient, and sustainable supply chain. It has been 10 years since we incorporated as a non-profit organization in the US, and looking back over my tenure as Chair, I'm proud to say we've made tremendous advances towards that original vision.

Having formerly led the Capability Building workstream, it has been great to support their ongoing effort to support, capture and recognize the developments that suppliers are making in their practices. Complementing our successful, in-person Supplier Conferences in China and India, we launched our first Global Supplier Conference in 2023. It was delivered virtually and focused on engaging suppliers in the Europe and North America regions. Our webinar program was the most numerous and best attended it has ever been, reaching over 1,800 suppliers through 24 webinars; and we launched our brilliant online learning platform, Learnster, featuring interactive courses across the Principles topics. Collectively, these efforts resulted in over 2,800 interactions with suppliers across the world.

Foundational to these activities are our Principles. Members commit to upholding these in their supply chains, ensuring suppliers understand what is expected of them and providing a clear blueprint for responsible practices. The latest update of the Principles was completed in 2023, following consultation with members and external stakeholders to ensure they properly reflect the latest expectations on businesses. The Principles are now well supported by our Maturity Models, which map out the path to best practice across all the topics in the Principles, and link to courses and resources in our learning library.

I looked forward to announcing a new web platform this year, but this is taking longer than we hoped. Digitalization is going well within specific workstreams. Besides the launch of our Learnster platform, our supplier Self-Assessment Questionnaire (supportive to an audit) is now available in a user-

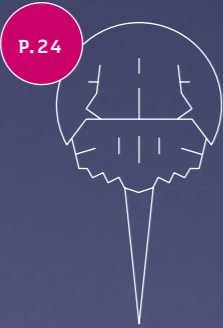
friendly, digital format which allows for both online and offline completion.

2023 was the final leg of a three-year strategic cycle, during which our focus included: strengthening our regional presence, delivering truly engaging training, partnering strategically, maintaining focus on our audit program, and improving our communications. I'm proud of the achievements we've made and was also glad to help develop our next strategic plan, which is outlined later in the report. I know Deirdre O'Reilly and the rest of the PSCI Board will do an excellent job in delivering these ambitions. Veel succes!



It has been 10 years since we incorporated as a non-profit organization in the US, and looking back over my tenure as Chair, I'm proud to say we've made tremendous advances towards that original vision.

Launched progressive position paper on horseshoe crab blood usage for the sector



Developed new Supplier Partnership pathway



Total Members

79 37 Full
42 Associate



Audit Data

Audits on the platform

983

Audits uploaded in 2023

186

Audits shared

132

Audits downloaded

70000+



Updated the PSCI Principles



2023

at a Glance

Launched new on-demand e-learning platform, Learnster

Learnster



24 webinars reached

1800+

attendees



900

attendees at three Supplier Conferences delivered in-person in China & India and virtually for a global audience



What We Stand for

The Pharmaceutical Supply Chain Initiative (PSCI) is the leading membership association for pharmaceutical and healthcare companies. Through our three modes of impact – Audit, Capability Building, and Projects – we work as one voice across the industry to build responsible value chains.

Vision

Our **vision** is for excellence in safety, environmental, and social outcomes across the global pharmaceutical and healthcare value chain.

Purpose

Our **purpose** is sector collaboration, using one voice to define, instil, and drive responsible value chain practices.

We achieve our vision and purpose through the **PSCI Principles for Responsible Supply Chain Management**. They are the blueprint for responsible practice in the pharmaceutical and healthcare industry, setting out members' expectations for five relevant topics. Members embed the Principles into their supplier codes, programs, and operations, seeking to drive good practices and support improvements over time.

The PSCI Principles

1. are foundational
2. set members' expectations of suppliers
2. form the base for all the PSCI's tools and materials
4. apply to all locations engaged in supply to PSCI members



The founding member companies initially came together to work on a project basis, resulting in the first PSCI Principles document in 2006.

10 Years of Impact

During our Spring Meeting in Paris, we enjoyed celebrating our 10th birthday: 2023 marked 10 years since the incorporation of the PSCI as a separate Not-For-Profit entity in June 2013. The founding member companies initially came together to work on a project basis, resulting in the first PSCI Principles document in 2006. By 2013 it had become clear that a collaborative approach to responsible supply chain management offered the best route to impact, and a dedicated group of leaders from the pharma companies made it happen, overseeing the process of incorporation and becoming the first PSCI Board.

We were very pleased to be joined at our birthday party by some of those individuals: Heinke von Seggern, Gary Wilson, Steve Meszaros, Katja Sbkowski, Dave Lapinski, and Birgit Skuballa (who still plays a key role in the PSCI today). It was their vision and commitment that laid the foundations for all that happens today, and we were pleased to reconnect and salute them.



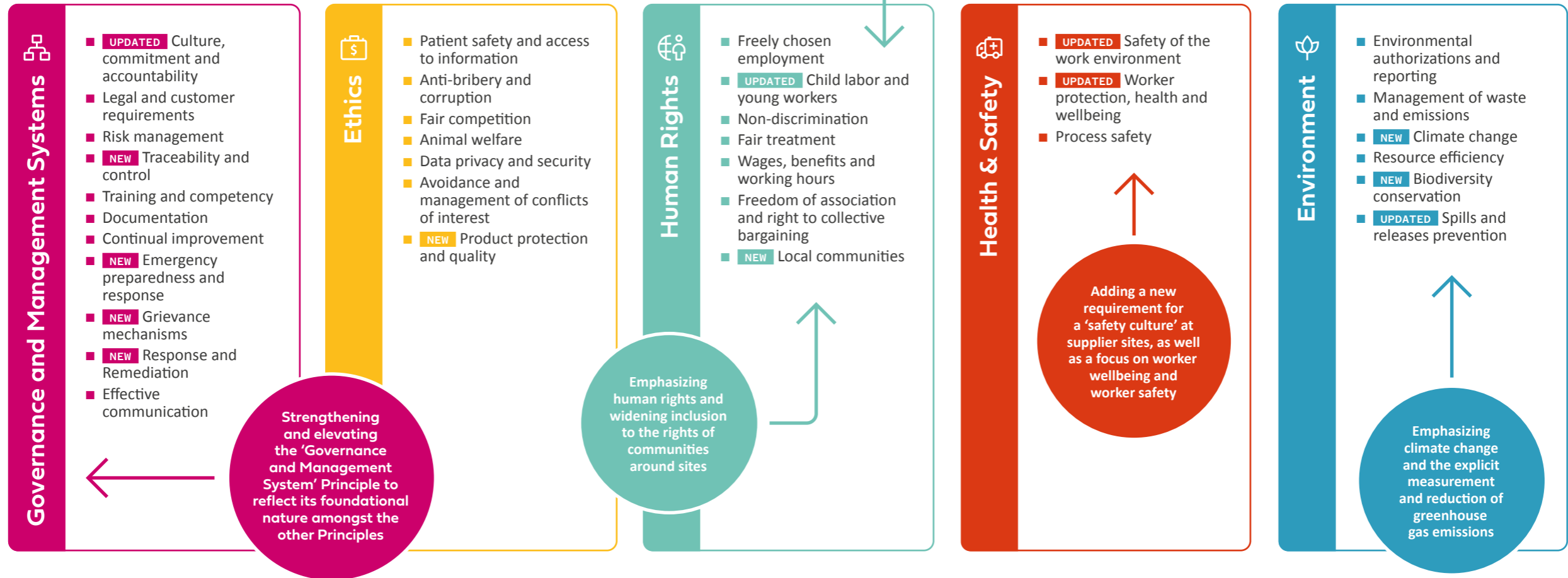
The PSCI Principles

Throughout 2022 and as part of our three-year cycle, the Principles were reviewed in consultation with members, suppliers, partners, advisory panellists, and external stakeholders to ensure they reflected up-to-date approaches and continue to drive responsible practices. Following this process, all members were invited to vote to approve the updated version of the Principles, which was formally

adopted at the PSCI Spring Meeting on 23 May 2023. Throughout 2024, PSCI members will reflect the changes in their policies, codes, processes, and practices. All PSCI member companies are expected to have integrated the revised PSCI Principles by November 2024, in line with their membership expectations. Updates and additions to the Principles are highlighted below.

Including the wider concepts of 'grievance' and 'remediation' in line with human rights soft law

In addition, the preamble of the Principles was updated to clarify the definition of scope and reference the PSCI's new topic-specific Maturity Models and learning plans for suppliers. A glossary of terms is also provided as an addendum to the Principles to provide further clarity and guidance.



Our Members

PSCI membership is open to companies in the pharmaceutical and healthcare industry that share our vision of excellence in safety, environmental, and social outcomes across the global pharmaceutical and healthcare value chain and meet at least one of the following requirements:

- Substantial revenues¹ from patented / proprietary medicines or medical devices
- Substantial revenues¹ from medical products sold direct to consumer under the company's brand
- Manufacture generic (off patent) medicines and medical products where these are substantially¹ sold direct to customers under the company's own marketing licenses
- Provide ingredients or components where these are substantially¹ patented or trade-marked by the supplying companies

We have two levels of membership, enabling companies at different stages of the sustainability journey to join the level that aligns with their position.

Full membership provides companies full participation in the PSCI through sharing audits, joining Committees and the Board, and attending member meetings.

Associate membership enables companies to develop their Audit programs with our tools and resources and learn from a community of peers. Associate membership is intended as a pathway to Full membership, moving towards more responsible supply chain practices and supporting implementation of a PSCI audit program. From January 2024, Associate members are required to progress to Full membership within three years.

¹ more than 50% of the company's sales



INTERVIEW

Thomas Wuester

HEAD OF COMPLIANCE, RISK & EHS SERVICES MANAGEMENT, CORPORATE EHS&S, BOEHRINGER INGELHEIM

Why are you a PSCI member?

At Boehringer Ingelheim we want to tackle the challenges of our time and make lives better – for humans and animals. Being part of a global community of companies focused on supply chain resilience in the PSCI helps us to achieve this. We know that we can create more impact together with partners. Speaking with one voice, supporting our suppliers to improve their practices, and aligning our own approach with the PSCI Principles provides credibility to our programs internally, and with our stakeholders up and down the value chain.

What value does it bring to you and your suppliers?

As pharmaceutical and healthcare companies, we have a unique relationship with our suppliers compared to other sectors. We are part of a highly regulated industry and as such want to develop long-term relationships with our suppliers. One of the PSCI's main virtues is enabling us at Boehringer Ingelheim to support these relationships through training, resources, and shared audit protocols; but more importantly, it enables us as a sector to speak with one voice to our suppliers towards a common set of frameworks and goals. Leveraging our reach as an industry to improve practices is tremendously powerful.

 **The PSCI's shared audit platform delivers significant value for us.**

What projects or tools are key for your company?

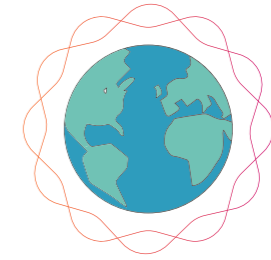
The PSCI's shared audit platform delivers significant value for us. We see it as a fruitful exchange between us and our suppliers, saving everyone time and money. We see this as part of developing supply chain resilience and reducing risk, in addition to improving practices. We also engage with the PSCI's work on Human Rights & Labor and Decarbonization. These areas are fast-moving due to new regulations such as the German Supply Chain Act and we value having a community of experts and peers to share updates and ideas with. Overall, this combination of tools sets us up for success to keep pace with incoming legislation and support our suppliers to become more resilient.

What are you excited about in our new strategy and projects?

I am excited to see that the PSCI's new strategy has a focus on impact. It's in our interest as an industry to build sustainability in from the start of what we do. Overall, we want to achieve sustainable and positive impact in the supply chain. With the PSCI focused on creating impact through projects, I believe we can increase our impact across the entire value chain. I am also looking forward to the launch of the new Supplier Partnership category. It will provide a clear engagement pathway for suppliers to share their views and gain recognition for their maturity and approach.

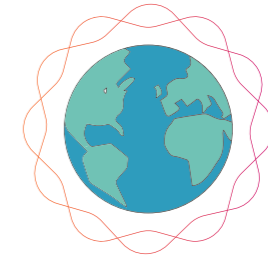


Our Members



Full members contribute to the development of the PSCI and achievement of our vision through leadership positions and audit sharing.

Our Members



37 Full Members



42 Associate Members

79 Members Worldwide in 2023

Associate membership is intended as a pathway to Full membership, enabling companies to develop their audit programs and learn from peers.

Board & Governance

We are led by an elected **Board of Directors** made up of representatives from our member companies that acts as our primary decision-making body. They ensure the delivery of the PSCI strategy, oversee our Committee-led workstreams, and represent the membership publicly. In 2023, the membership approved changes to the PSCI Bylaws on the terms of Board members. With effect from January 2024, the term of office for all Board positions will be three years, changing from two years' service for the Treasurer and Secretary track roles. This provides important continuity particularly in relation to the PSCI's finances, meaning that a new Treasurer will always have a chance to deliver on the specific budget they set.

The Board meets bi-annually with an **Advisory Panel** of external advisors and experts in areas relevant to the PSCI and pharmaceutical industry. Their role is to provide input on the PSCI's direction, vision, and act as an independent sounding board.

Our three areas of work are led by **Committees**. The Committees consists of members company representatives who work together to drive our Audit, Capability, and Projects workstreams.

Topic Teams infuse our programs and resources with expert, specialist knowledge on topics reflected in the PSCI Principles. They create content for our Maturity Model, webinars, and Supplier Conferences, and input to the review of our Audit Templates.

Regional Sub-Teams provide country-specific insight on the needs and interests of members and suppliers in regions of significant relevance to the PSCI, making our resources and programs more accessible and applicable to local contexts. In 2023, we had teams focused on China, India, and Latin America.

The Board would like to recognize and thank the leaders and members of the Advisory Panel, Committees, Topic Teams, and Regional Sub-Teams for their time and dedication to the PSCI.


The PSCI is supported by a professional **Secretariat** provided by ESG and Sustainability consultancy Carnstone Partners Ltd, part of SLR Consulting.

Board

Advisory Panel

Secretariat


2024-2023



Robert Williams
AstraZeneca

Vice-Chair


Vice Chair



Deirdre O'Reilly
Viartis

Vice-Chair


★ Chair



Ingrid Vande Velde
Johnson & Johnson


★ Chair

Past Chair



Victoria Stone-Bjarup
Novo Nordisk


Past Chair



Enric Bosch
Boehringer Ingelheim

Treasurer


Treasurer



Ranjana Ganguly
Pfizer

Treasurer-Designate


Treasurer



Aimee Pasquier
Novartis

Secretary

Secretary



Rincy Joseph
Bayer

Secretary-Designate

Secretary


↓

Committees


Audit Committee

Capability Committee


Operations Committee




Birgit Skuballa
Bayer




Roy Agostini
Mallinckrodt




Daniel Rehm
Elanco Animal Health




Sarah Turiano
Viartis



Rincy Joseph
Bayer



David McCarthy
Pfizer



Silke Oeschger-Delautre
Dr Reddy's

Members

Topic Teams

Management Systems



Aimee Pasquier
Novartis



Sean Jackson
Charles River Labs

Ethics



Anne-Christine Eisland
AstraZeneca

Process Safety



Vijaya Kumar Bendi
Johnson & Johnson

Safety



Germano D'Arasmo
Gilead

Industrial Hygiene



Vivian Rivera Turo
Lilly

Human Rights



Tanya Murphy
AstraZeneca

PIE & AMR



Samuel Maynard²
AstraZeneca



Jeff Brenchley³
Merck & Co.



Vince Parker⁴
Elanco

Environment



Andrea Fasano
Pfizer



Lynette Cartagena
AbbVie

Decarbonization



Bridget Ferarri
Takeda



Robert Williams⁵
AstraZeneca



Lucy Pickett⁶
Roche



Topic Teams infuse our programs and resources with expert, specialist knowledge on topics reflected in the PSCI Principles. They create content for our Maturity Model, webinars, and Supplier Conferences, and input to the review of our Audit Templates.

Advisory Panel



Hillary Amster⁷
The Copper Mark



Esther Tsang
The Body Shop



Sarah Steingruber
Independent Advisor



Magdalena Kettis
Nordea



Gerald Pachoud
Pluto Advisory



Sophie Ogilvy
Transparency Intl.



Kristine Mangan
Johnson & Johnson



Klaus Moosmayer⁸
Novartis

² until November
³ until November
⁴ from December
⁵ until November
⁶ re-joined December
⁷ stepped down November
⁸ stepped down October

Strategy & Materiality

2013 VISION, MISSION, AND FOCUS

The PSCI's first formal strategy was developed 10 years ago at our Annual General Meeting (AGM) in 2013. It identified a vision, mission, and focus areas, as well as a focus on how we should prioritize and achieve our goals.

Our second strategy in 2018 included further detail and established our first vision statement and a clear definition of our purpose.



2023 EFFECTIVE GOVERNANCE

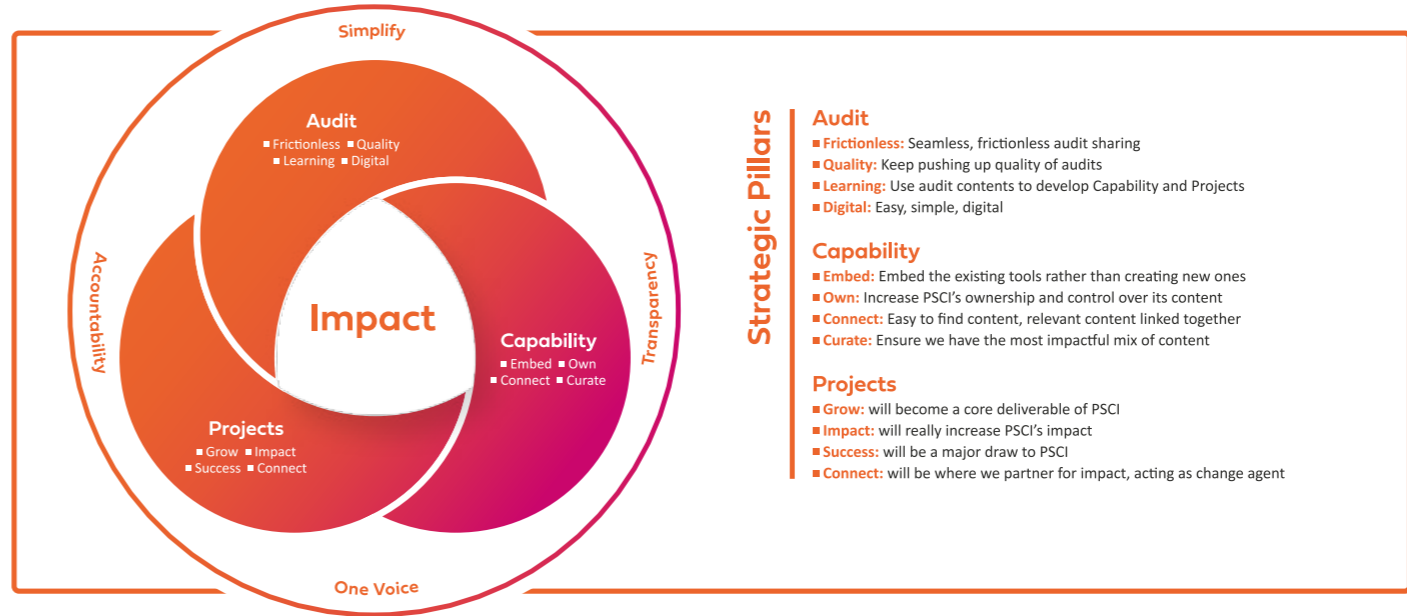
Our most recent strategy took us to the end of 2023 and focused on ensuring we had effective governance structures in place and produced compelling communications. This strategy also established six themes that were central to the delivery of our vision: leadership, audit, partnering, regional presence, effective training, and innovation. In each strategic cycle, our operational structure and key activities have evolved to support the delivery of our objectives, such as creating an Operations Committee, establishing an Advisory Panel, and launching a Global Supplier Conference. Each strategy allows the PSCI to innovate on our approach to deliver greater impact. And our 2024-2026 strategy is no exception.



2024 SIMPLIFIED FOCUS

Throughout 2023, members provided input to the creation of our new strategy, which included a materiality assessment, consultation session led by the Board at our Spring Meeting, and a member approval vote at our AGM. Our 2024-2026 strategy simplifies our focus to three strategic pillars—Audit, Capability, and Projects—and places impact at the heart of what we deliver. Our vision and purpose were also refreshed to reinforce our focus on excellence for the entirety of the value chain and sector collaboration, speaking as one voice to drive responsible practices.

Strategy 2024-26



Key Achievements 2021-2023 Strategy

- Establishment of Operations Committee
- Official Sustainability Partner of CPHI Worldwide
- Launch of e-learning platform, Learnster
- Inaugural Global Supplier Conference
- Finalization of Maturity Models

2026

Purpose
Our purpose is sector collaboration, using one voice to define, instil, and drive responsible value chain practices.

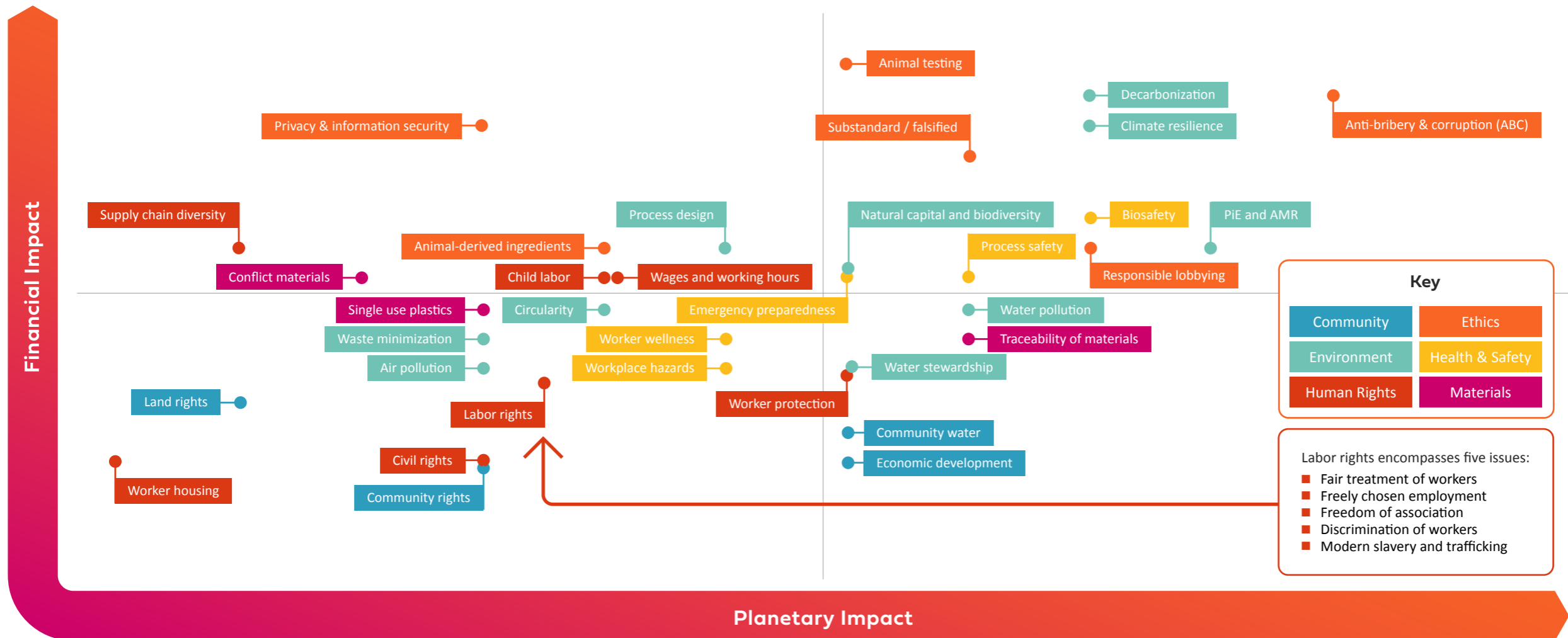
Vision
Our vision is for excellence in safety, environmental, and social outcomes across the global pharmaceutical and healthcare value chain.

Materiality Review – using the Double Materiality Approach

As part of our strategy development process, the PSCI conducts a materiality review for the pharma and healthcare sector. This assessment is focused on supply chain responsibility and helps us identify gaps in our program and emerging issues.

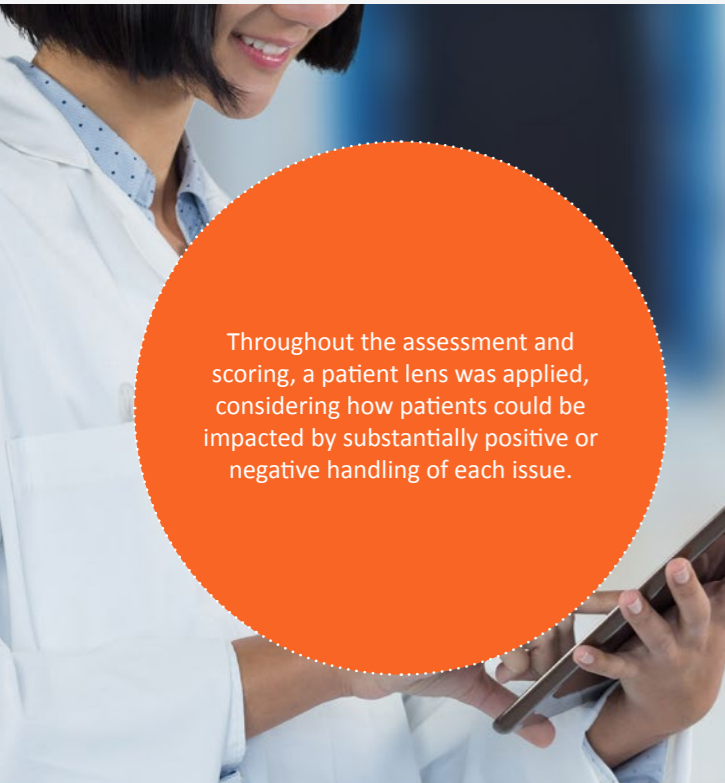
This year we applied a double materiality framework⁹, scoring issues on a 1-5 scale against criteria related to planetary as well as business & financial impacts, without further quantification (which would be challenging to do meaningfully at a sectoral level). Given the variety of issues that each member company deems material, our assessment is not applicable to any member individually. However, it does provide a sector-wide overview of issues to be considered internally and which the PSCI would expect to see addressed.

⁹ The initial review was conducted before the release of guidance on double materiality as part of the European Union’s Corporate Sustainability Reporting Directive (CSRD). The review was updated in early 2024 to take this guidance into account and opened to member feedback at a company-level, adding valuable input and rigor. The [final matrix](#) was published in Spring 2024.



Materiality Review

The PSCI Board uses this assessment as a control point, ensuring the PSCI's strategic focus captures material issues for the industry and our suppliers. Members can compare their own programs to the assessment in order to gauge how comprehensive their approach is and which issues are emerging. For those outside the sector, the assessment can help them understand how supply chain risks are viewed within the industry. The assessment should not be used as a blueprint for any individual companies' programs; the scoring methodology represents a sector view and will not align with any individual company. Since the assessment is specifically focused on supply chains, it also will not align to organizations' corporate materiality assessments or frameworks such as SASB.



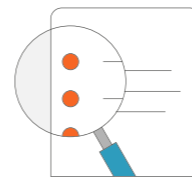
Throughout the assessment and scoring, a patient lens was applied, considering how patients could be impacted by substantially positive or negative handling of each issue.

The issues list

Ethics	NEW Responsible engagement on policy (lobbying)	Ensuring political engagement (lobbying) activity is transparent and aligned with the public interest
Human Rights	NEW Housing conditions in supply chain	This refers to the safety, hygiene, and privacy conditions of the dorms / flats / houses offered by the company to the workers
	UPDATED Diversity and inclusion in the supply chain	Ensuring that supply chain includes businesses benefiting all types of owners/managers
Health & Safety	NEW Biosafety	This concerns containment of biological substances in a labor manufacturing context
	UPDATED Workplace hazards	The identification, labelling and control of hazards in the workplace
Environment	UPDATED Climate change resilience	The resilience of supply chains to the weather and other changes that will result from a changing climate
Materials	UPDATED Traceability of raw materials	Incorporating the systems to trace and control the origins of materials
Community	NEW Communities' human rights	Respecting and safeguarding the rights of communities

Using the results

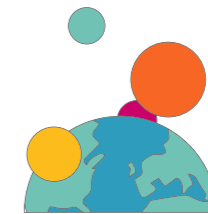
The PSCI uses the assessment in the following ways:



to ensure new and emerging topics are considered – and top issues given due focus - within our activities;



to systematically understand the position of important stakeholders on supply chain responsibility topics;



and, to ensure members' responsibility programs are covering all material issues.

Our Modes of Impact

The PSCI seeks to build responsible supply chains for the whole of the pharmaceutical and healthcare supply chain. We do this through three main workstreams: audit, capability building, and projects.



Audit



The PSCI Audit Framework is at the heart of realizing the PSCI's vision for excellence. The PSCI Audit Framework, Self-Assessment Questionnaire and supporting tools embed the PSCI Principles into the supply chain and have become a recognized framework across the industry. We work in partnership with approved audit firms and PSCI internal auditors to support the undertaking of PSCI audits, which are then shared on our digital platform. Members and suppliers can gain efficiency through our audit sharing platform, undertaking one audit in place of multiple. Every year, we analyze the findings from PSCI audits to identify trends, hotspots, and develop complementary resources and projects through the Capability and Projects workstreams to ultimately improve practices and build knowledge.

Key Audit Stats

Audits on the PSCI platform

983 🔍

Audits uploaded to the PSCI platform in 2023

186 ⬆️

Audits shared

132 ➡️

Audits downloaded

7000+ ⬇️

Approved audit firms

19 ✓

The Audit Committee oversees this workstream with dedicated Sub-Teams focused on Audit Self-Assessments and Guidance, Audit Sharing, and Auditor Training projects.







Committee Co-Leads



Birgit Skuballa
Bayer

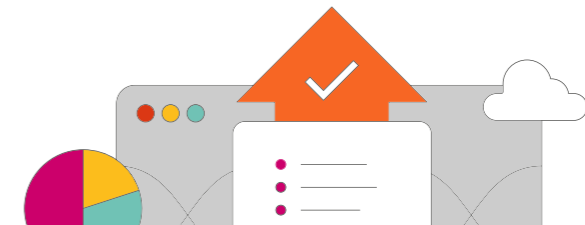
Roy Agostini
Mallinckrodt

Sub-Team Leads

Audit Sharing	Auditor Training	SAQ / Audit & Audit Guidance
 <p>Mary Walsh Pfizer</p>	 <p>Birgit Skuballa Bayer</p>	 <p>Birgit Skuballa Bayer</p>
 <p>Kaitlyn Etienne Abbott</p>	 <p>Dorota Wiacek Roche</p>	 <p>Dorota Wiacek Roche</p>

The PSCI Audit Tools

- Audit Guidance for PSCI Audits
- Self-Assessment Questionnaire (SAQ) & Audit Report Template (Full & Abbreviated)
- Self-Assessment Questionnaire (now available online)
- Pre-Audit Document Request List
- Auditor Evaluation Tool
- Audit Program Supplier FAQ
- Data Sharing Agreement





Ensuring our Tools are up-to-date

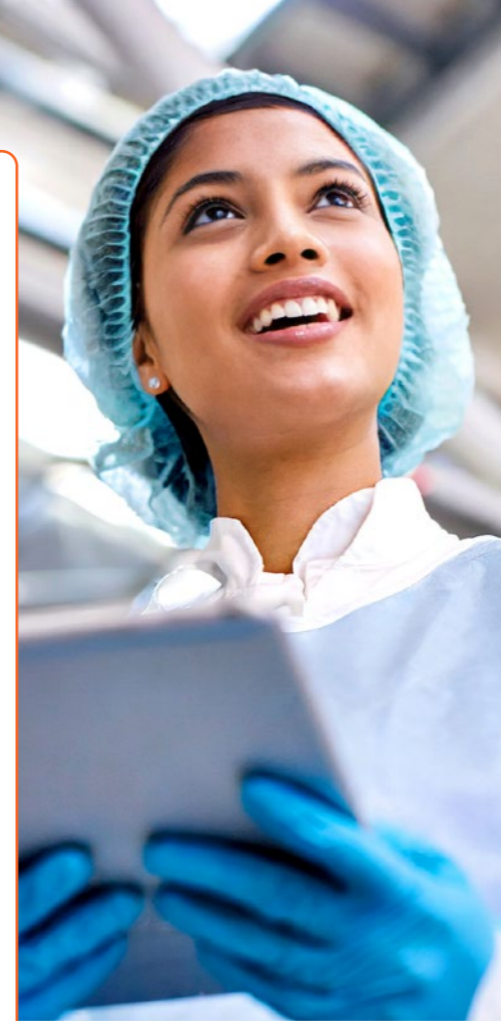
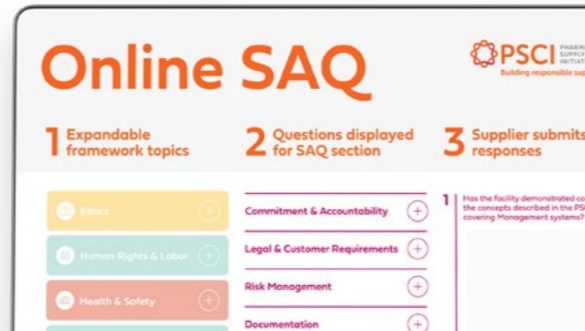
Online SAQ

Our Self-Assessment Questionnaire allows suppliers to assess their own performance in advance of a PSCI audit. Providing an online version is not only more accessible and user friendly, but also allows members and suppliers to better track progress over time. Our easy-to-use interface provides suppliers with a simple way to provide key information in advance of their audit, all in line with the PSCI Audit Framework. In 2023, the SAQ was launched online for the first time, representing a significant move in our path towards continued digitization.



Updating our Protocols

Our SAQ and audit templates are reviewed on a regular cycle to ensure they continue to reflect industry best practices. The latest update process occurred throughout 2023 in partnership with the Topic Teams, and took into account the updated Principles, significant legislation, and member-suggested clarifications to improve audit responses. The updated SAQ and Audit Protocol will be published in 2024.



Working with Approved Audit Firms

PSCI audits are carried out by approved audit firms or qualified PSCI member internal auditors. Our Auditor Training Sub-Team qualifies and approves third-party audit firms and organizes our ongoing engagement and training with these firms. Overall, 19 firms are approved to carry out PSCI audits. Throughout 2023, our Auditor training resources were reviewed and updated in partnership with subject matter experts from our Topic Teams. We also took steps to ensure the continued delivery of good quality, comprehensive audits by engaging in discussions with our approved firms and reviewing our agreements. The [full list of approved audit firms](#) is available on our website.

19 firms are approved to carry out PSCI audits



Experienced and well-trained auditors are key to value-adding and high-quality audits. The Audit Committee has thus developed together with experts from our Topic Teams tailored and hands-on training to support auditors from both our approved third-party audit firms and well as from PSCI member companies. These trainings cover a large variety of topics, from practical tips for auditing up to very specific topics like active ingredients in wastewater or at the workplace. These trainings are now available online, so our auditors can access them from anywhere at any time and continue to build their knowledge.



Birgit Isabelle Skuballa, Head of HSE Audit & Supplier Management, Bayer

Audit Findings Analysis

The Audit Committee conducts an annual Audit Findings Analysis to examine suppliers' practices captured in PSCI audit reports. This year, we analyzed 1,776 findings from the 180 PSCI audits uploaded to the platform in 2023 to identify key risk areas and opportunities in suppliers' practices. By leveraging the analysis and addressing these findings through our audit program and capability building initiatives, we empower suppliers to mitigate risks and foster a more sustainable and responsible supply chain. Audits included in the analysis were PSCI audits uploaded to the PSCI platform by the end of 2023. These include PSCI audits covering all PSCI Principle areas (Management System, HSE + Labor & Ethics) or parts of them (Management System and either HSE or Labor & Ethics). This analysis does not include non-PSCI audits on our platform, or PSCI audits which have not been uploaded to the platform.

What we found

Health & Safety remains the area with most findings (55%), followed by Environment (20%). One contributing factor towards this is that there's still a higher number of full or HSE only audits on the platform than Labor and Ethics only audits.

Top Main Health & Safety Findings

- Worker protection
- Occupational health and Industrial Hygiene
- Process safety
- Emergency preparedness and response

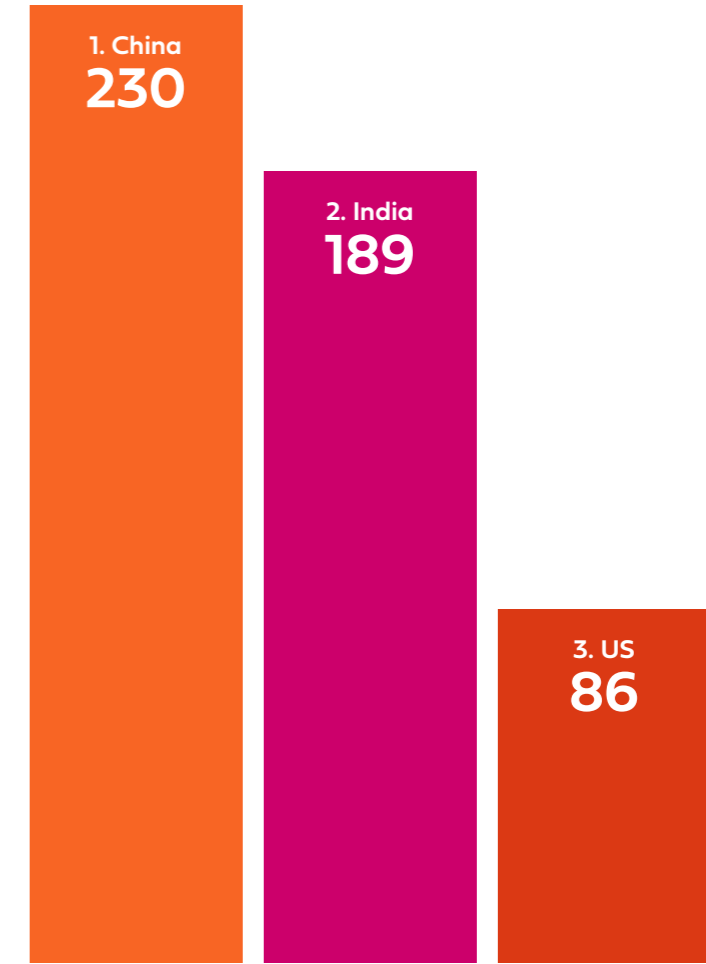


Takeaways and focus areas

- **Process Safety Management (PSM):** establish or strengthen PSM systems to include thorough process hazard analyses, risk assessments, and regular safety audits to ensure process hazards are identified and mitigated.
- **Process hazard analyses:** complete HAZOP studies, update safety information, and train staff to properly implement safety measures and emergency responses.
- **Explosion protection:** conduct risk assessments and implement corresponding mitigation measures.
- **Fire safety:** upgrade fire protection systems, especially in flammable liquid storage areas. Routine maintenance must be enforced to ensure all fire safety equipment is regularly tested and compliant with safety regulations.
- **Work permit systems:** establish comprehensive work permit systems to include stringent checks, comprehensive training on permit protocols, and a robust monitoring process to ensure adherence during high-risk activities.
- **Electrical safety:** conduct risk assessments, improve lockout/tagout procedures, and ensure ongoing training and strict maintenance schedules for all electrical systems.



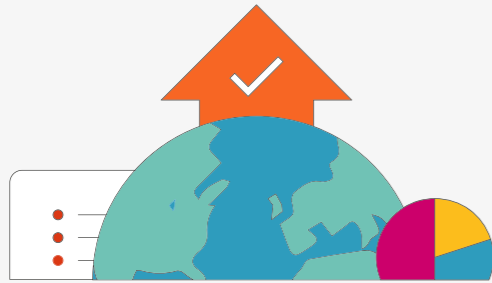
Cumulative number of audits on platform by country



43% Total percentage of audits from China and India

Top Main Environment Findings

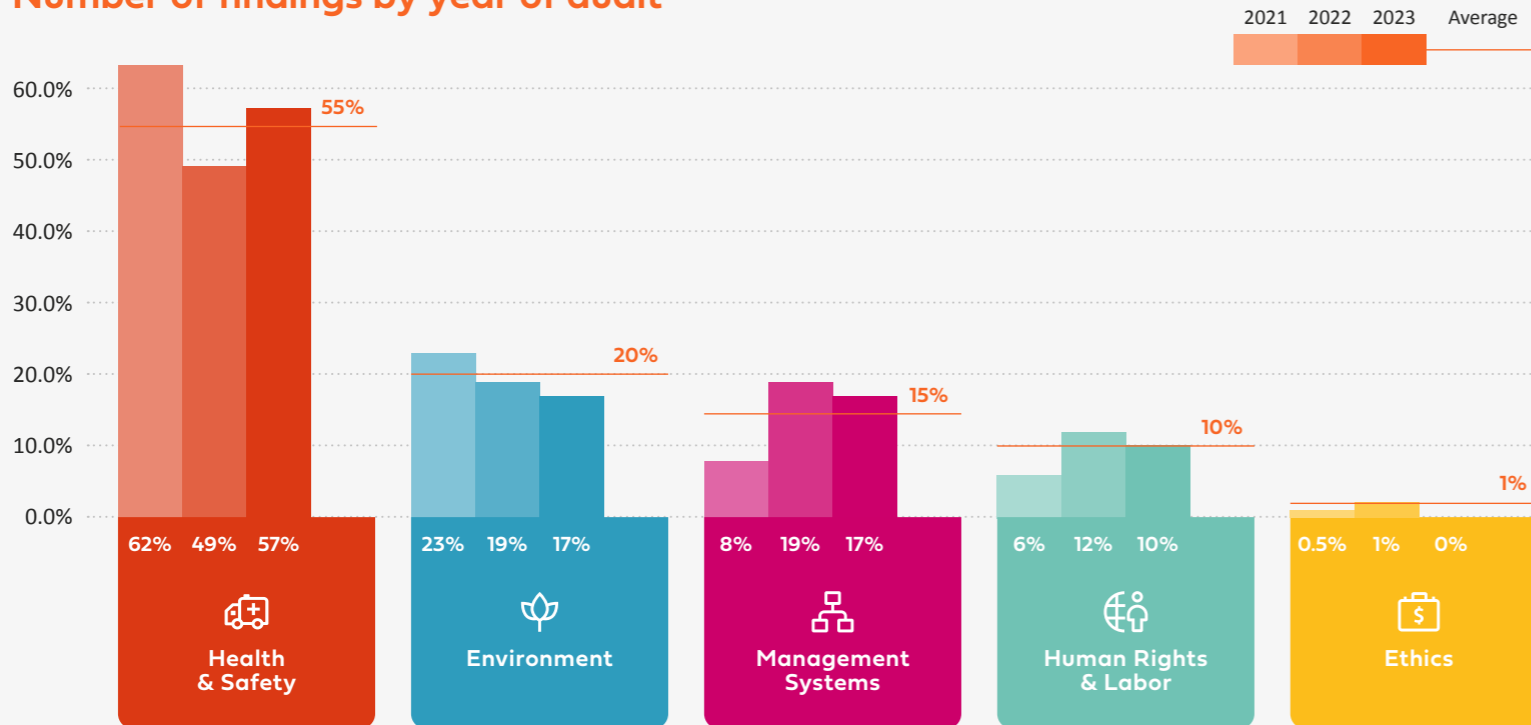
- Waste and emissions management
- Transport, storage, & spill prevention
- General Environmental policies and practices



Takeaways and focus areas

- **Environmental policies:** establish comprehensive and transparent policies that include clear objectives, targets, and metrics. These policies should be communicated effectively throughout the organization and in all applicable local languages to ensure widespread understanding and compliance.
- **Regular reviews:** implement regular reviews and updates to environmental policies and procedures, particularly those pertaining to hazardous waste management and spill prevention to adapt to regulatory changes and evolving best practices.
- **Waste handling and disposal:** develop more stringent criteria, including better oversight of third-party vendors.
- **Community and stakeholder engagement:** invest in fostering greater transparency and engagement with local communities and other stakeholders. This can be achieved through regularly disclosing environmental performance and sustainability practices.

Number of findings by year of audit¹⁰



¹⁰ It's important to distinguish between when the audit was conducted and when it was uploaded to the PSCI platform. Here, we use the year when the audit was conducted.

Audit type by year of audit¹¹

	2021	2022	2023	Total	%
Full HSE, Labor & Ethics	73	105	46	224	53%
Full HSE	50	49	37	136	32%
Full Labor & Ethics	2	7	4	13	3%
Abbreviated HSE, Labor & Ethics	2	6	4	12	3%
Abbreviated HSE	4	9	1	14	3%
Non-Standard PSCI Member Internal Audit Protocol	13	10	2	25	6%
Total by year	144	186	94	424	100%

¹¹ It's important to distinguish between when the audit was conducted and when it was uploaded to the PSCI platform. Here, we use the year when the audit was conducted.

Full HSE, Labor & Ethics audit: covers all five PSCI Principles

Full HSE audit: covers H&S, Environment, and Management Systems

Full Labor & Ethics audit: covers Management Systems, Human Rights & Labor, and Ethics

All three types of audits above use the PSCI Standard SAQ Template (Full Version), applicable for core suppliers, such as, API manufacturer, finished formulations, chemicals, etc.

The Abbreviated HSE, Labor & Ethics audit is a simplified version of PSCI Standard SAQ Template, tailored to service providers which are likely to have lower EHS risks.

Non-Standard Audit PSCI Member Internal Audit Protocol stands for audits that use member internal audit template, rather than the PSCI Standard SAQ Template (Full or Abbreviated).



Capability Building

Supporting suppliers to improve their practices is at the core of the PSCI's purpose. We want to support continual improvement for suppliers by delivering high-quality, impactful learning and development content. Our Maturity Model and digital learning plans provide suppliers with a structured curriculum to improve their practices in line with the PSCI Principles. This is accompanied by a wider portfolio of educational content including expert-led conferences, topic-specific webinars, and specialist tools. These courses and tools reflect the good practices that are expected by the industry, created by subject matter experts, and assessed via the PSCI Audit Framework.

This work is led by the Capability Committee with expert input from our Topic and Regional Sub-Teams.

Committee Co-Leads



Daniel Rehm
Elanco

Rincy Joseph¹²
Bayer

Sarah Turiano¹³
Viartis

Regional Sub-Teams

China



Wenjia Xu
Merck & Co.
(known as MSD outside the U.S. and Canada)

Latin America



Edgar Flores Ruvalcaba¹⁴
Novartis

India



Dinesh Subhedar
Novartis



Vijaya Sarathy
West

¹² until May
¹³ from May
¹⁴ until October

Key Capability Stats

Supplier Conferences:
China, India, Global

3

Total conference attendees

900+

Capability building interactions

2800+

Individual supplier representatives on the PSCI platform

2200+

Supplier sites registered on the PSCI platform

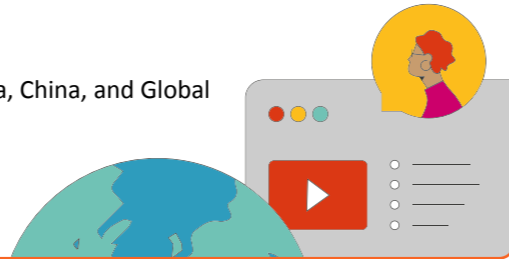
1800+

Total number of webinar attendees
1800+
45% INCREASE!

Total number of webinars
24

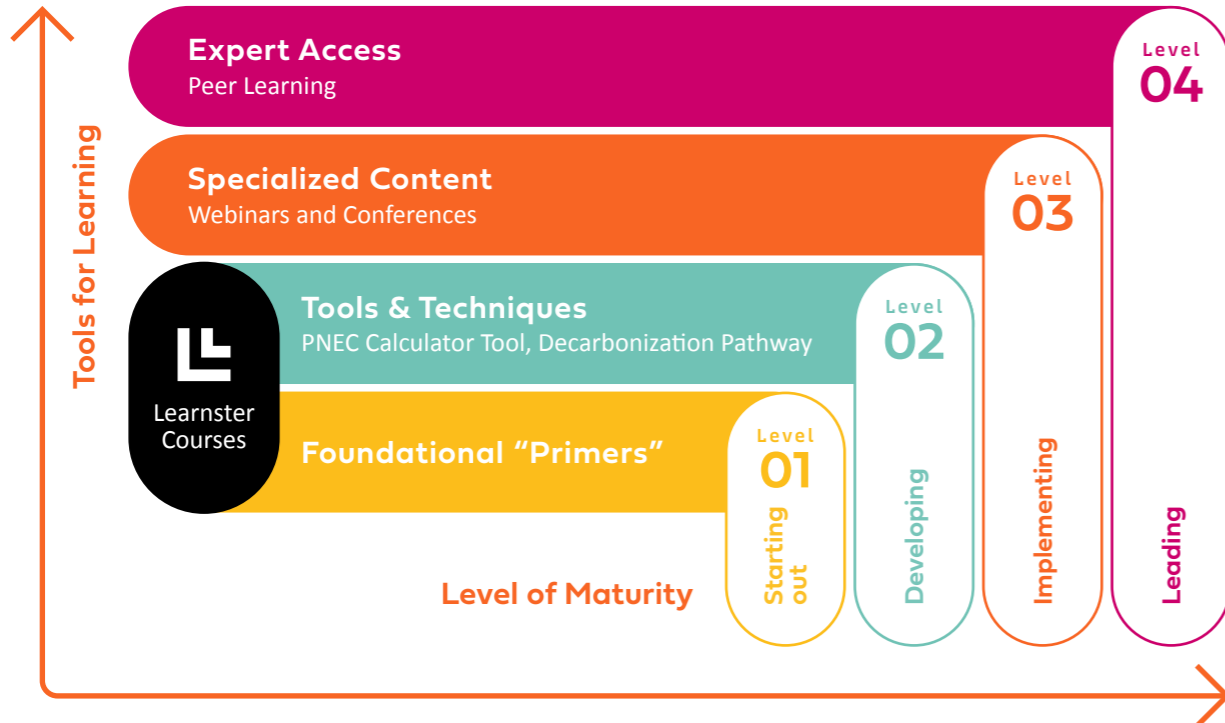
The PSCI Capability Building Tools

- Maturity Models
- Supplier Learning Plans
- Legislation Tracker
- Topic-based Webinars
- Supplier Conferences: India, China, and Global
- Environment Survey
- PNEC Calculator Tool



A pathway to improved practices

The PSCI Maturity Model provides a clear, structured path for suppliers at any stage of their EHS and Sustainability journey to understand their position, identify areas for improvement, and access engaging educational content developed by subject matter experts. Using the topic areas of the PSCI Principles as a framework, suppliers can use the model to understand where they meet the expectations for responsible practice set by PSCI member companies, as well as access resources to evolve their practices over time.



Learnster + PSCI

10+
ONLINE COURSE
AVAILABLE

The PSCI has partnered with e-learning platform Learnster to provide a one-stop-shop for pharma and healthcare suppliers to improve their practices in line with the PSCI Principles.

All courses provide an overview of the topic, share good practice, and align with the expectations set out in the PSCI Principles.

At the end of 2023, 10+ courses were available, with plans for further courses to be launched in 2024.



Courses include:

- 🔥 Fire Protection
- 👤 Freely Chosen Employment
- 💰 Fair Competition

Q As a learning professional, I'm impressed with Learnster's capabilities and with the PSCI's use of the platform to support its vision for excellence in safety, environmental, and social outcomes across the global pharmaceutical and healthcare value chain. Past and present members of the PSCI Board, Committees, and Topic Teams have collaborated to thoughtfully design learning plans that correspond directly to the PSCI Principles and Maturity Models. By progressing through these learning plans, suppliers can increase their knowledge and improve their practices to meet or exceed industry expectations. Through Learnster, our suppliers learn directly from PSCI member companies' subject matter experts about topics integral to becoming more sustainable, safe, and responsible.

Sarah Turiano, Senior Manager, Global EHS Training, Viatris



Webinar Program

Growing our reach

Led by our Topic Team members and specialist partners, our monthly webinar program provides attendees with foundational knowledge sessions on topics like water stewardship and labor rights in South Asia, as well as deep dives into legislation such as the German Supply Chain Act. These webinars are delivered by specialists from PSCI member companies as well as established PSCI partners.

Our China and India Regional Sub-Teams also deliver webinars in local languages, where appropriate, and on topics of specific relevance to suppliers within these countries. For example, the India team hosted a session on human rights and labor rights in an Indian and South Asian context, while the China team provided an introduction to the PSCI Maturity Model to suppliers in Mandarin.

Top 5 webinars by attendees

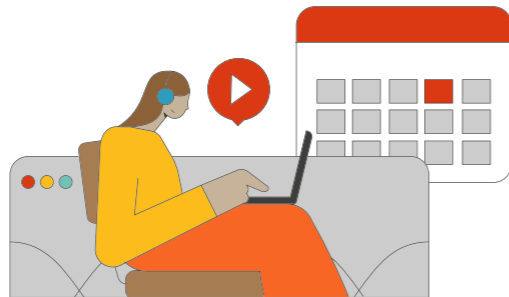
- 1 German Supply Chain Act (Part 1 - Human Rights & Due Diligence)
- 2 Dangerous Goods Handling
- 3 Industrial Hygiene Quantification
- 4 German Supply Chain Act (Part 2 - Environment)
- 5 Waste Vendor Vetting Checklist

Total number of webinars

24

Total number of webinar attendees

1800+



Decarbonization Pathway

Decarbonizing the pharmaceutical industry in line with global goals such as the Paris Agreement and the UN Sustainable Development Goals is a core component of the PSCI's Environment Principle. Action is needed and PSCI members realize the importance of working together with their suppliers, often the majority of the footprint across the whole value chain. Our Decarbonization Topic Team launched the PSCI Decarbonization Pathway, a free framework that the industry can use to move towards a net zero value chain. The model provides a clear pathway for suppliers to develop their capability and response towards reducing their carbon emissions and is aligned with the Common Supplier Standards published by the Sustainable Markets Initiative.



Decarbonization Pathway

This is intended to provide a framework that PSCI members can use to support their suppliers in decarbonization towards Net Zero, in line with global goals such as the COP Paris Agreement and UN Sustainable Development Goals.

- To deeply decarbonize, PSCI members need to address our Scope 3 emissions i.e. the GHG emissions generated by our suppliers in the course of delivering their contracts with us.
- PSCI members will require our suppliers to address their own Scope 1 & 2 GHG emissions and those of their suppliers own supply chain i.e. their Scope 3 emissions.
- The principle is embedded that our suppliers (PSCI members) would flow this framework down to their supply chains (members).
- This approach builds on Maturity Models for other PSCI focus areas.

Maturity model for Decarbonization



Legislation Tracker

The regulatory landscape around Environment, Social, and Governance (ESG) topics has evolved at a staggering pace over the last 12 months. The growth in legislation predominately comes from the European Union, but has implications for pharma and healthcare companies operating globally and will bring about new reporting and disclosure requirements on human rights due diligence, supply chain transparency, and environmental impact. To meet the needs of our members, we launched a Legislation Tracker in 2023 that provides a clear overview of key pieces of legislation, their overlap with the PSCI Principles and Sub-Principles, and signposts to available PSCI resources such as webinars, briefing notes, and tools like our Audit Protocol. Members can read overviews on the EU Corporate Sustainability Reporting Directive, Task Force on Climate-related Financial Disclosures, the German Supply Chain Act, and proposed EU Directive on Corporate Sustainability Due Diligence.

Supplier Sustainability Conferences

Expanding our regional presence

Our multi-day conferences provide attendees with an introduction to EHS and Sustainability topics like Biodiversity, Decarbonization, and Anti-bribery and Corruption. The conference agendas and sessions are created using inputs from our Annual Audit Findings Analysis, Topic Teams, and insight from regional Sub-Teams to ensure that the sessions are relevant and address the on-the-ground needs of the supplier community. Sessions are delivered by a combination of specialists from member companies, Sub-Team leads, approved audit firms, and local association partners. Our 2023 conferences in India and China were both held in-person and delivered in the local language in the case of China. In 2023, we hosted our first conference for suppliers based in the Europe and North America regions, welcoming 394 individual supplier representatives for 2 days of sessions focused on Sustainability Leadership – looking at leading practices at the corporate level.

Top sustainability conference sessions

- 1 Biodiversity: global trends & horizon-scanning**
- 2 Global and regional sustainability frameworks**
- 3 Carbon reduction through the whole supply chain**



Key Conference Stats

Total conference days

7

Total conference attendees

900+

Number of capability interactions with suppliers

2800+

Number of supplier users registered on our online platform, The Link¹⁵

2200+

¹⁵ this refers to an individual representative from a supplier site

The conference helped me gain a better understanding of how the pharmaceutical industry views leverage points to address environmental sustainability.

(from GSC 23 feedback report)



INTERVIEW

Daniel Rehm

LEAD TSMS ADVISOR BOVAER PROJECT, ELANCO

Why did the PSCI launch a Global Supplier Conference?

The PSCI discussed the idea of hosting a conference for suppliers in Europe and North America for a long time. Our conferences in China and India are well-established, so we want to extend this offering and provide advanced training that was tailor-made for a European and North American supplier base.

What were the outcomes?

Our first Global Conference was very well received by suppliers, with positive feedback and useful ideas for the next time. Interestingly, we had a significant number of participants from China and India, which encouraged us to improve the offering for the conferences we run specifically for suppliers in those regions.

Plans for the future?

We plan to continue hosting a Global Conference as part of our capability building effort for the global supplier community with content that is relevant, useful, and focused on helping suppliers in Europe and North America improve their practices.



Projects



With over 79 member companies representing a sizeable portion of the pharma and healthcare sector, we have both an opportunity and interest in collaborating on special projects that reflect our mission, leverage our scale, and ultimately create a positive impact. Our structure enables us to speak as one voice on emerging issues, while our scale can be leveraged to deliver greater impact via partnerships. Projects are set to become a key deliverable in the PSCI’s new strategy. Projects delivered through the PSCI will be overseen by a new Projects Committee and proposed and implemented through our Committees and Topic Teams.



At BNP Paribas Asset Management, we view nature loss as a key systemic risk to our global portfolios. When we learned about the biomedical industry’s use of Horseshoe Crab blood for endotoxin testing, we reached out to companies in our portfolios to start a dialogue. This included reaching out to the leadership of the PSCI, who formed a working group and ultimately published a progressive position paper on the topic. The PSCI helped us to put this issue squarely — and publicly — on the industry agenda. Thanks to the PSCI membership, we are now urging pharmaceutical companies in our portfolios to adopt this set of good practices developed by their peers. We are grateful for the PSCI’s partnership and hope that our work together will help to place public health – and biodiversity – on a more secure foundation.

Adam Kanzer,
Head of
Stewardship,
Americas,
BNP Paribas
Asset
Management



Position Paper on Horseshoe Crab Blood

One very valuable opportunity afforded by bringing the whole industry together is to share perspectives on challenging topics and perhaps to reach a common position. Over the last two years, PSCI members have worked together on the challenges and options presented by the industry’s use of Horseshoe Crab blood.

Horseshoe Crabs are an ancient group of crab species whose blood has the remarkable property of indicating certain types of endotoxins. For this reason, it has been harvested by the medical and pharma industries to use as a test for these harmful compounds - a key demand of the regulators who authorize pharmaceutical development and manufacturing. The connection between the Horseshoe Crab species and the pharmaceutical sector is an example of the importance of biodiversity for human health and acts an excellent example of interdependence between medicine and biodiversity. While this blood harvesting process does not require the death of the animal, there are still questions over possible animal welfare, biodiversity, and sustainability impacts from the collection of these materials from populations of wild crabs. →



The Pharmaceutical Supply Chain Initiative (PSCI)

Of the three affected species of Horseshoe Crabs across the US and Asia, one Asian species is listed as endangered, with concerns over the other Asian species where data is deficient.

The PSCI's [position paper](#) encourages members to commit to no further collection from endangered species, minimize the use of these materials overall, and share information to understand the animal welfare and conservation questions. How do members use this paper? Firstly, it is a valuable guide to what good practice looks like. Some PSCI members are already adjusting their positions to come into line with the PSCI position. It also allows the PSCI to monitor our impact. We can track (via a regular anonymous check-in with members) how the industry as a whole is moving towards our common position.

And finally, it is a valuable basis for discussions with stakeholders – for example investors and regulators – to demonstrate our commitment to biodiversity.



POSITION

The PSCI affirms these elements of good practice and encourages their adoption by members:



Protect all endangered species – no further collection of TAL (Tachypleus Amebocyte Lysate)



Minimize the requirements for naturally-derived testing materials



Understand the animal welfare and conservation position

The PSCI in turn commits to:



Monitor and review our members' approach and report it on an anonymized basis



Engage with others to learn and develop particularly on the US conservation position

Wastewater Treatment Labs

In 2023, the India Sub-Team reached a new stage of their project to support the development of wastewater testing capabilities on the Indian sub-continent.

Despite the large presence of pharmaceutical manufacturing, wastewater treatment analyses in India are minimal and samples for testing are consistently sent to laboratories in the US or Europe. In order to enable PSCI members and suppliers to utilize the services of India-based labs for wastewater analysis related to Pharmaceuticals in the Environment (PiE), the Sub-Team worked to identify existing labs and build their capability in the necessary analytical and detection methods. The PSCI is uniquely placed to do this work, having access to

subject matter experts, industry demand and capability-building skills. The outcome will be new capability in India, making life easier for members and suppliers and – perhaps – even supporting the Indian regulators as they tackle the important issue of PiE. Throughout 2023, the project created a shortlist of laboratories via site visits from an internal assessment team and peer and subject matter expert reviews. In 2024, a pilot will be launched to establish and develop the capability of the selected labs and ultimately support the detection of PiE by labs within India.



Financials

The PSCI is legally established in the United States as a non-profit membership organization and funded by annual membership fees. Each member's fees are determined by their respective company revenue. Full members pay less than Associates in recognition of their greater contribution to and engagement with the PSCI.

After a significant increase in members and revenues from fees between 2022 and 2023, growth continued but at a slower pace in 2023. Total revenues were \$1,830,214, 21% more than the previous year, and included \$265,262 derived from 2022 fees paid late.

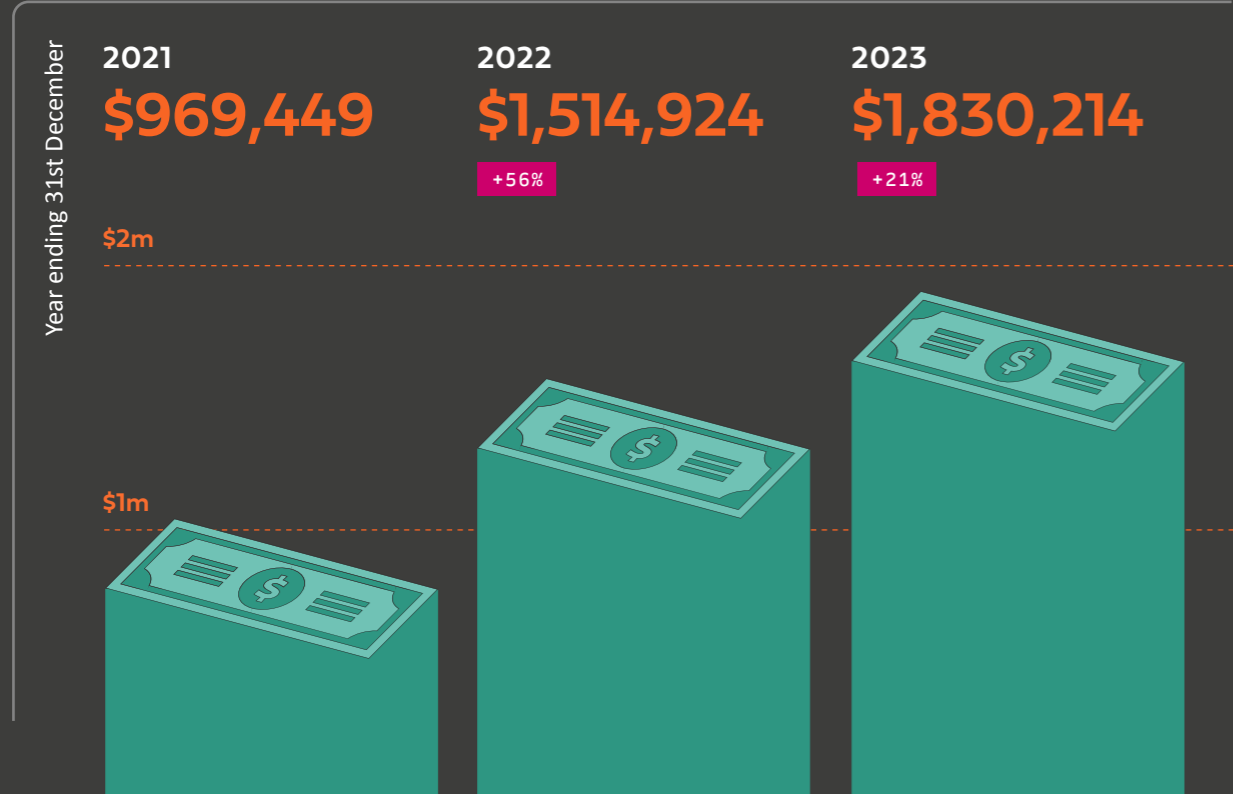
The PSCI incurs expenditure in the administration of the association itself and the delivery of projects, events, and resources to promote and instil responsible practices throughout the pharmaceutical and healthcare value chain in line with its mission and vision. Unspent membership fees are retained as reserves.

The PSCI's operating expenses increased in 2023 to accommodate several major new items. In addition to the two Supplier Conferences held in Asia, a third Global Supplier Conference was delivered, taking place virtually. Additionally, the PSCI for the first time held a member meeting in Asia, running in hybrid for in-person and virtual attendees, in the same week and location as the India Supplier Conference. Finally, a budget of \$125,000 was set aside to develop a new web platform and e-learning offering. The Learnster platform was launched with a suite of courses and resources for members and suppliers. We ended the web development part of the project

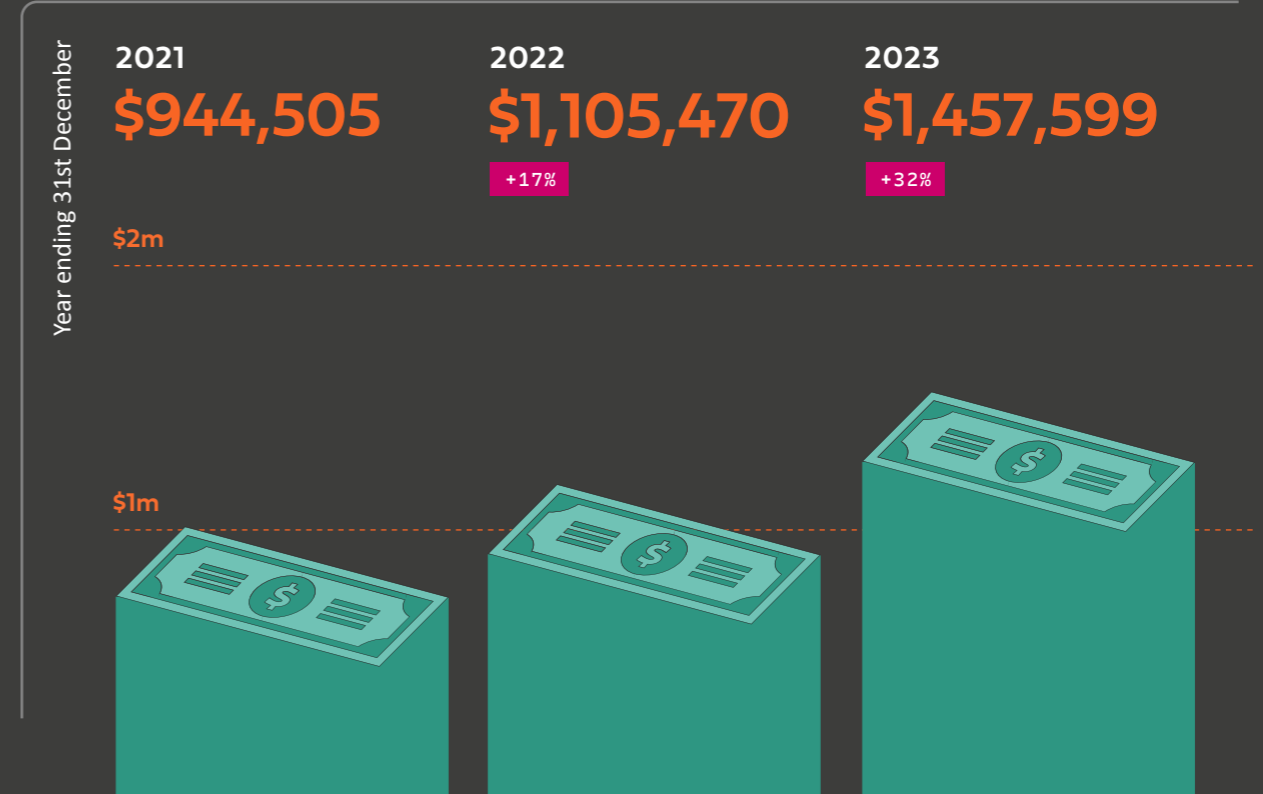
early after our supplier was unable to meet the requirements. Overall, approximately half of the total project budget was spent.

The PSCI Board consists of seven Directors, including a Treasurer, who provides budget and financial updates to the membership at two member meetings per year, including the PSCI's Annual General Meeting. The finances are overseen by the PSCI's Treasurer with support from independent accountants, BDO. This year an extension of term limits for the Treasurer and Treasurer-designate to three years was also approved by members. This supports this shift towards simplification and accountability, allowing each Treasurer to deliver on the budget they set. Also amongst future plans, the 2024 budget will be simplified to increase transparency, including the separation of fixed running costs from variable delivery costs and projects. A separate budget will be ringfenced for projects approved by the forthcoming Projects Committee.

Total revenue from membership fees



Total operating expenses



Collaborations & Partnerships

We enjoy a range of collaborations and partnerships with organizations that share our vision and help us achieve our strategic objectives. Here is a snapshot of two partners we worked closely with in 2023. You can see more information about our partners on our website.



We are pleased to enjoy a long-standing partnership with CPHI as one of their Official Sustainability Partners for their European event program, held in 2023 in Barcelona. CPHI creates connections and inspires partnerships across the global pharma community. They champion innovation at the heart of pharma at in-person and online events, granting access to a variety of opportunities. We engage with CPHI across their portfolio, from publishing content on CPHI Online to speaking on panels in China and North America, to meeting with current and potential members and suppliers at on-site conferences. As an Official Sustainability Partner, we provide valuable input to their events and content on Sustainability trends, approaches, and tools available to the CPHI community, acting as an expert voice to increase understanding and awareness of responsible supply chain practices and the expectations of our members. We exhibited for the second year in Europe at CPHI Barcelona and for the first time at Pharmapack.

- ✓ 3 conference engagements
- ✓ 1,400+ engagements with the CPHI community via thought leadership, webinars, and conference presentations

CPHI Collaborating with the PSCI isn't just about forging connections; it's about fostering excellence. By partnering with the Pharmaceutical Supply Chain Initiative, we ensure our events are not just informative but transformative. The PSCI's commitment to ethical, sustainable practices resonates with our mission to drive innovation and integrity in the pharmaceutical industry. Together, we amplify our impact, empowering stakeholders worldwide to shape a healthier, more sustainable future.

Silvia Forroova, Director – Partnerships & Sustainability, Informa Markets



Energize



The business case for decarbonization is well established and key to achieving the aims of the Paris Agreement. Whilst pharmaceutical companies are well on their way to reducing their direct Scope 1 and 2 emissions, the largest challenge and opportunity remains in the indirect (Scope 3) emissions found in their supply chains. Supporting supply chain decarbonization requires partnership and collaboration, all of which led to the partnership between the PSCI and Energize.

Energize is a first-of-its-kind program launched by Schneider Electric and leading global pharmaceutical companies to increase access to renewable electricity for the industry supply chain.

The program provides suppliers with access to renewable electricity education and support to explore their options to purchase renewable electricity. Energize is designed to assist companies of all sizes in overcoming typical barriers to renewable electricity procurement. These barriers include limited knowledge about renewable electricity transactions, small electricity volume, credit challenges, and the need for guidance throughout complex

contracting processes. Energize gives suppliers the opportunity to engage in the market for renewable electricity procurement through multi-buyer power purchase agreements (PPAs) or individual buyer solutions like Tax Credit Transfer Agreements, Energy Attribute Certificate purchasing, and on-site solar installations.

This transition to renewable electricity represents a long-term investment by the sponsor companies and their suppliers. By raising awareness about the renewable energy market and purchasing options, and providing a platform and solution for pharma companies and their suppliers to decarbonize, we are supporting the transition to net zero for the sector.

Over 500 pharmaceutical supplier companies have registered for the Energize program. Gaining brand awareness for a new program or initiative always has its challenges but the strong relationship between Energize and the PSCI has helped overcome those challenges and build recognition, including a 2023 CPHI Sustainability Pharma Award.

About Energize: Energize is a supply chain renewables program designed and delivered by Schneider Electric Sustainability Business and is endorsed by the PSCI.

Supplier Partnership

Throughout 2023, the PSCI worked to develop a new partnership model for those suppliers that share our vision and are consistently and highly engaged with us through audit sharing and capability building. We wanted to strengthen our collaboration with suppliers, recognize those who engage, and bring their voice into relevant discussions alongside the membership.

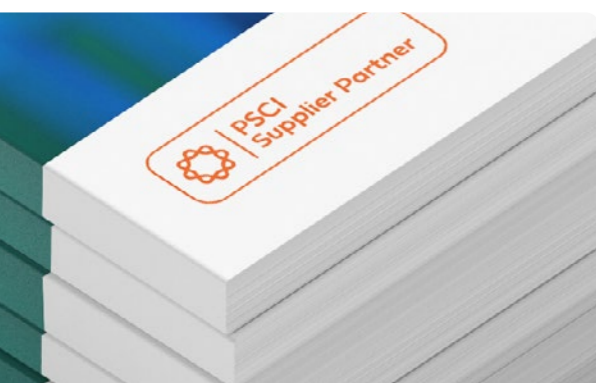
Through our new Supplier Partnership category, we will provide formal recognition for suppliers in the pharmaceutical and healthcare industry that can demonstrate their commitment to the PSCI's mission through engagement with our vision, programs, and projects. This option is open to companies in the industry that manufacture components or ingredients, manufacture finished pharmaceutical or medical products which are supplied to customers under the clients' brand name or licence (CMOs), or a 'white label' service provider (such as CDOs or CROs).

We're aware it may take prospective supplier partners some time to meet the criteria for eligibility if they are not yet actively engaged in the PSCI audit program. With that in mind, we've established a 'pathway to partnership' where the PSCI will help suppliers with regular contact and support until the criteria are met. In the meantime, prospective supplier partners registered on the platform will still have the same, free access to our shared audit platform and capability building resources as they have now.



By solidifying our PSCI partnerships with suppliers, we create a stronger collaboration that promotes responsible sourcing practices across the industry. This unified approach empowers suppliers to have a voice and be recognized for their commitment to ethical sourcing and contribute to the positive impacts of the PSCI. I look forward to working on this partnership model and watching it grow.

Deirdre O'Reilly, Senior Director of Global EHS Supplier Operations and Business Development, Viatris



Promoting Transparency

In addition to standard supplier access, Supplier Partners have special access to customized content and can request visibility of audits posted by other companies, subject to approval of the audited company and sponsor. Supplier Partners can invite their own suppliers to share audits and environmental data to continue embedding PSCI Audit Protocols down the supply chain.



Speaking as One Voice across the Value Chain

Supplier Partners can add their voice to the conversation on responsible business practices alongside customers and peers, contributing their first-hand expertise to the development of resources and events and collaborating on projects.



Recognizing Good Practices

Supplier Partners will be formally recognized and listed on the PSCI website, becoming part of the PSCI community for those dedicated to responsible value chain practices for the pharma and healthcare industry.

Criteria for Supplier Partners

- ✓ Complete the PSCI Maturity Models at a group level
- ✓ Share audit reports of your own manufacturing / operational facilities supplying PSCI members on the PSCI shared audit platform¹⁶
- ✓ Provide a transparent CAPR (with progress tracking) for any major or critical findings

¹⁶ Audits of at least 20% of the total business and all immediately available PSCI audits must be shared



Vice Chair's Close

We close 2023 in a strong position, with a clear and impactful plan.



Deirdre O'Reilly / 2023 PSCI Vice Chair
 SENIOR DIRECTOR OF GLOBAL EHS SUPPLIER OPERATIONS AND BUSINESS DEVELOPMENT, VIATRIS

Our strategy for 2024-2026 places impact at the heart of all we do, focusing on member and supplier accountability, streamlined structures, and fostering innovation within strong governance. Our new Projects workstream is a key part of this, providing a mechanism to harness and support project initiatives that advance supply chain practices and help maximize the impact of the PSCI. It creates a space for members to work together on industry-wide challenges, leveraging their collective power for greater impact.

Speaking with 'one voice' for the industry isn't straightforward. The PSCI represents a diverse mix of companies, geographies, business models, and product types - not to mention languages, cultures, and strategic priorities. However, I am confident in bringing the industry together towards our vision of excellence in supply chain responsibility. The organization is member-driven by passionate volunteers who believe in and recognize the power of collaboration and how we can make a difference if we put our minds to it. Reflecting on 2023, it's impressive and humbling to see the sheer energy and dedication of the members that drive the PSCI, especially those in leadership roles for our various Committees and Teams. Their commitment fuels the PSCI's success. With the launch of our new Supplier Partnership category, we're even better positioned to work together with our suppliers, allowing for even greater impact across the value chain.

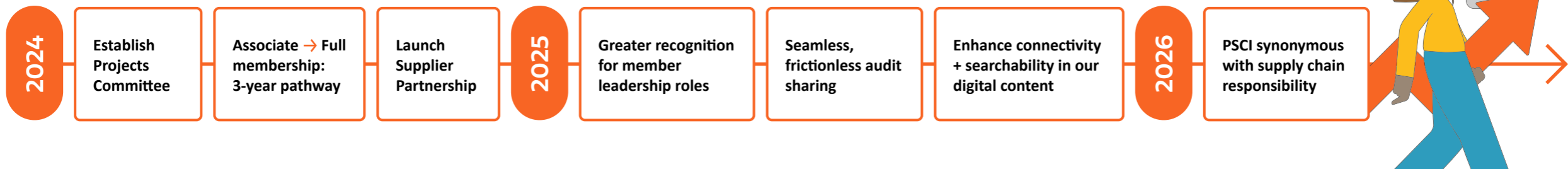
We remain committed to our core mission of reducing supplier audits while improving transparency and standards. Maintaining this core mission is crucial.

We need to refine and improve what we do constantly. I would like to thank Ingrid for her leadership as Chair and the entire Board. We have a strong foundation for a busy and impactful year ahead. Thank you all!



The organization is member-driven by passionate volunteers who believe in and recognize the power of collaboration and how we can make a difference if we put our minds to it.

Roadmap



Start the journey to a more sustainable future

 pscinitiative.org

 info@pscinitiative.org

 [@PSCInitiative](https://twitter.com/PSCInitiative)

 [PSCI](#)

For more information about the PSCI please contact:

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