

# The Pharmaceutical Supply Chain Initiative (PSCI):

**Evaluating supplier ethics and  
compliance practices and programs**

# AGENDA

## Welcome

Transparency International

Deloitte

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Questions



## SPEAKERS

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# INFLUENCING CORRUPTION IN PHARMACEUTICAL SUPPLY CHAINS

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PSCI WEBINAR, 25 JULY 2018

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Sarah Steingrüber, Programme Manager, TI Pharmaceuticals & Healthcare

# CORRUPTION & ETHICS

**Corruption:** the abuse of entrusted power for private gain

**Ethics:** moral principles that govern a person's behaviour or the conducting of an activity

# CORRUPTION IS BAD FOR BUSINESS

- Corruption adds 10% to the total cost of doing business.
- High levels of corruption is the equivalent of a 20% tax on foreign business.
- Corruption adds 25% to the cost of procurement contracts.
- Anti-corruption programmes and ethical guidelines lead to 50% fewer incidents of corruption, and to be less likely to lose business opportunities.

# CORRUPTION IS A UNIVERSAL PROBLEM

- USD 7 trillion annual global spend
- Estimate 10-25% public procurement funds lost to corruption
- 17% of people worldwide stated they had paid a bribe when interacting with the healthcare sector

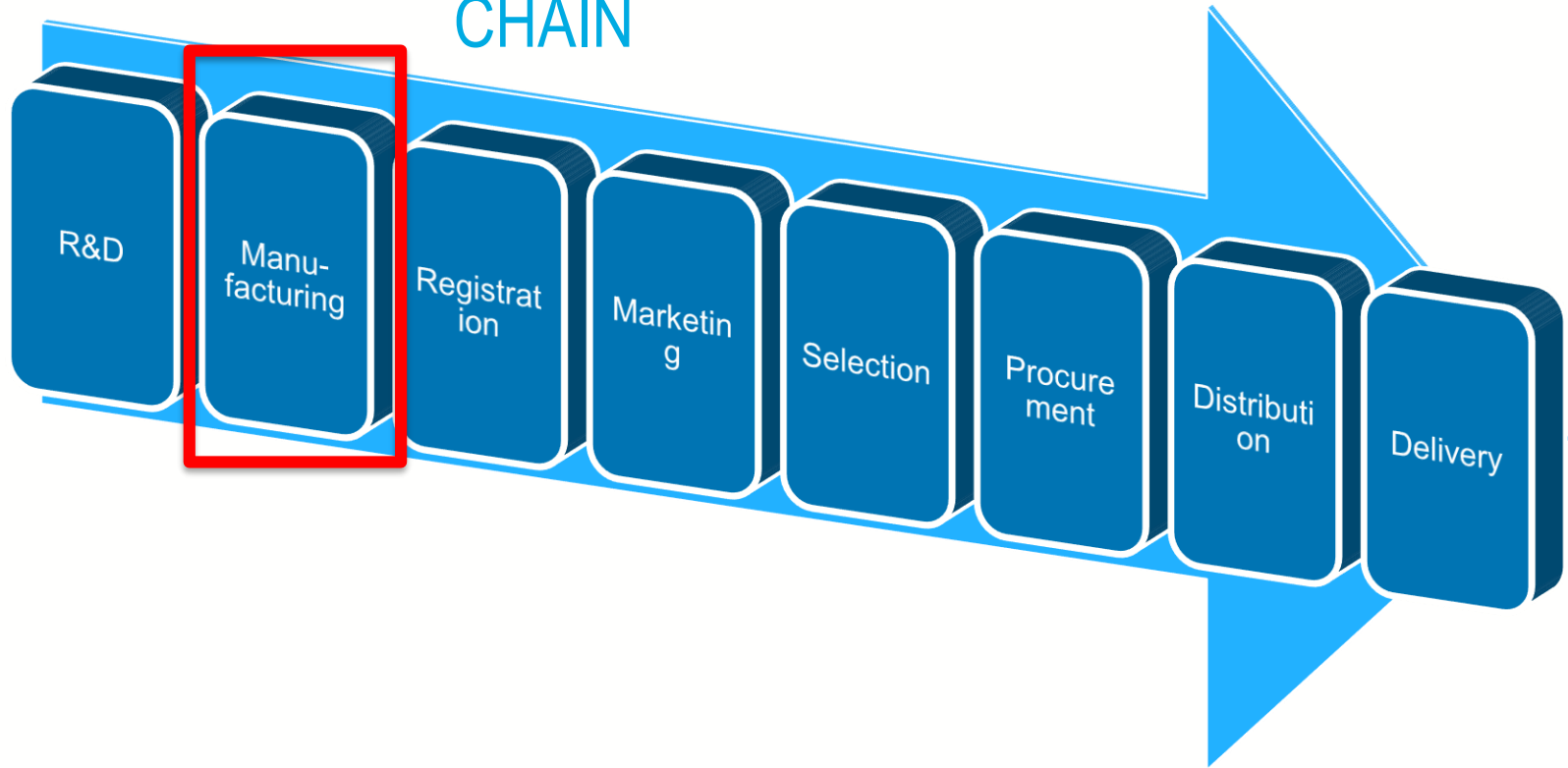




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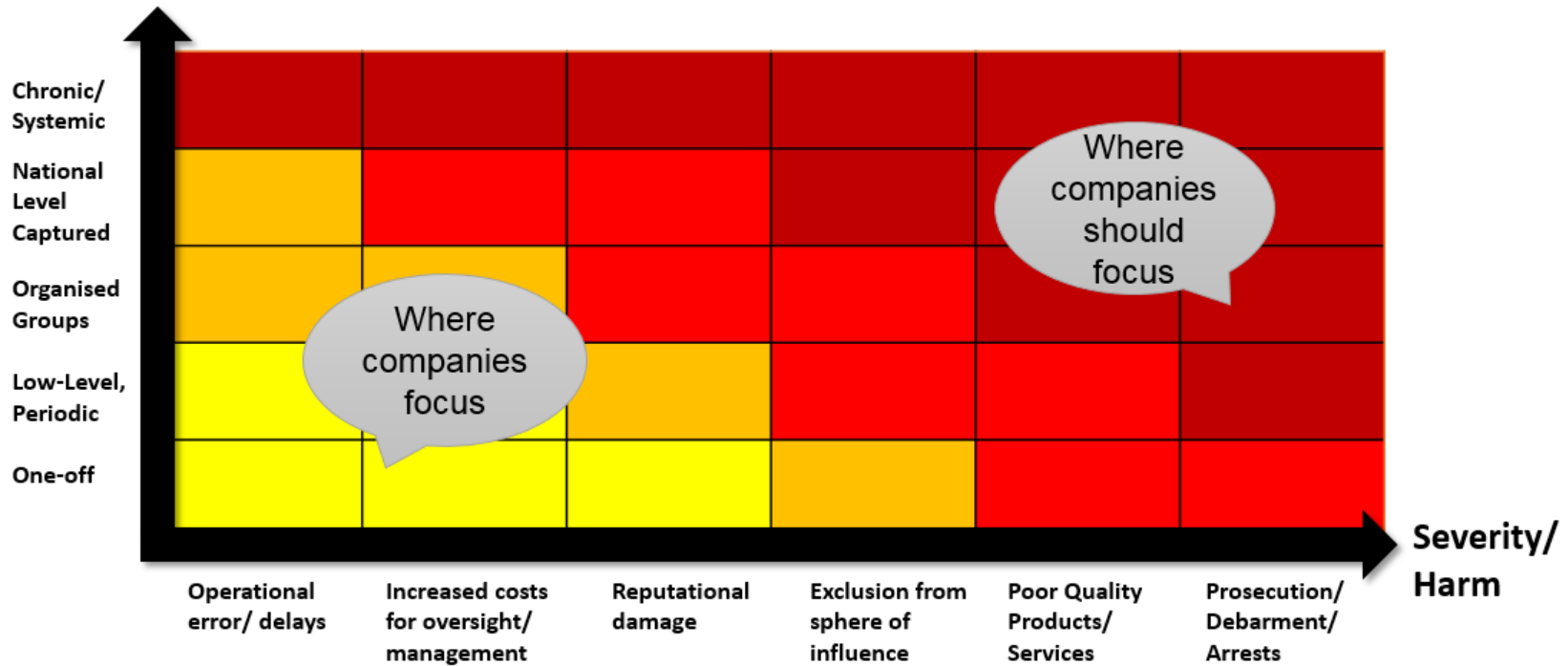
**HEAD  
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# VALUE SUPPLY CHAIN



# PUTTING YOUR MONEY WHERE IT MATTERS

Likelihood/Scale



# ENTERPRISE RISK MANAGEMENT

Questions to ask:

1. What kinds of corruption **pose the highest risk** to achieving our objectives?
2. Who within the supplier company is best positioned and **most incentivized** to be corrupt?
3. How could one **conceal and perpetuate** corruption over time?
4. How can you **best deter or detect** the most harmful corruption?

# FORENSIC ECONOMICS APPROACH

Apply economics to the detection and quantification of harm from behaviour.

- Identify “red flags” to define the objectives and there they are not aligned evaluate how they might best achieve their objective(s) within given constraints.
- Devise tailored mechanisms that align incentives or at least constrain undesirable behaviour

**Live the culture  
you want to  
see...**



**THANK YOU!**

**Sarah Steingrüber  
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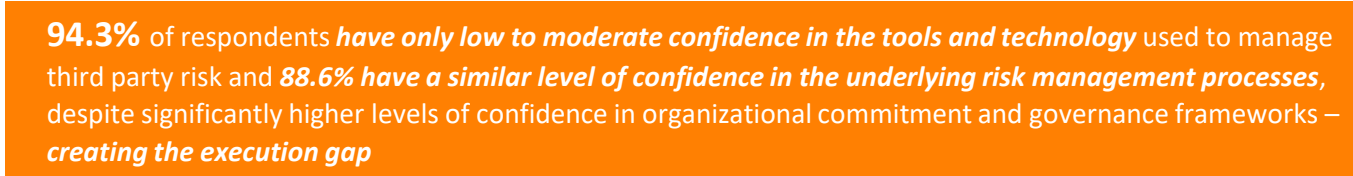
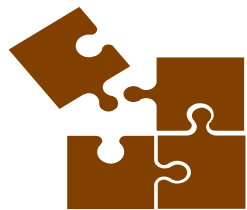
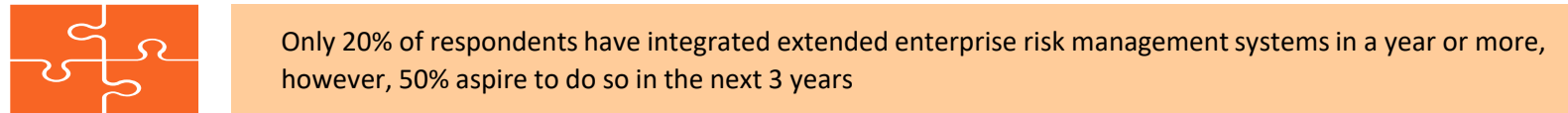
Questions





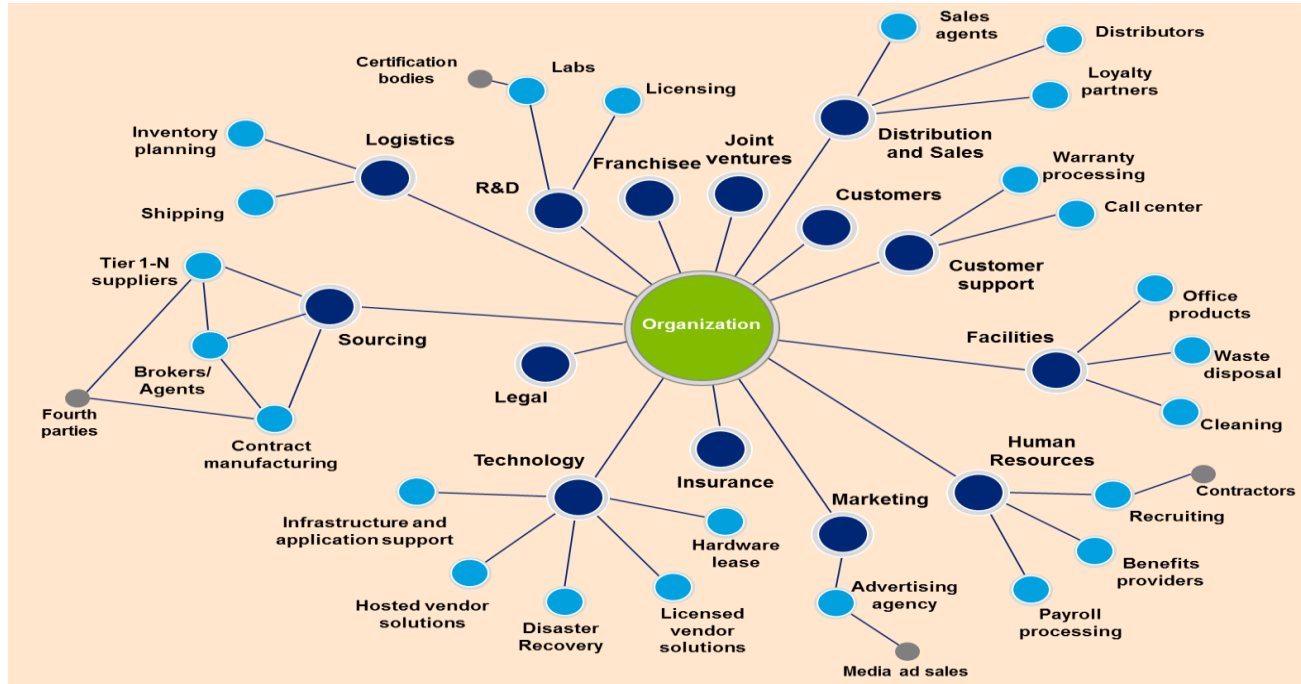
# Organizational Ethics Lapses Can Lead to Supply Chain Disruption

Recent data shows an overwhelming majority of respondents experienced supply chain risk events, including lapses of corporate ethics; however, few have confidence in their ability to effectively manage the risks



# Broaden or Redefine Your Organization's Concept of 3<sup>rd</sup> Parties

3rd parties are often defined as “vendors”, which effectively ignores a vast and complex ecosystem



# Managing supplier risks requires understanding the frequency, the velocity, and the severity of the type of risk

The spectrum of risks ranges from chronic to catastrophic

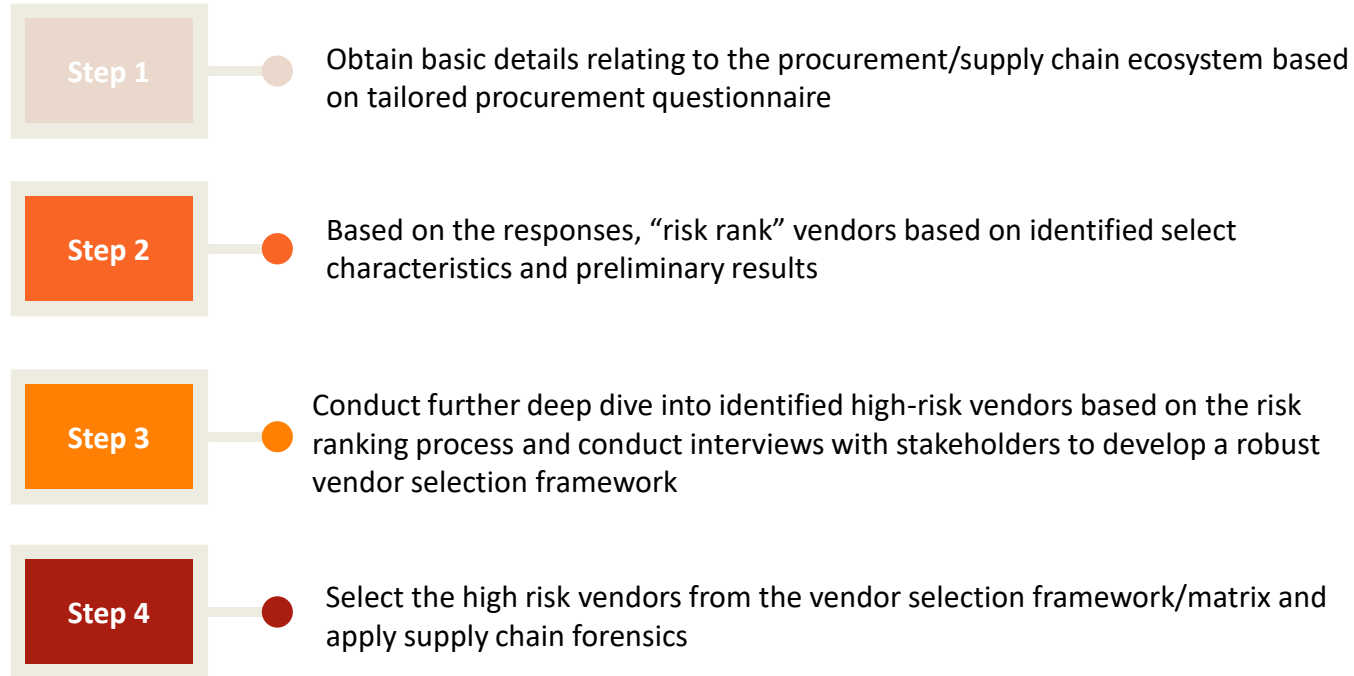
		Supply Disruptions		
		Chronic	Acute	Catastrophic
Characteristics		Persistent, frequent in nature often addressed in day-to-day operations, not likely to disrupt ability to meet demand. Efficiency gain opportunities; may be a leading indicator of a larger supply issues. These risk are managed through supplier analytics	Rapid onset, short-term in nature with potential to significantly impact ability to satisfy demand. Critical path vulnerability assessment, mitigation and continuity plans can eliminate, reduce exposure. These risks are managed through proactive risk sensing and BCP	Immediate loss of supply with potential severe business consequences. Requires strategic assessment, crisis management, disaster recovery, business continuity planning. These risk are managed through scenario planning and business continuity planning
	Examples	<ul style="list-style-type: none"> <li>COGS variances</li> <li>Cash-to-cash cycle time</li> <li>Obsolete/ slow inventory</li> <li>Returns management cost</li> <li>Production changes and asset efficiency</li> <li>Lead time changes and logistics volatility</li> <li>Production &amp; supply chain flexibility</li> <li>Schedule adherence and forecast volatility</li> <li>Production variances and order fill rates</li> <li>Return on assets</li> <li>Stock outs</li> <li>Product quality &amp; safety</li> </ul>	<ul style="list-style-type: none"> <li>Reputation &amp; social perception</li> <li>Working capital</li> <li>Return on asset</li> <li>R&amp;D funding and new product introduction</li> <li>Loss of key partner relationships</li> <li>Increased debt</li> <li>Revenue loss</li> <li>Operating margin</li> <li>Loss of products</li> <li>Return on investment</li> <li>Regulatory fines, plant shut-downs, consent decree</li> </ul>	<ul style="list-style-type: none"> <li>Reputation &amp; social perception</li> <li>Shareholder value</li> <li>Loss of market share</li> <li>R&amp;D funding and new product introduction</li> <li>Loss of manufacturing assets</li> <li>Inadequate capacity</li> <li>Long term strategy</li> <li>Loss of brand value</li> <li>Regulatory fines, plant shut-downs, consent decree</li> <li>Organization survival</li> </ul>

# Supply Chain Fraud & its Impact to Assessing Ethics

	Procurement	Inventory	Production	Distribution
Employee only	<ul style="list-style-type: none"> <li>• Phantom suppliers</li> <li>• False invoices</li> <li>• Redirection of delivery</li> <li>• Theft of intellectual property</li> </ul>	<ul style="list-style-type: none"> <li>• Theft of inventory</li> <li>• Fraudulent or improper inventory capitalization</li> </ul>	<ul style="list-style-type: none"> <li>• Theft of intellectual property</li> <li>• Inaccurate/falsified forecast of raw materials, spare parts or finished goods</li> </ul>	<ul style="list-style-type: none"> <li>• Theft of finished goods</li> <li>• Mark up transport costs</li> <li>• Falsified distribution records</li> </ul>
Employee & External Party	<ul style="list-style-type: none"> <li>• Bribery/kickbacks</li> <li>• Conflict of interest</li> <li>• Collusion in bidding</li> <li>• Unnecessary/ excess orders</li> <li>• Duplicate ordering</li> </ul>	<ul style="list-style-type: none"> <li>• Bribes from subcontractor</li> <li>• Invoices for goods not received</li> </ul>	<ul style="list-style-type: none"> <li>• Theft of intellectual property</li> <li>• Bribery of government employees</li> </ul>	<ul style="list-style-type: none"> <li>• Collusion with transporters</li> <li>• Channel stuffing</li> <li>• Theft of intellectual property</li> <li>• Theft of finished goods</li> </ul>
External Party i.e. Supplier/ Distributor Competitor	<ul style="list-style-type: none"> <li>• Bribery of third party</li> <li>• Improper government relationship</li> </ul>	<ul style="list-style-type: none"> <li>• Bribery of subcontractors</li> <li>• Inflated or fictitious invoices</li> </ul>	<ul style="list-style-type: none"> <li>• Unqualified consultants</li> <li>• Misrepresentation of technical capability and/or capacity by suppliers/vendors</li> </ul>	<ul style="list-style-type: none"> <li>• Distribution of counterfeit products by competitors</li> <li>• Bribery of customers by competitors</li> </ul>

# Supply Chain Risk Profiling — overview

Independence, objectivity and intellectual honesty are key to a valuable profile



# Supply Chain Risk Profiling— 3<sup>rd</sup> Party Risk Evaluation Framework

## Evaluating Ethics Risk Within Broader Context

Results of interviews with:

	Spend Amount and Type	Contract Type/Complexity	# of Subcontractors	Anti-Corruption Risk	Relationship Origin/Quality	Business Intelligence Results / Issues	Legal & Org Structure	Operations	A/P	Procurement	Compliance	Internal Audit
Vendor 1												
Vendor 2												
Vendor 3												
Vendor 4												
Vendor 5												
Vendor 6												
Vendor 7												
Vendor 8												

For illustrative purposes only

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## PSCI PRINCIPLES

### What we expect from our suppliers

- Business integrity and fair competition
- No corruption, extortion or embezzlement
- No bribes
- Compliance with anti-trust/competition laws
- Accurate and truthful advertising



### Identification of Concerns

- Workers encouraged to raise or report on concerns/illegal activities without fear of retaliation
- Suppliers should investigate and take corrective action, as needed, on issues raised

- A Code of Conduct/Standard Operating Procedures (SOPs)
- Training
- Management support
- Means to raise concerns (helpline, etc.)
- Act on issues raised: investigate, discipline, report and correct
- Audit/monitor
- Accurate books and records

# UNDERSTANDING ETHICAL ISSUES IN THE MANUFACTURING PLANT

- Accounting irregularities
- Conflict of interest
- Corruption or fraud
- Falsification of business records
- Import/export controls; customs
- Public/private partnerships

## UNDERSTANDING ETHICAL ISSUES IN THE MANUFACTURING PLANT

- Payments, gifts and benefits provided to healthcare professionals, patients, government officials or medical institutions
- Political contributions or lobbying
- Regulatory compliance (e.g., Quality, EHS )
- Procurement/PSM (direct and indirect suppliers)

# US LAW - OVERVIEW

## 2 key principles

Do not buy  
business or  
influence

Record  
payments  
accurately

**Do not give, pay, offer, promise or authorize the payment (directly or indirectly) of **anything of value** to a Healthcare Professional or a government official, to obtain or retain business or secure an unfair competitive advantage**

- Receiving kickbacks
- Slush funds
- Conflict of interests
  - VENDORS
    - Distributors
    - Custom brokers
    - Freight forwarders
    - Suppliers
    - Other agents or contractors

## NOTE...

- PSCI Audit questions focus on whether there are processes and procedures
- If possible, through interviews and document reviews, try to get evidence that such processes are actually followed
- Example questions:
  - Available helpline to raise issues; or through HR or impartial party
  - How are issues handled; number of calls handled within the past 2 years
  - Procurement system safeguards
  - Gifts allowed and when; value of gifts
  - Does management inquire if permits are quickly obtained? Off-site events with regulators
  - How does management balance between budget and production constraints and “doing the right thing” even if there is a cost
  - Incentives; targets; and tone from the top and middle

# FROM THE PSCI AUDIT QUESTIONNAIRE

MANAGEMENT SYSTEMS Self-Assessment Questionnaire - Questions marked with an asterisk (*) are for information only and should not be considered for potential findings by the auditor.		Auditor Verification
		Please provide observations, details, comments and any supporting documents
<b>Commitment and Accountability</b>		
1*	<p>Does the facility have any ethics, labor, environment, health and safety management system accreditations, certifications, or awards?</p> <p>OHSAS 18001 Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>ISO 14001 Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>ISO 50001 Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>SA 8000 Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Investors in people Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Other (e.g. Awards, OSHA VPP, EMAS) please list: _____</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p>
2	<p>Does management engage employees in open two-way communication? (e.g. Town Hall meetings, employee surveys, management factory rounds, management-employees Q&amp;A sessions)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please explain: _____</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p>
<b>Legal and Customer Requirements</b>		
3*	<p>Are there any issues related to Ethics, Labor, Environment, Health, and Safety (HSE) Regulatory Compliance?</p> <p>Is there any ongoing litigation or regulatory notices with respect to regulatory compliance? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Are there any historical major regulatory actions? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Any continuous / prolonged situations where regulatory compliance requirements are exceeded (within the past 12 months)? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please explain: _____</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p>
4	<p>Does the facility assess ongoing compliance with Health, Safety, and Environment, Business Ethics issues, and Labor regulations?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please explain: _____</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p>
5	<p>Does the facility ensure that suppliers and service providers operate good practices with regard to the PSCI Principles (i.e., labor, ethics, environment, health &amp; safety, and management systems)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, how? By on-site assessment / audit:</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p>



# FROM THE PSCI AUDIT QUESTIONNAIRE

ETHICS Self-Assessment Questionnaire - Questions marked an asterisk (*) are for information only and should not be considered for potential findings by the auditor.		Auditor Verification Please provide observations, details, comments and any supporting documents
<b>Business Integrity and Fair Competition</b>		
14	<p>Does the facility have formal ethics policies or Codes of Conduct that govern company and employee business practices?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please indicate if the following are included:</p> <p>Business integrity and fair competition <input type="checkbox"/></p> <p>Anti-corruption <input type="checkbox"/></p> <p>Investigation of employee concerns <input type="checkbox"/></p> <p>Privacy <input type="checkbox"/></p> <p>Please provide a web link to the policy on your web site, or alternatively attach a copy of the policy to this questionnaire.</p> <p>Comments: _____</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p> <p>Link or policy provided: Yes <input type="checkbox"/> No <input type="checkbox"/></p>
15	<p>Does the facility have tools or processes to prevent corruption and facilitation payments?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please explain: _____</p> <p>If yes, are the following elements included:</p> <ul style="list-style-type: none"> <li>- policy communicated to all employees Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>- periodical training Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>- effective monitoring system Yes <input type="checkbox"/> No <input type="checkbox"/></li> </ul>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p>
16	<p>Does the facility have tools or processes to support fair competition within the market of operation/business environment? (*Please note, fair competition refers to competing companies, not competition between employees)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please explain: _____</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p>
17	<p>Does the facility have a policy about employees receiving gifts or favors from external companies with whom your company does business?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please explain: _____</p> <p>Please provide a web link or attach a copy of the policy to this questionnaire.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p> <p>Link or policy provided: Yes <input type="checkbox"/> No <input type="checkbox"/></p>
18	<p>Is there a company policy on giving gifts and favors to Government officials / external companies / individuals that your company does business with?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Please explain: _____</p> <p>Please provide a web link or attach a copy of the policy to this questionnaire.</p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Comments _____</p> <p>Link or policy provided: Yes <input type="checkbox"/> No <input type="checkbox"/></p>

# FROM THE PSCI AUDIT QUESTIONNAIRE

Identification of Concerns			
19	Does the facility have practices to encourage employees to report concerns without fear of reprisal and ensure concerns are formally investigated?	Yes <input type="checkbox"/> No <input type="checkbox"/> Please explain: <input type="text"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Comments <input type="text"/>
Privacy			
20	Does the facility ensure confidentiality and privacy of information concerning companies, individuals, workers, patient rights and intellectual property?	Yes <input type="checkbox"/> No <input type="checkbox"/> Please explain: <input type="text"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> Comments <input type="text"/>
Animal Welfare			
21	Does the facility work with animals as a part of their business?	Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, do you follow an industry standard to ensure that animals are treated humanely and to reduce the number of animal tests (e.g. Association for Assessment and Accreditation of Laboratory Animal Care International). Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please indicate the Standard utilized: <input type="text"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> Comments <input type="text"/>

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For more information about the PSCI please contact:

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**carnstone**  
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