The Pharmaceutical Supply Chain Initiative (PSCI):

Evaluating supplier ethics and compliance practices and programs
AGENDA

Welcome

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Questions
SPEAKERS

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PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

JUL 18 PSCI CAPABILITY PROGRAMME WEBINAR
AGENDA

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Questions
INFLUENCING CORRUPTION IN PHARMACEUTICAL SUPPLY CHAINS

PSCI WEBINAR, 25 JULY 2018

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
THE FISH ROT FROM THE HEAD DOWN
VALUE SUPPLY CHAIN
PUTTING YOUR MONEY WHERE IT MATTERS

Adapted from A. Wierzynska
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 where 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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Pharmaceuticals and Healthcare Programme

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Questions
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.

- **87%** of respondents have faced a disruptive incident with third parties in the last 2-3 years...
- **28%** faced major disruption...
- **11%** experienced a complete third party failure

Only 20% of respondents have integrated extended enterprise risk management systems in a year or more, however, 50% aspire to do so in the next 3 years.

- **94.3%** of respondents have only low to moderate confidence in the tools and technology used to manage third party risk and **88.6%** have a similar level of confidence in the underlying risk management processes, despite significantly higher levels of confidence in organizational commitment and governance frameworks – creating the execution gap.

*Source: Deloitte Extended Enterprise Risk Management global survey 2016*
*Deloitte Extended Enterprise Risk Management global survey 2018*
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**

<table>
<thead>
<tr>
<th>Chronic</th>
<th>Acute</th>
<th>Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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 though proactive risk sensing and BCP.</td>
<td>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.</td>
</tr>
</tbody>
</table>

### Characteristics

- COGS variances
- Cash-to-cash cycle time
- Obsolete/ slow inventory
- Returns management cost
- Production changes and asset efficiency
- Lead time changes and logistics volatility
- Production & supply chain flexibility
- Schedule adherence and forecast volatility
- Production variances and order fill rates
- Return on assets
- Stock outs
- Product quality & safety

### Examples

- Reputation & social perception
- Working capital
- Return on asset
- R&D funding and new product introduction
- Loss of key partner relationships
- Increased debt
- Revenue loss
- Operating margin
- Loss of products
- Return on investment
- Regulatory fines, plant shut-downs, consent decree
- Organization survival
- Reputation & social perception
- Shareholder value
- Loss of market share
- R&D funding and new product introduction
- Loss of manufacturing assets
- Inadequate capacity
- Long term strategy
- Loss of brand value
- Regulatory fines, plant shut-downs, consent decree
- Organization survival
# Supply Chain Fraud & its Impact to Assessing Ethics

## Procurement
- Phantom suppliers
- False invoices
- Redirection of delivery
- Theft of intellectual property

## Inventory
- Theft of inventory
- Fraudulent or improper inventory capitalization

## Production
- Theft of intellectual property
- Inaccurate/falsified forecast of raw materials, spare parts or finished goods

## Distribution
- Theft of finished goods
- Mark up transport costs
- Falsified distribution records

<table>
<thead>
<tr>
<th>Employee only</th>
<th>Procurement</th>
<th>Inventory</th>
<th>Production</th>
<th>Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Phantom suppliers • False invoices • Redirection of delivery • Theft of intellectual property</td>
<td>• Theft of inventory • Fraudulent or improper inventory capitalization</td>
<td>• Theft of intellectual property • Inaccurate/falsified forecast of raw materials, spare parts or finished goods</td>
<td>• Theft of finished goods • Mark up transport costs • Falsified distribution records</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Employee &amp; External Party</th>
<th>Procurement</th>
<th>Inventory</th>
<th>Production</th>
<th>Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Bribery/kickbacks • Conflict of interest • Collusion in bidding • Unnecessary/excess orders • Duplicate ordering</td>
<td>• Bribes from subcontractor • Invoices for goods not received</td>
<td>• Theft of intellectual property • Bribery of government employees</td>
<td>• Collusion with transporters • Channel stuffing • Theft of intellectual property • Theft of finished goods</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>External Party i.e. Supplier/Distributor Competitor</th>
<th>Procurement</th>
<th>Inventory</th>
<th>Production</th>
<th>Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Bribery of third party • Improper government relationship</td>
<td>• Bribery of subcontractors • Inflated or fictitious invoices</td>
<td>• Unqualified consultants • Misrepresentation of technical capability and/or capacity by suppliers/vendors</td>
<td>• Distribution of counterfeit products by competitors • Bribery of customers by competitors</td>
</tr>
</tbody>
</table>
Independence, objectivity and intellectual honesty are key to a valuable profile

**Step 1**
Obtain basic details relating to the procurement/supply chain ecosystem based on tailored procurement questionnaire

**Step 2**
Based on the responses, “risk rank” vendors based on identified select characteristics and preliminary results

**Step 3**
Conduct further deep dive into identified high-risk vendors based on the risk ranking process and conduct interviews with stakeholders to develop a robust vendor selection framework

**Step 4**
Select the high risk vendors from the vendor selection framework/matrix and apply supply chain forensics
### Evaluating Ethics Risk Within Broader Context

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Spend Amount and Type</th>
<th>Contract Type/Complexity</th>
<th># of Subcontractors</th>
<th>Anti-Corruption Risk</th>
<th>Relationship Origin/Quality</th>
<th>Business Intelligence</th>
<th>Legal &amp; Org Structure</th>
<th>Operations</th>
<th>A/P</th>
<th>Procurement</th>
<th>Compliance</th>
<th>Internal Audit</th>
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<tbody>
<tr>
<td>Vendor 1</td>
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<td>Vendor 4</td>
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<td>Vendor 5</td>
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<td>Vendor 6</td>
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<td>Vendor 7</td>
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<td>Vendor 8</td>
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</tbody>
</table>

For illustrative purposes only
AGE N D A

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Questions
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)
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
VENDOR RISKS

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

<table>
<thead>
<tr>
<th>Commitment and Accountability</th>
<th>Auditor Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the facility have any ethics, labor, environment, health and safety management system accreditations, certifications, or awards?</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>GHAS 16001 Yes ☑ No ☐</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>ISO 14001 Yes ☑ No ☐</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>ISO 60001 Yes ☑ No ☐</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>SA 8000 Yes ☑ No ☐</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>Investors in people Yes ☑ No ☐</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>Other (e.g. Awards, OSHA VPP, EMAS) please list: ___________________________________________</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. 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)</th>
<th>Yes ☑ No ☐ Please explain: ______________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☑ No ☐ Please explain: ______________________</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Legal and Customer Requirements</th>
<th>Auditor Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Are there any issues related to Ethics, Labor, Environment, Health, and Safety (HEC) Regulatory Compliance?</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>Is there any ongoing litigation or regulatory notices with respect to regulatory compliance?</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>Yes ☑ No ☐ Are there any historical major regulatory actions?</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>Yes ☑ No ☐ Any continuous / prolonged situations where regulatory compliance requirements are exceeded (within the past 12 months)?</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>No ☐ Please explain: ___________________________________________________________________________________________</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Does the facility assess ongoing compliance with Health, Safety, and Environment Business Ethics issues, and Labor regulations?</th>
<th>Yes ☑ No ☐ Please explain: ______________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☑ No ☐ Please explain: ______________________</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. 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)?</th>
<th>Yes ☑ No ☐ Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☑ No ☐ If yes, how? By on-site assessment / audit: ______________________________________________________________________</td>
<td>Yes ☑ No ☐ Comments</td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----</td>
</tr>
<tr>
<td>14. Does the facility have formal ethics policies or Codes of Conduct that govern company and employee business practices?</td>
<td>Yes</td>
</tr>
<tr>
<td>If yes, please indicate if the following are included:</td>
<td></td>
</tr>
<tr>
<td>Business integrity and fair competition</td>
<td></td>
</tr>
<tr>
<td>Anti-corruption</td>
<td></td>
</tr>
<tr>
<td>Investigation of employee concerns</td>
<td></td>
</tr>
<tr>
<td>Privacy</td>
<td></td>
</tr>
<tr>
<td>Please provide a web link to the policy on your website, or alternatively attach a copy of the policy to this questionnaire.</td>
<td></td>
</tr>
<tr>
<td>15. Does the facility have tools or processes to prevent corruption and facilitation payments?</td>
<td>Yes</td>
</tr>
<tr>
<td>Please explain:</td>
<td></td>
</tr>
<tr>
<td>If yes, are the following elements included:</td>
<td></td>
</tr>
<tr>
<td>- Policy communicated to all employees</td>
<td>Yes</td>
</tr>
<tr>
<td>- Periodic training</td>
<td>Yes</td>
</tr>
<tr>
<td>- Effective monitoring system</td>
<td>Yes</td>
</tr>
<tr>
<td>16. 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)</td>
<td>Yes</td>
</tr>
<tr>
<td>Please explain:</td>
<td></td>
</tr>
<tr>
<td>17. Does the facility have a policy about employees receiving gifts or favors from external companies with whom your company does business?</td>
<td>Yes</td>
</tr>
<tr>
<td>Please explain:</td>
<td></td>
</tr>
<tr>
<td>Please provide a web link or attach a copy of the policy to this questionnaire.</td>
<td></td>
</tr>
<tr>
<td>18. Is there a company policy on giving gifts and favors to Government officials/external companies/individuals that your company does business with?</td>
<td>Yes</td>
</tr>
<tr>
<td>Please explain:</td>
<td></td>
</tr>
<tr>
<td>Please provide a web link or attach a copy of the policy to this questionnaire.</td>
<td></td>
</tr>
<tr>
<td>Identification of Concerns</td>
<td>Yes □ No □</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>19 Does the facility have practices to encourage employees to report concerns without fear of reprisal and ensure concerns are formally investigated?</td>
<td>Yes □ No □</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Privacy</th>
<th>Yes □ No □</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 Does the facility ensure confidentiality and privacy of information concerning companies, individuals, workers, patient rights and intellectual property?</td>
<td>Yes □ No □</td>
<td>Comments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Animal Welfare</th>
<th>Yes □ No □</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 Does the facility work with animals as a part of their business?</td>
<td>Yes □ No □</td>
<td>Comments</td>
</tr>
</tbody>
</table>

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 □ No □ 
If yes, please indicate the Standard utilized: □
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Questions?
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