

# Pharmaceutical Supply Chain Initiative (PSCI)

## PRE-AUDIT DOCUMENT REQUEST LIST

	Available	Not Available	Not Applicable
<b>1 General Management Systems</b>			
Organization chart			
Site drawings showing: <ul style="list-style-type: none"> <li><input type="checkbox"/> property borders,</li> <li><input type="checkbox"/> tanks,</li> <li><input type="checkbox"/> detailed building layouts</li> <li><input type="checkbox"/> hazardous chemicals, solvents, oils and wastes storage,</li> <li><input type="checkbox"/> stacks and vents</li> <li><input type="checkbox"/> buried services (pipes, drains, sewers)</li> <li><input type="checkbox"/> buried tanks</li> <li><input type="checkbox"/> sumps, pits, oil separators</li> <li><input type="checkbox"/> lagoons and any points of discharge to local watercourses</li> <li><input type="checkbox"/> on site waste disposal areas (used and abandoned and disused)</li> </ul>			
Site HSE policies and programs			
Management of change documentation			
Inspection and follow-up records			
Compliance self-assessment reports			
HSE training records			
Incident and Emergency Response Plans.			
Roles and responsibilities matrix			
Previous audit reports			
Reports of regulatory agency inspections and enforcement actions			
Regulatory agency correspondence			
Copies of previous social and HSE audits/review reports			
Details and outcome of complaints if any (plus			

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correspondence).			
Government Inspection reports, e.g. sanitation, fire safety, structural safety, environmental compliance, etc			
<b>2 ENVIRONMENT – General</b>			
Correspondence with authorities relating to any environmental violations and pollution incidents (air, water, effluent, wastes, odor and noise).			
Emission Reduction Plan			
Waste reduction plan			
Spill, incident and upset reports			
Documented procedures and operating manuals relating to environmental matters (e.g. emergency response, spill containment, waste handling and disposal).			
<b>3 AIR EMISSIONS</b>			
All current air permits			
Air monitoring data for the past 36 months			
Air emissions inventory			
Air emissions reports submitted to regulatory agencies			
Copies of any violation notices received in the past three years			
Copies of any federal/national, state/provincial and/or local emissions standards			
Chlorofluorocarbon compounds (CFC) equipment maintenance records			
Air pollution abatement equipment maintenance records			
<b>4 WATER SUPPLY, STORM WATER, AND WASTEWATER</b>			
Wastewater discharge permits			
Wastewater discharge inventory			
Wastewater sewer drawings			
Wastewater treatment permits			
Wastewater discharge monitoring data/reports for flow and permit parameters for last 36 months			
Wastewater treatment plant maintenance records and as-built drawings			
Site's water balance			
Water abstraction permits			

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Storm water discharge permits			
Water supply drawings			
Storm water sewer drawings			
Copies of violation notices received in the past three years			
Well construction diagrams for on-site water supply or groundwater monitoring wells			
Water quality analyses from water supply or groundwater monitoring wells for the past 36 months			
List of active pharmaceutical ingredients (API) being discharge in the waste water and a list of known Predicted No Effects Concentration Levels for these APIs.			
Copies of waste water risk assessment studies detailing the Predicted Exposure Concentration of API discharges and potential impact evaluations			
<b>5 WASTE MANAGEMENT</b>			
Waste inventory			
Waste transport and disposal documentation (manifests, receipts, invoices)			
Waste generation, storage, treatment or disposal permits or registrations			
Disposal records of halons, refrigerants, PCBs and asbestos including costs			
Any waste-related reports to regulatory authorities			
Copies of violation notices received in the past three years			
Waste storage area Inspection records			
Waste analyses and classification determinations			
<b>6 HAZARDOUS MATERIALS CONTROL AND REPORTING</b>			
Tank inventory (number, location , age, construction, volume, content, alarms, vent pumps and cathode protection fitted to bulk tanks			
Documented procedures for filling and unloading bulk storage tanks			
Procedures and records for tank maintenance - integrity testing (bulk tanks and pipe work) etc			
Hazardous material inventory			
Tank and containment inspection records			
Tank integrity and tightness test records			

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Drum management plan			
Spill response plans			
Hazardous materials reports (e.g., Tier II, Form R, NPRI)			
Copies of spill and release notifications or reports and remediation			
Hazard communication training records			
<b>7 ASBESTOS, PCBs AND OZONE-DEPLETING SUBSTANCES</b>			
Asbestos survey			
Inventory of asbestos-containing materials			
Records of asbestos abatement and disposal			
Polychlorinated Biphenyl (PCB)-containing equipment inventory			
PCB test results from analysis on electrical equipment			
Pesticide inventory			
<b>8 HEALTH &amp; SAFETY DOCUMENTATION</b>			
Summary of occupational injuries and illnesses for the past 3 years			
Permit to Work program			
Lockout/tagout program			
Hazard communication program			
Respiratory protection program			
Industrial hygiene monitoring results			
Personal protective equipment program			
Hot Work Program			
Noise, chemical, or indoor air quality monitoring data			
Hearing Conservation Program and Test Records			
Bloodborne Pathogens Program and Records			
Confined Space Entry Program and Permits			
Fire protection plan			
Piping & Instrumentation Diagrams			
Hazard Area Classification			
Basis of Safety			
Health and Safety training records			

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Radioactive material inventory and licenses			
Safety Inspection Reports			
Safety Manual			
Records of baseline physical examinations and periodic examinations.			
Medical Surveillance program			
Risk assessment reports demonstrating characterization of the toxicity of Active Pharmaceutical Ingredients and the protection requirements for employee exposure to APIs			
<b>9 LABOR DOCUMENTATION</b>			
Labor contracts			
Labor standards policies/Codes of Conduct including: <ul style="list-style-type: none"> <li>▪ Non discrimination</li> <li>▪ Fair compensation</li> <li>▪ Working hours freedom of association</li> <li>▪ Child Labor</li> <li>▪ etc</li> </ul>			
Employee handbook (terms and conditions of employment)			
Collective Bargaining Agreements (cba)			
Child labor policies			
Wage and hours of work (pay slips, overtime records)			
Disciplinary policies and practices			
Benefits and allowances			
Discrimination and harassment policies			
Home workers, outworkers and Sub-contractors policies			
Time records for the past 36 months			
Payroll records for past 36 months			
Piece rate records for the past 36 months (if applicable)			
Insurance, tax and other required receipts			
Minutes of joint committees on HS and disciplinary matters			
<b>10 ETHICS</b>			
Policy/Codes of Conduct.			
Business integrity & fair competition			

	<b>Available</b>	<b>Not Available</b>	<b>Not Applicable</b>
Anti-corruption			
Investigation of employee concerns			
Policy on Animal Testing			