

Pharmaceutical Supply Chain Initiative (PSCI) Corrective Action Plan Report (CAPR) for PSCI Audit at Supplier

AUDITOR AND AUDIT REPORT INFORMATION

Report Number:	Redacted		
Date of audit:	Redacted	Date and type of previous audit:	Redacted
Audit Firm Name:	Redacted		
Lead Auditor Name:	Redacted	Title:	Redacted
Names of other auditors	Redacted	Title:	Redacted
International Phone Number:	Redacted	Email Address:	Redacted

FACILITY DETAILS

Company Name:	Redacted		
Parent Company Name (if applicable)	Redacted		
Street Address:	Redacted		
City:	Redacted	Site State/Province/County:	Redacted
Postal/Zip Code:	Redacted	Site Country:	Redacted

Facility Background Information

<p>Please indicate which of the following best describes this facility (check all that apply):</p>	<input type="checkbox"/> API (Drug substance and intermediates) <input type="checkbox"/> Drug product <input type="checkbox"/> Primary Packaging <input type="checkbox"/> Secondary Packaging, <input type="checkbox"/> Distribution, <input type="checkbox"/> Biological manufacture, <input type="checkbox"/> Chemical <input type="checkbox"/> R&D <input type="checkbox"/> Service provider <input checked="" type="checkbox"/> Other (describe) Redacted
<p>Describe type of work currently being, or proposed to be, performed at this facility, and product type(s):</p>	Redacted

SITE CONTACT INFORMATION

Site Representative Name (host):	Redacted	Title:	Redacted
International Phone Number:	Redacted	Email Address:	Redacted

PSCI Supplier Corrective Action Plan Report (CAPR)

Findings, Corrective Actions and Follow-up

Finding Number <i>The reference number of the Finding from the Audit Report</i>	PSCI Principle <i>(e.g. Ethics, Management Systems)</i>	Finding Type (Critical, Other) <i>Please state whether Critical, Other finding</i>	Description of Finding <i>(as done in the PSCI Audit Report)</i>	Agreed Corrective Actions <i>Details of actions to follow up on the Findings</i>	Recommended Completion Timescale <i>Timescale (Immediate, 30, 60, 90, 180, 365 days)</i>	Verification Method <i>Desktop / Follow-Up Visit</i>	Agreed by Management and Name of Responsible Person: <i>Note if management agree to the Finding, and document name of responsible person</i>	Verification Evidence and Comments <i>Details on corrective action evidence</i>	Status <i>Open/Closed or comment</i>
No. 1 Q 3	Management System Legal and Customer Requirements	Minor	The company did not assess ongoing compliance with Health, Safety, and Environment, Business Ethics issues, and Labor regulations. Labor and Ethics regulations are not included in the list of laws and regulations of the company.	The company should identify all related law and regulations and assess the effectiveness of the company Health, Safety, and Environment, Business Ethics issues, and Labor practices and programs.	90	Desktop			
No. 2. Q 4	Management System Legal and Customer Requirements	Minor	The company did not systematically evaluate its suppliers' practices around Labor, Ethics, Environment, Health & Safety aspect by on-site assessment/audit or desk-top assessment (e.g. questionnaires).	The company should establish processes to enforce responsible business practices, aligned with the PSCI Principles, with their suppliers, i.e. Labor, Ethics, Environment, Health & Safety.	90	Desktop			
No.3 Q 5	Management System Risk Management	Major	There was no systematically policies or practices in place to risk assess their programs and potential business impacts on reputation risks and legal risk.	The company should establish policies and/or practices in place to risk assess their programs and potential business impacts including business interruption risks, reputation risks and legal risk.	180	Follow Up			

No.4 Q 6	Management System Risk Management	Minor	The Change Control Procedure of company did not consider the impact from changes on Ethics and Labor aspects, and the procedure was not implemented.	The Change Control Procedure should consider the impact from changes on HSE, Ethics and Labor aspects.	90	Desktop			
No. 5 Q 11	Management System Continual Improvement	Minor	The company did not have formal processes and procedures to assess the effectiveness of its labor, ethics and HSE practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions. No regular internal audit, corrective action plan tracking or management review conducted.	The company should conduct regular internal audit, corrective action plan tracking or management review to to assess the effectiveness of its labor, ethics and HSE practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions.	180	Desktop			
No.6 Q 12	Ethics Business Integrity and Fair Competition	Minor	The current ethics policies did not cover fair competition, investigation of employee concerns.	The company should improve the current ethics policy to cover fair competition, investigation of employee concerns.	90	Desktop			
No.7 Q 16	Labor General	Major	The company did not have a policy regarding Prohibition of child labor, freely chosen employment, freedom of association, non-discrimination, Grievance mechanism, Whistle blower reporting and anti-retaliation policy, Anti-Human Trafficking, Freedom of Movement, etc.	The company should improve the current labor management system to include all required policies, regarding Prohibition of child labor, freely chosen employment, freedom of association, non-discrimination, Grievance mechanism, Whistle blower reporting and anti-retaliation policy, Anti-Human Trafficking, Freedom of Movement, etc.	90	Desktop			

No. 8 Q 17	Labor Freely Chosen Labor	Major	The company did not perform a risk assessment to determine if there are areas of their business at risk for forced, bonded, or involuntary prison labor.	The company should perform a risk assessment to determine if there are areas of their business at risk for forced, bonded, or involuntary prison labor.	90	Desktop			
No. 9 Q 21	Labor Child Labor and Young Workers	Major	The company did not establish any employment procedure regarding the policy of "Prohibition of child labor" and "Child labor remediation".	The company should establish any employment procedure regarding the policy of "Prohibition of child labor" and "Child labor remediation" in case any child labor detected.	90	Desktop			
No. 10 Q 23	Labor Non-Discrimination and Fair Treatment	Minor	The company did not establish any policy regarding anti-discrimination. And related non-discrimination training could not be provided to the employees.	The company should establish policy regarding anti-discrimination and communicate it with the employees.	90	Desktop			
No. 11-1 Q 24	Labor	Major	Based on the company policy, the overtime work on weekday will be just exchanged for deferred rest instead of be paid for overtime wage. For example, 1 out of 10 sampled employees have worked overtime on weekdays for 130 hours since January 2019, but 57 out of 130 hours have been exchanged for deferred rest, the other 73 hours overtime have been not paid. Besides, based on company policy, the overtime worked will be calculated by hour, overtime less than 1 hour will not be accounted or paid. Law reference: Article 44 of the Labor Law of the PRC	The company should ensure employees are properly compensated for all overtime worked.	180	Follow Up			

No. 11-2 Q 24	Labor Wages, Benefits, and Working Hours	Major	Based on 10 sampled workers' time records of May 2019, August 2019 and November 2019, 1 out of 10 sampled workers exceeded the daily overtime working hours limited of 3 hours per day in November 2019, August 2019 and May 2019 respectively, the maximum daily overtime working hours were 5 hours per day in August 2019; none out of 10 sampled workers exceeded the monthly overtime working hours limited of 36 hours per month in November 2019, 3 out of 10 sampled workers exceeded the monthly overtime working hours limited of 36 hours per month in August 2019, 3 out of 10 sampled workers exceeded monthly overtime working hours limited of 36 hours per month in May 2019, the maximum monthly overtime hours are 99 hours per month in August 2019. Law reference: Article 41 of the Labor Law of the PRC	The company should ensure that employee overtime hours do not exceed the statutory limits.	180	Desktop			
No. 12 Q 25	Labor Wages, Benefits, and Working Hours	Major	Based on 10 sampled workers' time records of May 2019, August 2019 and November 2019, 2 out of 10 sampled workers worked consecutively for 9-14 days in November 2019, 3 out of 10 sampled workers worked consecutively for 7-10 days in August 2019, 3 out of 10 sampled workers worked consecutively for 9-19 days in May 2019. Law reference: Article 38 of the Labor Law of the PRC	The company should ensure that employees have at least one day off every seven consecutive days.	180	Desktop			
No. 13 Q 26	Labor	Major	Based on company employee manual, it was noted that employees would be fined if they	The company should abolish the Monetary fine policy.	90	Desktop			

	Wages, Benefits, and Working Hours		violated factory's rules, such as fine RMB 50 for swipping attendance card for others, fine RMB 50 once for being late for work more than three times, and etc. But no actual case happened during the reviewing of samples. Law reference: Article 50 of the Labor Law of the PRC						
No. 14 Q 27	Labor Wages, Benefits, and Working Hours	Minor	The wages due were paid to employees on next pay day (within one month). Law reference: Article 7 of Regulations of the Shanghai city on the wage payment to employees	The company should ensure that resigned / terminated employees are properly compensated per legal requirement.	180	Desktop			
No.15 Q 30	Labor Logistics Subcontractors	Minor	The company did not establish process for managing human rights risks at third party logistics (3PL) providers, including not assess 3PL's process on monitoring subcontractors.	The company should establish process for managing human rights risks at third party logistics (3PL) providers.	180	Desktop			
No.16 Q36	Environment Protection Environmental Authorizations	Major	1) Site 1 operated on Aug 2019 after renovation, but the company did not receive the environmental inspection and final approval, the company did not monitor the wastewater and air emission yet and did not receive the full pollutant discharge permit. 2) Site 2 renovation project was on going, the EIA was ongoing by 3rd party, but not completed yet by now.	1)The company should monitor the air emission and wastewater, pass the environment inspection from authority for site 1 and receive the pollutant discharge permit. 2)The company should complete the EIA for site 2 asap.	180 days	Desktop			
No.17 Q39	Environment Protection	Minor	The company did not establish the wastewater treatment procedure to manage the wastewater.	The company should establish the wastewater treatment	60 days	Desktop			

	Waste and Emission			procedure to manage the wastewater.					
No.18 Q40	Environment Protection Waste and Emission	Minor	There was no air emission monitoring outlet for 5 new exhaust fans at roof.	The company should install the air emission monitoring outlet for 5 new exhaust fans at roof.	180 days	Follow up visit			
No.19 Q45	Environment Protection Spill and releases	Minor	1)Total 6 barrels of waste chemicals (20Litre each) were stored in 5cm high container. The spill containment system (about 2 Litre containment) cannot meet the requirement 2)There was no spill kit at Mass Spectrometry room and hazardous chemical storage room.	1)The company should expand the containment to meet the requirement. 2) The company should set the spill kit at Mass Spectrometry room and hazardous chemical storage room.	60 days	Follow up visit			
No.20 Q48	Health & safety General	Minor	The company had not the detail action plan and track the performance trend for the target.	The company should setup the detail action plan and track the performance trend for the target.	60 days	Desktop			
No.21 Q65	Health and Safety Occupational Health and Industrial Hygiene	Minor	There was no forced ventilation system for 5 flammable cabinets at room 135, chemical storage area.	The company should install the forced ventilation system for 5 flammable cabinets at room 135, chemical storage area.	60 days	Follow up visit			
No.22 Q68	Health and Safety Occupational Health and Industrial Hygiene	Major	The company did not perform the occupational health medical monitoring to new employee and health surveillance monitoring to present employee, including post job employee in 2019	The company should perform the occupational health monitoring to employee who exposed to hazardous chemicals annually.					
No.23 Q70	Health and Safety Occupational Health and	Major	1) The Nitrogen gas was widely used at the Mass Spectrometry room. But the company did not assess the risk of N2 leakage,	1)The company should assess the risk of N2 leakage risk, take action and establish	180 days	Follow up visit			

	Industrial Hygiene		take action and establish the n emergency response plan. 2) The company did not perform the site exposure monitoring for chemicals at lab for site 1. 3) The company did not receive the final inspection and acceptance for occupational health for site 1.	emergency response plan. 2)The company should perform the site exposure monitoring for chemicals at lab for site 1. 3)The company should pass the final inspection and acceptance for occupational health for site 1.					
No.24 Q71	Health and Safety Occupational Health and Industrial Hygiene	Minor	The company did not inform employees of the results of exposure evaluations and monitoring results. No occupational hazard notification was the labor contract.	The company should inform employees of the results of exposure evaluations and monitoring results and occupational hazard notification in the labor contract.	180 days	Desktop			
No.25 Q85	Health and Safety Emergency Preparedness and Response	Minor	The site 1 was put into use in Aug 2019 after renovation, but the company did not inspect the extinguisher regularly.	The company should inspect the extinguishers regularly.	30 days	Follow up visit			
No.26 Q86	Health and Safety Emergency Preparedness and Response	Minor	There was no fire alarm handling process at the company. The FM200 (HFC-227ea) fire system at archives room was on manual status.	The company should make sure the FM200 system on normal operation.	30 days	Follow up visit			
No.27 Q88	Health and Safety Emergency Preparedness and Response	Major	There was no evacuation map posted at the labs and office area.	The company should post the evacuation map at each area.	60 days	Follow up visit			
No.28 Q92	Health and Safety	Minor	1) There was no SDSs at chemical storage room (room 135)	1)The company should post the SDSs for the chemical storage room.	60 days	Follow up visit			

	Hazard information		2) There was no GHS labelling for compound chemicals at preparation room.	2)The company should post the GHS label for the compound chemicals.					
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Note:

Critical Observations: Are high or very high risk observations that *require immediate action* to protect human life, the health of employees or the environment; may result in loss of license to operate, damage to reputation. *A critical observation requires immediate corrective action by the supplier.*

Other Observations: Are observations that require corrective actions that are managed against a timeline commitment by the audited site.

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Confirmation

Must be signed by both parties and returned to PSCI@bsr.org within 30 days of on-site audit

Please sign this document confirming that the above findings have been discussed with and understood by you: (site management)

Site Representative Signature:	Redacted	Name: Redacted Title: Redacted Date: Redacted
Auditor Signature:	Redacted	Name: Redacted Title: Redacted Date: Redacted

Please indicate below if you, the site management, dispute any of the findings
I dispute the following numbered Findings:

None

Signed:	Redacted	Title: Redacted Date: Redacted
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Site Comments:

None