

Pharmaceutical Supply Chain Initiative (PSCI) Self Assessment Questionnaire for Pharmaceutical Industry Suppliers

制药工业负责的供应链制药工业供应商自我评估问卷

GUIDANCE FOR COMPLETION 完成指南

Companies are asked to complete all questions that apply. If a question does not apply please mark it NA (Not Applicable). **We would expect the following types of suppliers to complete all questions: API, Dosage Formulation, Chemicals, Intermediate Chemical manufactures**

供应商要求完成全部相关问题. 如果一个问题不适应, 请填入 NA. 我们期望所有提供以下物料的供应商完成全部问题: 制剂活性成分, 药品剂型, 化学制品, 化学品中间体生产产商

FACILITY DETAILS 企业详细信息

Company Name: 公司名称			
Parent Company Name (if applicable) 总公司名称(如适用)			
Street Address: 地址			
City: 城市		State/Province/County: 县/省	
Postal/Zip Code: 邮编		Country: 国家	

CONTACT INFORMATION FOR PERSON(S) COMPLETING THE QUESTIONNAIRE 完成问卷联系人信息

Name: 姓名		Title: 职务	
Phone Number: 电话		Email Address: 邮箱地址	
Date Completed: 完成日期			

Facility Background Information 企业背景信息

<p>Please indicate which of the following best describes this facility (check all that apply): 请说明以下描述那个更适合这个企业(说明所有适用的)</p>	<ul style="list-style-type: none"> API (Drug substance and intermediates) 制剂活性成分(药品和中间体) Drug product ****checkboxes 药物成品 Primary Packaging 初级包装 Secondary Packaging, 二级(成品)包装 Distribution, 发运 Biological manufacture, 生物制品生产 Chemical 化学制品 R&D 研发 Service provider 提供服务 Other (describe) 其它(请说明)
<p>Describe type of work currently being, or proposed to be, performed at this facility: 说明企业现在从事的或计划从事工作类型</p>	
<p>Please describe your EHS resources (number of staff or time spent on EHS): 请说明企业 EHS 资源(从事 EHS 工作的人员数量或时间)</p>	

Total Employee Population (including temporary/contract employees): 企业员工总数(包括临时和合同员工)		Total Full-Time Employees: 全制员个总数	
Total Part-Time Employees: 兼职员工总数		Total Temporary/Contract staff: 临时或合同员工总数	
Total Site Area: 现场总面积		Manufacturing Area: 生产区域面积	
Indicate if the site is in a rural, industrial, residential or mixed commercial setting 说明企业位于农业, 工业, 居民居住或混合商业区域			

Eth	Ethics 道德规范	Please provide details, comments and supporting documents 请提供详细描述和支持文件
1	<p>Does your facility have formal ethics policies or Codes of Conduct that govern company and employee business practices? If yes, what does it cover? (e.g. business integrity & fair competition, anti-corruption, investigation of employee concerns, privacy). If the policy is available on your web site, please provide a link, or attach a copy to this questionnaire.</p> <p>企业是否有正式道德规范方针或行为准则来管理公司和员工业务行为规范? 如果有,包括哪些内容? (例如: 业务中正直诚实, 公平竞争, 反对腐败, 调查员工关心问题, 商业机密) 如果这些政策在企业的网站上, 请提供网址, 或提供附件.</p>	
2	<p>What issues have you had regarding ethics in the past 3 years? 过去三年期间企业在道德规范方面有什么问题?</p>	
3	<p>How do you encourage employees to report concerns without fear of reprisal? Please explain.</p> <p>企业是否鼓励员工报告相关问题不担心被报复? 请解释</p>	
4	<p>What tools or processes have you implemented to prevent corruption? 企业实施什么工具或流程来预防腐败?</p>	
5	<p>What tools or processes have you implemented to support fair competition?</p> <p>企业实施什么工具或流程来支持公平竞争?</p>	
6	<p>How do you ensure confidentiality and privacy of information concerning companies, individuals and intellectual property?</p> <p>企业如何保证公司,个人和知识产权相关信息的保密性?</p>	
7	<p>Under what circumstances or with what limits are employees allowed to receive gifts or favors from external companies with whom your company does business? If policy is available on your web site, please provide a link; alternatively, attach a copy of the policy.</p> <p>员工进行企业活动时, 在哪种情况下能够接受来自外部公司的礼品或馈赠或有何限制? 如果这些政策在企业的网站上, 请提供网址, 或提供附件.</p>	
8	<p>Does your facility work with animals as a part of your business?</p> <p>If yes, what industry standards do you follow to assure animals are treated respectfully/humanely and to reduce the number of animal tests?</p> <p>企业活动中是否使用动物? 如是, 企业依据什么标准确保友善对待动物? 并减少动物试验?</p>	

Lab	Labor 劳工	Please provide details, comments and supporting documents 请提供详细描述和支持文件
9	<p>Does your facility have a policy (or statement of commitment) regarding labor practices? If so, what does it cover? (e.g. freely chosen employment, child labor, non-discrimination, recruiting and termination, wages, benefits, working hours, overtime, and vacation). If policy is available on your web site, please provide a link, or attach the policy statement to this questionnaire</p> <p>企业是否有关于劳工的政策(或承担的义务声明)? 如有, 是否包括(如: 自由选取员工, 童工, 不歧视员工, 雇用和终止, 工资, 福利, 工作时间, 加班和休假)? 如果这些政策在企业的网站上, 请提供网址, 或提供附件.</p>	
10	<p>Do you keep any original documents belonging to employees (e.g., passports or birth certificates) during the term of employment? If yes, which documents and why?</p> <p>企业是否在雇用期间保存员工的原始文件(如: 护照, 身份证或出生证)? 如是, 保存哪些文件? 为什么?</p>	
11	<p>How do you prevent the use of child labor? What is the age of the youngest worker on site?</p> <p>企业如何避免使用童工? 最年轻的员工年龄是多少?</p>	
12	<p>Do you ensure that workers under age 18 are not involved in hazardous or overly hard work?</p> <p>企业是否保证年龄 18 岁以下的工人不从事危险或重体力劳动?</p>	
13	<p>Please describe any labor issues in the past 3 years, such as strikes, protests or work stoppages.</p> <p>请描述过去三年发生的劳工问题, 如罢工, 抗议或劳工纠纷.</p>	
14	<p>How do you ensure that there is no discrimination or harassment in the workplace? For example, how does your facility prevent harassment, coercion, threatening behavior, physical abuse, sexual abuse, or verbal abuse toward workers? How are employees trained on this?</p> <p>企业如何保证在工作区域没有歧视或被折磨? 例如: 如何预防对工人的折磨, 高压, 胁迫行为, 体罚, 性虐待或口头辱骂? 怎样对员工进行相关培训?</p>	
15	<p>How do you ensure fair working conditions for temporary workers and contractors?</p> <p>企业如何保证对临时人员和合同工采取公平的工作条件?</p>	
16	<p>Is overtime voluntary? How is overtime recorded and compensated?</p> <p>加班是否是自愿? 加班时间如何记录和补偿?</p>	
17	<p>How do you ensure that all wages are at or above the legal minimum? Please indicate the lowest wage paid at the facility and the legal minimum.</p> <p>企业如何保证所有工资在法律最低工作标准或以上? 请说明企业的最低工资和法律最低工资标准.</p>	
18	<p>To what extent do you provide housing and/or living expenses as partial or complete payment of wages for any employees?</p> <p>企业是否对员工住房或生活提供部分或全部工资补贴?</p>	

19	<p>Do workers have the right to join or not join labor unions, workers' councils, or other collective bargaining organizations? If no, please explain.</p> <p>员工是否有权利参加或不参加工会? 或其它工人组织? 如果不, 请解释.</p>	
20	<p>How does the facility ensure the provision of safe and potable drinking water and hygienic facilities to its employees?</p> <p>企业如何保证食品和饮用水安全及员工相关个人卫生?</p>	
21	<p>Do you disclose the terms and conditions of employment and termination to a new employee prior to hiring and in a language workers understand?</p> <p>新员工被雇用条款或解除员工条款使用的语言是否能让员工读懂?</p>	

Env	Environmental Compliance and Risk Management 环境合规和风险管理	Please provide details, comments and supporting documents 请提供详细描述和支持文件
22	Do you have an environmental policy? If yes, please attach or provide a link to it on your web site. 企业是否有环境方针? 如有, 请提供附件或网址链接	
23	Does the facility have written environmental procedures or programs? If yes, provide a list of titles. 企业是否有文字的环境管理程序或规程? 如有, 请提供目录清单	
24	Describe any formal environmental objectives or goals for performance improvement, including metrics and targets. 描述正式的环境绩效改进目标? 包括管理矩阵和指标?	
25	Describe any improvements in environmental performance achieved in the last three years. 描述过去三年来环境绩效的改进	
26	Indicate the top 3 environmental risks for your facility (e.g. contamination of drinking water sources, chemical release to sensitive receptors). 说明企业 3 个最高的环境风险(如: 饮用水源污染, 化学品泄漏至敏感区域)	1 2 3
27	List environmental permits or authorizations the facility has. Please indicate the permit type, the name of the permit, and the expiry date 企业环境许可证或授权许可清单. 请说明许可证类型, 名称和失效日期	
28	Describe any environmental incidents, non compliance events, spills, notices of violation, fines or other environmental events at your facility in the last three years. 说明企业过去三年环境事故, 违规事件, 泄漏, 整改通知, 罚款或其它环境事件	
29	List the five hazardous chemicals stored in the greatest quantity. Please indicate the method of storage (e.g., drums, above ground tanks) and spill containment system. 列出 5 种储量最高危险化学品. 请说明储存方法(如: 桶, 地上储罐)和泄漏控制方法.	
30	Is any waste treatment or disposal conducted on site? If yes, please describe. 企业现场是否进行废水或废物处理? 如是, 请详细描述.	
31	Describe how waste that is sent offsite is treated and disposed, how offsite waste treatment and disposal facilities and service providers are selected and managed, and what records/documentation of waste disposal is maintained. Please give specific details on landfilling of waste. 描述废物如何运输到厂外进行处理? 处理方式? 如果选择处理商并进行管理? 保存哪些废物处理记录? 详细描述废物掩埋具体细节.	

Env	Environmental Compliance and Risk Management 环境合规和风险管理	Please provide details, comments and supporting documents 请提供详细描述和支持文件		
32	<p>Indicate which of the methods below are used to manage process wastewater from this facility. 说明使用以下哪种方法管理企业生产废水</p> <ul style="list-style-type: none"> ○ Onsite wastewater treatment 现场废水处理 ○ Discharge to an offsite treatment facility 排放至外部处理企业 ○ Discharge to a settling pond or other surface water (e.g., river, lake) 排放至沉淀池或其它表面水体(如: 河流,湖) ○ Collection and transfer to a waste management facility/company 收集并转移至废水处理企业/公司 ○ Other (Please describe) 其它(请说明) 			
33	<p>Indicate which of the following types of air emissions are generated at your facility. Describe pollution control activities. 说明企业产生哪种类型的大气排放.说明污染控制方法</p>	Pollution Type 污染类型	Generated? (Yes or No) 是否产生?	Pollution control activities 污染控制方法
		Volatile organic chemicals 挥发性有机化学品		
		Corrosive vapors (e.g., HCl) 腐蚀性气体(如 :氯化氢)		
		Particulates or dusts 颗粒或粉尘		
		Ozone depleting substances 臭氧消耗物质		
		Combustion by-products 燃烧副产物		
		Other Hazardous Air Pollutants (e.g., CN, H2S, NH3, Br2, Phosgene) 其它有害气体 (如: 氰化物, 硫化氢, 氨, 溴, 光气)		
34	<p>Describe any programs the facility has to measure and reduce the following impacts from operations: 说明企业是否有程序衡量并减少以下运作的影响</p> <ol style="list-style-type: none"> a. energy consumption 能源消耗 b. water consumption 水消耗 c. amount of waste 废物产生量 d. greenhouse gas emissions 温室效应气体排放 <p>Please indicate if you report any of this data publically and if so where it can be found 请说明企业是否将这些数值公布与众, 如是从哪里能够找到.</p>			

H&S	Health & Safety Compliance and Risk Management 健康和安全管理合规风险管理	Please provide details, comments and supporting documents 请提供详细描述和支持文件
35	Do you have a Health & Safety policy? If yes, please provide a link to it on your web site or attach the policy. 企业是否有健康和安全管理方针? 如有, 请提供附件或网址链接	
36	Does the facility have written H&S procedures or programs? If yes, provide a list of the titles. 企业是否有文字的健康和安全管理程序或规程? 如有, 请提供目录清单	
37	Please indicate the top 3 H&S hazards for employees at this facility. 请说明企业对员工三个最大的健康和安全管理风险	1 2 3
38	If available, provide your lost time incident rate (# lost time incidents per 200,000 hours worked) for the last 3 years. 如可能, 请提供企业过去三年有工时损失事故比率(每工作 200,000 小时发生的有工时损失事故的比率)	Year Year Year
39	Describe any formal H&S objectives and targets or goals for performance improvement, including metrics. 描述企业正式健康和安全管理目标或绩效改进指标及矩阵	
40	Describe any improvements in Health & Safety performance achieved in the last three years. 描述企业过去三年健康和安全管理绩效的改进	
41	Describe any significant incidents that have occurred at this facility over the past three years. (A significant incident is defined as: causing serious injuries or fatalities; a fire resulting in damage to process equipment, building, storage areas; physical explosions, fires or violations.) 描述企业过去三年发生的重大事故(重大事故指导致重伤或死亡, 火灾导致设备, 建筑或储存区域损失, 暴利爆炸, 罚款或违规)	
42	How do you assess health risks (e.g., workplace occupational exposures)? What parameters do you measure (e.g., organic solvents, dusts, noise, radiation)? 企业如何评估健康风险(如工作区职业暴露)? 检测的参数值如何(如: 有机溶剂, 粉尘, 噪音或辐射)?	
43	Describe control strategies for reducing occupational exposure to highly active substances handled on site (e.g. glove boxes, isolators, enclosed material transfer systems). 描述企业降低高活性物质职业暴露的控制方法(如: 手套箱, 隔离装置, 密闭物料转移系统)	
44	Describe any risk-based medical monitoring or employee health surveillance program you undertake (e.g. initial pre-employment physical, routine physical exams, regular lung function testing). 描述企业基于风险的医疗监督或员工健康监督程序(如雇用前体检, 常规体检, 常规肺功能检查)	
45	Describe how the facility manages processes and chemical hazards safely in order to prevent catastrophic events involving highly toxic, flammable,	

H&S	Health & Safety Compliance and Risk Management 健康和安全管理合规风险管理	Please provide details, comments and supporting documents 请提供详细描述和支持文件
	<p>reactive and/or corrosive substances. 描述企业如何管理生产过程和有害化学品的安全预防重大事件包括高毒性,易燃,反应或腐蚀性物质</p>	
46	<p>Describe how employees (including temporary workers and contractors) are trained in the operation of the process before being allowed to operate on a newly assigned process. Also indicate the frequency of “refresher” training. Does the training involve safety and health hazards, emergency operations, and safe work practices? 描述企业员工(包括临时员工和合同工)在到任新岗位或流程之前如何接受操作培训的?并说明再培训的周期?培训是否包括安全和健康危害?应急操作和安全公司方法?</p>	
47	<p>List the precautions in place to prevent ignition of flammable liquids, vapors and gases in processing operations (including storage, transfer and charging). 列出企业实施的在操作过程中(包括储存,转移和投料)预防易燃液体,蒸汽和气体点燃的预防措施?</p>	

H&S	Health & Safety Compliance and Risk Management 健康和安全管理合规风险管理	Please provide details, comments and supporting documents 请提供详细描述和支持文件
48	List the precautions in place to prevent ignition of <u>combustible dusts</u> in processing operations (including charging, drying, milling, dust collection systems). 列出企业在工艺操作过程中(包括投料,干燥,粉碎,粉尘收集系统)预防可燃粉尘被点燃的措施?	
49	Describe the program to ensure the mechanical integrity and safe operation of the following components: 描述企业规程来保证以下项目的机械完整性和安全操作 <ul style="list-style-type: none"> a. Pressure safety relief valves/rupture disks 压力安全伐/泄爆片 b. Bonding/earthing systems 接地系统 c. Mass transfer systems (e.g. piping systems) 大规模传送系统(如管道系统) d. Pressurized vessels 压力容器 e. Explosion prevention (e.g., prevention of electrical charge build-up) 防爆(如:防止电荷聚集) 	
50	Does the facility have a safe work permit system for the following categories? 企业对于以下工作是否有安全工作许可系统 <ul style="list-style-type: none"> a. Hot Work (includes burning and welding) 热作业(包括高热和电弧) b. Confined Space Work 狭窄空间 c. Energy Isolation or Lock Out/Tag Out 能源隔离或上锁挂牌 d. Line Opening 管线开口 e. Other, please specify 其它,请说明 	
51	Describe the process for managing risks related to contractor activity onsite. 描述企业如何管理现场作业的合同商相关的风险	

MS	Management Systems 管理体系	Please provide details, comments and supporting documents 请提供详细描述和支持文件
52	Describe risk assessment and risk mitigation methodologies used to assess and manage business, reputation, and legal risks? 描述企业风险评估和风险缓解的方法用来管理企业,声誉和法规风险	
53	Describe any business continuity plans designed to minimize business interruption in the event of an incident. 描述企业连续性计划来应对一旦发生事故, 将供应中断的损失将至最低.	
54	Describe security systems for controlling physical access to your facilities. 描述企业安保体系如何控制进入企业	
55	How does your facility assess ongoing compliance with Environment, Health and Safety, and labor regulations. 企业如何保证符合新的环境健康安全 and 劳动法规?	
56	Describe how workers are made aware of policies and procedures, how these are communicated and implemented and describe training programs in each of the following areas 描述员工如何了解相关政策 and 程序? 如何与员工沟通? 说明以下方面的培训 <ul style="list-style-type: none"> • ethics 道德规范 • labor, 劳工 • environment, 环境 • health & safety 健康与安全 • emergency preparedness response 应急反应 	
57	How do you engage employees in open two-way communication with management? 企业如何保证管理层与员工进行公开双向交流?	
58	How frequently do you conduct emergency evacuation drills? 企业进行紧急疏散演练的周期是多长时间?	
59	Describe how you assess, audit or improve the effectiveness of your labor, ethics and EHS practices and programs (e.g., internal audits). 描述企业如何评估, 审计或改进劳工, 道德规范 and 环境健康安全行为 and 规程(如: 内部审计)	
60	Describe your investigation and corrective action program to address recommendations from incident investigations and audits/inspection findings. 描述企业调查 and 整改规程中如何应对来自事故调查 and 审计/检查中的发现	
61	Describe how the facility identifies and plans for response to potential accidents, emergency situations or other significant events that might plausibly occur (e.g., fires, explosions, medical incidents) in the workplace and company-provided living quarters? 描述企业如何识别 and 计划来应对在工作区 or 在厂区发生的潜在事故, 应急状况 or 其它可能发生的重大事件(如: 火	

MS	Management Systems 管理体系	Please provide details, comments and supporting documents 请提供详细描述和支持文件
	险,爆炸,紧急医疗事件)?	
63	<p>Does the facility have an on-site emergency response organization? If yes, please describe the organization (e.g., fire brigade; first aid organization). If no, please explain how these services are provided (state, local, private, etc.). How does the service work on weekends or holidays?</p> <p>企业现场是否有应急响应组织?如是,请对应急组织进行描述(如:消防队,急救组织).如没有,请说明如何提供这些服务(公立,当地,私人组织等).这些组织是否在周末或假期提供服务?</p>	
64	<p>Describe onsite fire detection, notification, suppression and response systems (e.g. sprinkler systems, alarms, training and drills). Provide information on inspection and maintenance of these systems.</p> <p>描述现场火灾识别,报警,抑制和反应系统(如:喷淋系统,报警,培训和演练). 请提供这些系统检查和维护信息.</p>	
65	<p>How do you ensure adequate water for fire protection? What is the source of water?</p> <p>企业如何保证消防水充足?水源来自何处?</p>	
66	<p>Describe how the facility manages change control (e.g., raw materials, processes, personnel etc.).</p> <p>描述企业如何管理变更(如原料,工艺,人员等)?</p>	
67	<p>How does your facility ensure that your suppliers operate good practices with regards to the PSCI principles (i.e., labor, ethics, environment, health & safety, and management systems)?</p> <p>企业如何供应商运作符合 PSCI 的原则(劳工,道德规范,环境,健康和安全管理)?</p>	
68	<p>List any ethics, labor, environment, health and safety management system accreditations or certifications the facility holds (e.g., OHSAS 18001, ISO 14001, SA8000)</p> <p>列出所有道德规范,劳工,环境,健康和安全管理系统的认证和证书(如: OHSAS 18001, ISO 14001, SA8000)</p>	
69	<p>Describe any awards your facility has received recognizing achievement in any area of labor, ethics, environment, H&S or management systems.</p> <p>描述企业在劳工,道德规范,环境,健康和安全管理或管理体系方面获得的奖励</p>	