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| **Pharmaceutical Supply Chain Initiative (PSCI)****Self-Assessment Questionnaire and Audit Report** **for Pharmaceutical Industry Suppliers** **API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers****药品供应链倡议（PSCI）****自我评估问卷和审计报告****制药业供应商****原料药,剂型制剂，化学品和中间化学品制造商** |
| **GUIDANCE FOR COMPLETION****报告填写指导** |
| **Sections marked in orange need to be filled in by the supplier before the audit. Sections marked in grey will be filled by the audit team during / after the onsite audit.** Please do not change the report format and do not change the answers given by the other party. Supplier and auditors 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 the questions: API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers.****标注为橙色的部分需要供应商在审计之前填写。标注为灰色的部分需要审计团队现场审计中/后填写。**请不要改变报告格式，不要改变另一方的答案。供应商和审计人员需要完成所有适用的问题。如果某个问题不适用，请注明NA（不适用）。**我们期望以下类型的供应商完成所有的问题：: API，剂型制剂，化学品和中间化学品制造商。** |
| **AUDITOR AND AUDIT REPORT INFORMATION****审计员及审计报告信息** |
| **Report Number:****报告编号:** |       |
| **Report Owner:****报告所有者：** |      Note: this is the company paying for /sponsoring the audit. If a PSCI Member, the name should be removed before the report is uploaded to the PSCI audit sharing platform注意：这是指支付/发起这个审计的公司。如果是PSCI成员公司，在报告上传到PSCI审计分享平台之前，名字应该要删掉。 |
| **Date of Audit:****审计日期:** |       DD/MM/YYYY 日/月/年[ ]  initial 首次[ ]  follow up 跟踪[ ]  other, please specify其它，请说明       | **Date and Type of Previous Audit** (if applicable)**:****上次审计的日期及类型（如果适用）:** |       DD/MM/YYYY 日/月/年[ ]  initial 首次[ ]  follow up 跟踪[ ]  other, please specify其它，请说明       |
| **Audit Firm Name:****审计公司名称:** |       |
| **Lead Auditor Name:****主任审计员姓名:** |       | **Title:****职位名称：** |       |
| **Names of further auditors:****其他审计员姓名:** |       | **Title:****职位名称：** |       |
| **Phone Number:****联络电话:** |       | **Email Address:****电邮地址:** |       |
| **FACILITY DETAILS****被审计设施详情** |
| **Company Name:**公司名称： |       |
| **Site Name** (if different): 工厂名称（如果不同）： |       |
| **Parent Company Name** (if applicable):**母公司名称（若适用）:** |       |
| **Site Street Address:****工厂街道地址：** |       |
| **Site City:****工厂所在城市:** |       | **Site State/Province/County:****工厂所在的州/省/县:** |       |
| **Site Postal/Zip Code:****工厂的邮政编码：** |       | **Site Country:** **工厂所在的国家:** |  |
| **SITE CONTACT INFORMATION****厂区联系信息** |
| **Site Representative Name** (host)**:****工厂代表姓名（主方）:** |       | **Title:****职位名称：** |       |
| **Phone Number:****联络电话:** |       | **Email Address:****电邮地址:** |       |
| **Management Representative Name:****管理层代表姓名:** |       | **Title:****职位名称：** |       |
| **HSE (Health, Safety, Environmental Protection) Representative Name:****健康、安全及环境****代表姓名:** |       | **Title:****职位名称：** |       |
| **HR (Human Resources) Representative Name:****人力资源代表姓名:** |       | **Title:****职位名称：** |       |

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| **EXECUTIVE SUMMARY****执行摘要** |
| **Overall findings****总体调查结果** | **Please check applicable box(es) and indicate the number of findings****请在适用的方格打勾并注明调查结果的数目** |
|  |  | **Critical****重要的调查结果** | **Number of Criticals****重要的调查结果的数目** | **Other****其它****问题** | **Number of Others****其余的调查结果的数目** | **None****没问题** |
| **A**  | **Management Systems****管理体系** | [ ]  |       | [ ]  |       | [ ]  |
| **B** | **Environmental Protection****环境保护** | [ ]  |       | [ ]  |       | [ ]  |
| **C**  | **Health & Safety Compliance and Risk Management****健康与安全合规以及风险管理** | [ ]  |       | [ ]  |       | [ ]  |

***It is not possible in an audit, with a limited time frame, to identify every area requiring attention. It is the responsibility of the audited party to establish, implement and maintain effective systems and procedures that comply with the regulatory requirements. Due to the size of the site only the most important buildings, facilities, and HSE topics could be inspected or discussed during the audit.***

***一次评估是在有限的时间范围内，不可能辨识出每一个区域的风险。被审核方有责任来建立、执行和维护有效的系统和程序来符合法规要求。由于工厂大小不同，只有最重要的建筑、设施和HSE话题可以在这次评估之中进行检查和讨论。***

***Critical Findings****: Are very high risk findings that require immediate action to protect human life, the health of employees or the environment; May result in loss of license to operate or serious damage to reputation; Require immediate corrective action by the supplier; Need to be communicated to the audit sponsor prior to audit report finalization.*

***Other Findings****: Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time.*

***重要的调查结果****: 是观察到具有高或非常高风险的问题，必须立即采取行动，以保护人身安全、员工健康或环境安全;* *可能导致失去经营许可，使声誉受损。一个重要的调查结果的发现要求供应商立即采取纠正行动。需要在审计报告最终确定之前与审计发起者沟通。*

***其余的调查结果****: 是其它观察到的问题，要求被审计的厂区按照一定的时间安排采取纠正行动。*

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| **Attitude of workers (towards management, workplace, and the interview process):** **员工（对管理层、工作场所、以及采访过程）的态度:**      **Note: do not document information that could put the worker at risk****注意: 不要记录可能让员工承担风险的信息** |
| **Attitude of management (to audit and audit process):****管理人员（对审计和审计过程）的态度:**      |
| **Summary of main findings:****主要调查结果总结:**      |

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| **Facility Background Information****设施的背景资料** |
| Please indicate which of the following best describes this facility (check all that apply):请指出下列哪一项最能恰当地描述该设施（选择所有适用的）: | [ ]  API (active pharmaceutical ingredient) manufacture API（原料药和中间体）[ ]  Biological manufacture 生物制造[ ]  Chemical manufacture化学制造[ ]  Contract Research Laboratories 合同研究实验室[ ]  Finished Formulations 成品制剂[ ]  Logistics / Warehouse 物流/仓库[ ]  Primary Packaging 初级包装[ ]  Other (please describe) 其它（请说明）Comments: 注解      |
| Is the facility located in a region that has experienced any of the following natural disasters in the previous 50 years:该设施是否位于一个在过去五十年来经历了以下任何自然灾害的地区: | Flood洪水[ ] Earthquake地震[ ]  Damaging windstorm破坏性风暴[ ] Wildfires森林火灾[ ]  | Volcanic Activity火山活动[ ] Tsunami Impact海啸冲击[ ] Hurricane/Typhoon飓风/台风[ ] Tornado龙卷风[ ]  |
| Describe the type of work currently being, or proposed to be performed at this facility (include product types such as antibiotics, solvents):描述目前正在或拟在该设施进行的工作的类型（包括产品类型，如：抗生素、溶剂）: |       |
| Please describe the facility HSE (Health Safety & Environment) resources (number of staff or time spent on HSE):Please provide a copy of the company’s organization chart indicating areas of expertise in HSE and whether they are full time. Please provide qualifications of the full time HSE people.请描述该设施的HSE（健康、安全及环境）资源（人员数或花费在健康、安全及环境上的时间）:请提供一份公司组织架构图的复印件，上面应显示相关人员的HSE专长领域以及他们是否为全职。请提供全职健康、安全及环境人员的资格证明。 |       |
| What is the primary language spoken by the majority of the employees at this location? 在这个区域大多数员工口头交流的主要语言是什么？     Primary language:主要语言      Other languages (spoken by at least 10% of the workforce): 其它语言（至少职工总数的10%使用来口头交流）      | Is company sponsored housing provided to any contract or full time employees working at this location? Yes [ ]  No [ ] 公司会对工作在此区域的的任何合同工或者全职员工提供住宿吗？是 [ ]  否 [ ] If yes, what is the approximate number of workers living in company-provided housing:      如果是，住在公司提供的住房内的员工数目大约为多少？ |
| **Number of Employees/Workers by Category** (Provide data for the entire site. Also, please note that there may be workers/employees who fit into multiple categories and should be accounted for under each applicable category (i.e., there is overlap between categories)员工/工人数目，分类如下（请提供整个工厂的数据。另外，请注意可能有员工/工人适合多重分类，在每个可适用的分类下需要单独计算（例如：在分类之中会有重叠）） | **Male****男性** | **Female****女性** |
| Total employee population onsite (including temporary, part-time and contract workers)厂区员工总人数（包括临时工，兼职和合同工） |  |  |
| Full time employees/workers directly employed by the company公司直接雇佣的全职员工/工人数目 |  |  |
| Part-time employees/workers directly employed by the company公司直接雇佣的兼职员工/工人数目 |  |  |
| Indirect, contract or dispatch employees/workers间接雇佣、合同工或者派遣员工/工人数目 |  |  |
| Total Site Area (m2):      总占地面积（m2） | Manufacturing Area (m 2):      生产区域（m 2） |
| Does your company own the facility?您的公司是否拥有该设施? | Yes [ ]  No [ ] If no, who owns the facility?      如果否，谁拥有该设施？ |
| If the facility is not owned by the parent company, are the following within your operational control?如果该设施不被母公司所拥有，下述是在您的营运控制范围内吗？ | Waste water treatment plant? 废水处理站Yes是 [ ]  No 否[ ] Utilities? 公用工程Yes 是[ ]  No 否[ ] Security? 安全保卫Yes 是[ ]  No 否[ ] Management of the roadways? 管理的道路Yes 是[ ]  No 否[ ]  |
| Indicate if the site is in a rural, industrial, residential or mixed commercial setting请说明该厂区是在农村、工业区、住宅区、或商住混合区 | Rural农村[ ] Industrial工业区[ ] Residential住宅区[ ] Mixed commercial setting商住混合区[ ] Please attach a local area map with water sources if available.如果可行的话，请附上一份带有水源的工厂区域图 |
| When was this site initially constructed? Please indicate the years of industrial use of the site.该厂区最初是什么时候建造的? 请注明该厂区投入工业使用的年份。 |  |

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| **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.****管理体系 自我评估问卷-标注有星号（\*）的问题，仅仅是为了收集信息，审计员不会考虑其作为潜在的发现项。** | **Auditor Verification**Please provide observations, details, comments and any supporting documents**审计员核实**请提供观察结果、细节、注解以及任何支持文件 |
| Commitment and Accountability承诺与责任 |  |
| 1\* | Does the facility have any ethics, labor, environment, health and safety management system accreditations, certifications, or awards?该设施是否获得过任何道德规范、劳工、环境、健康和安全管理体系方面的认可、认证或奖励? | OHSAS 18001 Yes 是[ ]  No 否[ ] ISO 14001 Yes 是[ ]  No 否[ ] ISO 50001 Yes 是[ ]  No 否[ ] SA 8000 Yes 是[ ]  No 否[ ] [ ] Investors in people Yes 是[ ]  No 否[ ] 有没有获得过机构“ Investors in people”的认证Other (e.g. Awards, OSHA VPP, EMAS) please list:      其它（例如，奖励、OSHA VPP、 EMAS），请列出: | Yes 是[ ]  No 否[ ] Comments 注解      |
| 2 | Does management engage employees in open two-way communication?(e.g. Town Hall meetings, employee surveys, management factory rounds, management-employees Q&A sessions)管理层是否让员工从事开放式的双向沟通?（例如：员工大会、员工调查、管理层工厂巡视、管理层-员工问题/回答会议） | Yes 是[ ] No 否[ ] Please explain:      请说明:  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Legal and Customer Requirements法律和客户要求 |  |
| 3\* | Are there any issues related to Ethics, Labor, Environment, Health, and Safety (HSE) Regulatory Compliance?在道德规范、劳工、环境、健康和安全（HSE）合规性方面目前的情况如何? | Is there any ongoing litigation or regulatory notices with respect to regulatory compliance? 在合规性方面，是否有任何正在进行的诉讼或监管通告? Yes 是[ ]  No 否[ ] Are there any historical major regulatory actions? 是否有任何重大的历史监管行动? Yes 是[ ]  No 否[ ] Any continuous / prolonged situations where regulatory compliance requirements are exceeded (within the past 12 months)? 是否有任何超出了合规性要求的持续/经久的情况（过去12个月内）? Yes 是[ ]  No 否[ ] Please explain:      请说明: | Yes 是[ ]  No 否[ ] Comments 注解      |
| 4 | Does the facility assess ongoing compliance with Health, Safety, and Environment, Business Ethics issues, and Labor regulations?该设施是否对健康、安全、环境、商业道德和劳动法规的持续遵从进行考核? | Yes 是[ ] No 否[ ] Please explain:      请说明:  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 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 & safety, and management systems)您的设施是否能确保您的供应商按照符合PSCI（亦即劳工、道德规范、环境、健康与安全，以及管理体系）原则的良好实践方式经营? | Yes 是[ ] No 否[ ] If yes, how? 若是，如何评估By on-site assessment / audit:通过现场评估/审计Yes 是[ ] No 否[ ] By desk-top assessment (e.g. questionnaires):通过问卷评估（例如，调查表）Yes 是[ ] No 否[ ] Please explain:      请说明:  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Risk Management风险管理 |  |
| 6 | Does the facility use risk assessment and risk mitigation methodologies to assess and manage business, reputation, and legal risks?该设施是否采用风险评估和风险规避方法来考核和管理业务、声誉以及法律风险? | Business risks: 商业风险Yes 是[ ]  No 否[ ]  Reputation risks: 声誉风险 Yes 是[ ]  No 否[ ]  Legal risks: 法律风险 Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 7 | Does the facility have a process to manage change control for HSE (e.g. raw materials, processes, personnel etc.)? 该设施是否拥有一套管理HSE（例如，原材料、工艺过程、人员等）的变更控制的流程? | Yes 是[ ] No 否[ ] Please explain:      请说明:  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 8 | Has the facility developed and implemented a site-based Business Continuity Management plan that includes the following elements:该设施是否制定并实施了一套包括以下要素的厂区基础业务持续管理计划： | Identification of the major facility dependencies that can create business interruption at the site? 识别了可能导致厂区业务中断的主要设施的依赖性? Yes 是[x]  No 否[ ] A risk assessment of the identified dependencies and developed a prioritized remediation of those risks? 对所识别的相关的风险评估，并针对这些风险制定了依照优先顺序的补救措施? Yes 是[x]  No 否[ ] Prioritized key supply initiatives and determined the recovery time objective for key production areas? 制定了优先的关键供应措施，并确定了重点生产区域的恢复时间目标? Yes 是[x]  No 否[ ] Please explain:      请说明: | Yes 是[ ]  No 否[ ] Comments 注解      |
| 9 | Does the facility have security systems for controlling physical access to the facilities? 该设施是否有用于控制人员进入您的设施的安全防卫系统? | Yes 是[ ] No 否[ ] Please explain:      请说明:  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Documentation文件资料 |  |
| 10 | Does the facility maintain documentation for key issues?该设施是否保存了关键问题的文件资料? | Yes 是[ ]  No 否[ ] Does this include这是否包括:Audit findings审计调查结果[ ] Injury and Illness Logs损伤和疾病登记[ ] Worker Benefits and Pay Information员工福利和薪酬信息[ ] Inspections by Regulatory Agencies监管机构的巡查[ ] Worker Complaints员工投诉[ ] Performance Assessments 绩效评估[ ] Documentation of Training 培训资料[ ]  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Training and Competency培训与能力 |  |
| 11 | Are workers made aware of policies and procedures, and are they trained accordingly?是否让员工了解政策和程序，他们是否获得了相应的培训? | Yes 是[ ]  No 否[ ] Please explain how they are communicated and implemented 请说明政策和程序是如何传达并实施的:      Please describe trainings in each of the following areas请描述在下列各个方面的培训:Ethics道德规范:      Labor劳工:      Environment, health & safety环境、健康和安全:      Emergency preparedness/response应急准备/响应:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| Continual Improvement持续改进 |  |
| 12 | Does the facility perform self-assessments and/or internal audits to improve the effectiveness of its labor, ethics and HSE (Health, Safety & Environment) practices? 该设施是否从事自我评估和/或内部审计，以提高在劳工、道德规范和HSE（健康、安全和环境）方面的实践效益? | Yes 是[ ]  No 否[ ] How often 多久一次：     Please explain:      请说明  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 13 | Does the facility have formal procedures to track corrective actions to address recommendations from incident investigations and audits/inspection findings to improve the effectiveness of labor, ethics and HSE (Health, Safety & Environment) practices?该设施是否有正规程序来跟踪就事故调查和审计/视察结果的建议所实施的纠正措施，以提高在劳工、道德规范和HSE（健康、安全和环境）方面的实践效益? | Yes 是[ ]  No 否[ ] Please explain:      请说明  | Yes 是[ ]  No 否[ ] Comments 注解      |

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| **ENVIRONMENTAL PROTECTION - Questions marked an asterisk (\*) are for information only and should not be considered for potential findings by the auditor****环保-标注有星号（\*）的问题，仅仅是为了收集信息，审计员不会考虑其作为潜在的发现项。** | **Auditor Verification**Please provide observations, details, comments and any supporting documents**审计员核实**请提供观察结果、细节、注解以及任何支持文件 |
| General概要 |  |
| 41 | Does the facility have written environmental policy, procedures, and practices? 该设施是否备有书面的环保政策、程序和实施方法? | Policy: Yes 是[ ]  No 否[ ] Procedure: Yes 是[ ]  No 否[ ] Comments 注解     Please provide a copy of the policy and a list of procedure titles.请提供一份政策的复印件以及一份程序标题的列表。 | Yes 是[ ]  No 否[ ] Comments 注解     Link or policy provided: Yes [ ]  No [ ] 提供链接或者书面的政策： Yes 是[ ]  No 否[ ] List of procedures provided: Yes [ ]  No [ ] 提供程序列表：Yes 是[ ]  No 否[ ]  |
| 42 | Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets? 该设施是否有正规的环境目标或绩效改进目的，包括度量标准和对象? | Yes 是[ ]  No 否[ ] If yes, please include goals, metrics, and/or targets若是, 请包括目的、度量标准和/或对象:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 43\* | Has the facility achieved any improvements (goal or non-goal related) in environmental performance in the last three years?Has the facility achieved any improvements in environmental performance in the last 3 years?过去三年来该设施是否在环境绩效方面实现了任何改进（目标或非目标相关）?. | Yes 是[ ]  No 否[ ] If yes, please explain若是, 请说明:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 44\* | Has the facility experienced pending or recent (last three years) environmental incidents (for example, non-compliance events, spills, notice of violation, fines or other environmental events)?过去三年来该设施是否有任何正在进行的或近期的环境事故（例如，违规事件、泄漏、违例通告、罚款或其它环境事件）? | Yes 是[ ]  No 否[ ] If yes, please explain若是, 请说明:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 45\* | Describe any procedures the facility has to measure and reduce environmental impacts from operations.请描述任何该设施所具有的、可衡量并减少运营对环境的影响的程序。 | Tracking and reduction programs exist for the following impacts:有应对下列影响的减排项目:Energy consumption能源消耗: Yes 是[ ]  No 否[ ] Program description项目描述:      Water consumption水耗: Yes 是[ ]  No 否[ ] Program description项目描述:      Amount of hazardous waste有害废弃物量: Yes 是[ ]  No 否[ ] Program description项目描述:      Amount of non-hazardous waste非有害废弃物量: Yes 是[ ]  No 否[ ] Program description项目描述:      Greenhouse gas emissions温室气体排放: Yes 是[ ]  No 否[ ] Program description项目描述:      Does the facility publicly report data该设施是否公告这些数据:Yes 是[ ]  No 否[ ] Program description项目描述:      If yes, where can the information be found若是, 可以在哪里找到这些信息:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 46 | If the site operates in a water scarce region[[1]](#footnote-1), has the facility developed a long-term strategy for future water sourcing and management?若厂区位于一个缺水地区，该设施是否制定了长期战略来应对未来的供水及其管理? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| Chemical Registrations化学品登记 |  |
| 47 | Is the site affected by a chemical registration program such as EU REACH (**R**egistration, **E**valuation; **A**ssessment, Authorization and Restriction of **Ch**emicals), China REACH, or TSCA (**T**oxic **S**ubstances **C**ontrol **A**ct) which requires registration or authorization to import or use a specific compound?该厂区是否受化学品登记法规影响，在进口或者使用一种特定的化合物时需要登记或授权？如欧盟REACH（化学品登记、评估、许可和限制），中国REACH，或者TSCA（毒性物质控制法令）。 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] If yes, please identify the program:      若是，请确定遵守什么法规In case of yes, do you have a process in place to comply with the regulation? 若是，是否有适当的流程来符合法规要求？Yes 是[ ]  No 否[ ] N/A 不适用[ ] If yes, is the process applied to comply with regulations in:若是，是否已应用此流程来符合法规要求？应用于：Finished Products produced in the site厂区生产的成品Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明Raw materials used for finished products 用于成品的原材料Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明Other 其它Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 48 | Do you send material to a region where REACH or similar regulations apply?是否已发送材料到REACH或者类似法规管控的地区？ | Yes 是[ ]  No 否[ ] If yes, how do you ensure compliance in this region and what is your role in this case?      若是，你如何确保符合这个地区的法规要求，以及在这个过程中您的角色是什么？ | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| Environmental Authorizations环境授权 |  |
| 49 | Does the facility have the required environmental permits or authorizations? 该设施是否拥有环境许可或授权? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] If yes, please list the permit type, the name of the permit, and the expiry date若是，请列出的许可证类型、许可证的名称、以及失效日期: | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| Waste and Emissions废弃物和排放 |  |
| 50 | Does the facility have a process to select and manage third-party waste treatment and disposal facilities and service providers? 该设施是否有一套选择和管理第三方废弃物处理和处置设施以及服务供应商的流程? | Please provide specific details on land filling of waste (categories and volumes):      Yes 是[ ]  No 否[ ] N/A 不适用[ ] What records or documentations of waste disposal are maintained保存了哪些废弃物处理的记载或文件:       Please provide specific details on land filling of waste请提供垃圾填埋的具体细节（类别及数量）:       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 51 | Does the facility use any of the following waste disposal methods & locations (explain as applicable)?该设施是否采用下列任何废弃物处置方法 & 位置（如适用，请说明）? | Disposal method弃置方法 | Off-site厂区外 | On-site厂区内 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Incineration焚烧 | [ ]  Please explain:      请说明 | [ ]  Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Landfill填埋 | [ ]  Please explain:      请说明 | [ ]  Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Deep Well深井 | [ ]  Please explain:      请说明 | [ ]  Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Land Application土地利用 | [ ]  Please explain:      请说明 | [ ]  Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Other 其它 | [ ]  Please explain:      请说明 | [ ]  Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 52 | Indicate which methods are used to manage processwastewater from this facility.请指明用什么方法管理来自设施本身的过程废水。 | On-site wastewater treatment厂区内的废水处理设施:Yes 是[ ]  No 否[ ] Please describe请说明:      Discharge to an offsite treatment facility排放到一个厂区外的处理设施:Yes 是[ ]  No 否[ ] Please describe请说明:      Discharge to a settling pond or other surface water (e.g., river, lake) 排放到沉降池或其它地表水中（例如，河流、湖泊）: Yes 是[ ]  No 否[ ] Please describe请说明:      Collection and transfer to a waste management facility/company收集并转移到一个废弃物管理厂/公司: Yes 是[ ]  No 否[ ] Please describe请说明:      Other, e.g. wastewater for irrigation其它，例如污水灌溉:Yes 是[ ]  No 否[ ] Please describe请说明:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 53 | Indicate which of the following types of air emissions are generated at the facility. Describe the types of pollution control activities if used?请指明该设施造成下列哪种类型的大气排放。如果采取了污染防治活动，请说明是什么类型？ | Emission Type排放类型 | Generated?设施造成的? | Emission control systems used采用的污染排放控制系统 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Volatile organic chemicals挥发性有机化学品 | Yes 是[ ]  No 否[ ]  |  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Corrosive vapors (e.g HCl)腐蚀性蒸气（例如，盐酸） | Yes 是[ ]  No 否[ ]  |  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Particulates or dusts颗粒或粉尘 | Yes 是[ ]  No 否[ ]  |  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Ozone depleting substances臭氧层破坏物质 | Yes 是[ ]  No 否[ ]  |  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Combustion by-products燃烧副产物 | Yes 是[ ]  No 否[ ]  |  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Other Pollutants (e.g., GHG, cyanides, sulfides, ammonias, bromines, phosgene)其它污染物（例如， 温室气体，氰化物，硫化物，氨，溴，光气） | Yes 是[ ]  No 否[ ]  |  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 54 | Has the facility developed and implemented a hazardous substances management program that includes development and maintenance of a current inventory of all hazardous chemicals used, manufactured or stored on-site, including those for production, maintenance, utilities, and laboratory purposes? 该设施是否制定并实施了一套有害物质管理程序，包括制定并维护一份所有危险化学品的现有库存清单? 所谓的危险化学品是指那些由设施使用或生产的、或在厂区内储存的危险化学品，包括那些用于生产、维修、公用事业和实验室目的的危险化学品。  | Yes 是[ ]  No 否[ ] Please explain and list site hazardous substances请说明并列出厂区的有害物质:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 55 | Has the facility developed and implemented waste and wastewater management practices?该设施是否制定并实施了一套废弃物和废水管理措施? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Do the practices cover:Characterization of all wastes generated at the facility, including returned products, with regard to regulatory classification (e.g. hazardous waste, special waste, infectious waste, non-regulated solid waste, low-level radioactive waste) and hazardous properties (e.g. flammability, corrosiveness, toxicity)? 所述措施是否涵盖了:按照分类监管（例如有害废弃物、特殊废弃物、传染性废弃物、非管制性固体废弃物、放射性废弃物）以及危险特性（例如易燃性、腐蚀性、毒性）对该设施所产生的所有包括回收产品在内的废弃物进行了表征归类? Yes 是[ ]  No 否[ ] Are wastes that contain Active Pharmaceutical Ingredients (APIs) managed in such a way that the API is destroyed via that waste management method? 含有活性药物成分（API）的废弃物的处理是否采用了能够破坏掉API的管理方法? Yes 是[ ]  No 否[ ] Are there measures in place to ensure that API, drug product, and branded materials are not diverted from the intended waste treatment/disposal method/facility? 是否有措施确保活性药物成分（API）、药品和品牌材料不会被从预定的废弃物处理/处置方法/设施挪作它用? Yes 是[ ]  No 否[ ] Does the facility have a system for collecting water from fire fighting? 该设施是否有收集消防废水的系统?Yes 是[ ]  No 否[ ] Does the facility evaluate the discharge of wastewater to surface waters, onsite treatment works or offsite treatment to determine potential Active Pharmaceutical Ingredient (API) impact? 该设施是否对排放到地表水、厂区内或厂区外的处理设施的废水进行考查，以确定活性药物成分（API）的潜在影响?Yes 是[ ]  No 否[ ] *(considerations include: treatability, bioaccumulation potential, bio-toxicity potential, and the capacity and capability of on-site treatment works, off-site treatment works, or Publicly Owned Treatment Works (POTWs) receiving the wastewater discharges to effectively perform treatment)* *（考虑因素包括:* *可处理性、生物蓄积性、生物毒性潜力、以及接收废水排放的厂区内的处理厂、厂区外的处理厂、或公有处理厂（POTWs）的容量和能力，以便有效地进行处理）*Are APIs in wastewater subject to treatment, capture, and containment practices to reduce API concentrations to predicted no effect concentration (PNEC) levels? 是否对废水中潜在的APIs采取了处理、捕获、以及遏制的做法，以便将活性药物成分（API）的含量减少到不再有影响的水平? Yes 是[ ]  No 否[ ] Comments:      注解 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Spills and Releases溢漏和释放 |  |
| 56 | If the facility uses hazardous substances, is there a spill containment system?List the five highest volume hazardous substances stored. Please indicate the method of storage (e.g., large storage cylinders, drums, above ground tanks, underground tanks) and spill containment system.如果该设施使用有害化学品，是否配备了溢漏遏制系统?列出五个储存容量最高的有害化学品。请指明储存的方法（例如，大型储瓶、储桶、地上储罐、地下储罐）以及溢漏遏制系统。 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Five highest volume environmental impact substances五种容量最高的环境影响物质：     Method of storage and containment system储存方法及遏制系统:      Comments:      注解 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 57 | Does the facility have any known soil or groundwater contamination?该设施是否有任何已知的土壤或地下水污染?  | Yes 是[ ]  No 否[ ] If yes, please provide a brief description of how this is being managed and whether it impacts neighboring properties:      若是，请提供一份简要的描述，说明它是如何进行管理的，是否影响到邻近的物业: | Yes 是[ ]  No 否[ ] Comments 注解      |
| 58 | Has the facility addressed potential environmental risks arising from storing and handling hazardous substances, including petroleum products, as follows:针对由于储存和操作包括石油产品在内的有害物质而产生的潜在环境风险，该设施是否采取了应对措施，具体如下: | Underground storage tanks, transfer lines, and sumps? 地下储罐、输送线、污水池? Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明Secondary containment in the form of double walled tank and piping or an external vault with a capacity equivalent to 110% of the largest tank or vessel in the containment area?次级遏制系统，以双层壁的罐和管道的形式、或是以一个其容量相当于位于遏制区域的最大储罐或容器的容量的110％的外部储存库的形式? Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明A leak detection system capable of detecting a leak and providing notification prior to the hazardous substance entering the environment? 一套能够检测到泄漏并在有害物质进入环境之前提供警报的泄漏检测系统? Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明Overfill protection (for underground storage tanks) consisting of an audible or visual alarm system and automatic fill shut-off, or overfill protection (i.e., containment) and equipped with a means of accurately determining the volume stored in the tank? 一套包括听觉或视觉警报系统以及灌满自动切断的（地下储罐的）过满保护装置，或一套具有精确地确定储罐内的储存容量的手段的过满保护装置（即遏制系统）? Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 59 | Are tank truck, railcar, and other bulk transportation unit loading and unloading areas for hazardous substances provided with containment equivalent to at least 110% of the largest transportation unit handled in that area, or for compartmentalized transportation units, equivalent to at least 110% of the single largest compartment? 油罐车，轨道车，和其它散装运输设备的危险物品装卸区是否配备了其容量相当于在这一区域里操作的最大输送设备的容量的110％的遏制系统，或就分隔输送设备而言，其容量相当于单一最大隔间的容量的110％的遏制系统? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |

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| **HEALTH & SAFETY COMPLIANCE AND RISK MANAGEMENT Self-Assessment Questionnaire Questions marked an asterisk (\*) are for information only and should not be considered for potential findings by the auditor.****健康和安全合规及风险管理 自我评估问卷****标注有星号（\*）的问题，仅仅是为了收集信息，审计员不会考虑其作为潜在的发现项。** | **Auditor Verification**Please provide observations, details, comments and any supporting documents**审计员核实**请提供观察结果、细节、注解以及任何支持文件 |
| General概要 |  |
| 60 | Does the facility have a written Health & Safety policy, procedures, and practices? 该设施是否备有书面的健康与安全政策、程序和实施方法?  | Policy: Yes 是[ ]  No 否[ ] Procedures: Yes 是[ ]  No 否[ ] If yes, provide a copy of the policy and list the procedure titles若是, 请提供一份政策的复印件并列出程序标题:       | Yes 是[ ]  No 否[ ] Comments 注解     Link or policy provided: Yes [ ]  No [ ] 提供链接或者书面的政策： Yes 是[ ]  No 否[ ] List of procedures provided: Yes [ ]  No [ ] 提供程序列表：Yes 是[ ]  No 否[ ]  |
| 61 | Does the facility have any documented Health & Safety objectives and targets or goals for performance improvement, including metrics? 该设施是否有任何正规的健康与安全目标和对象，或绩效改进目的，包括度量标准?  | Yes 是[ ]  No 否[ ] Please describe 请说明:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 62\* | Have any significant Health & Safety incidents occurred at this facility over the past three years? (Significant incidents are defined as: causing serious injuries or fatalities; a fire resulting in damage to process equipment, building, storage areas; physical explosions, fines or violations.) 过去三年来在该设施是否发生了任何显著的健康&安全事件?（显著事件的定义是: 造成严重伤害或死亡;造成工艺设备、建筑物、仓储区等的损坏的火灾;物理爆炸，罚款或违规。） | Yes 是[ ]  No 否[ ] If yes, please describe 若是,请说明:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 63 | Does the facility provide HSE (Health, Safety & Environment) training to employees (full-time, temporary, or contractor)?该设施是否向（全职、临时、或合同）员工提供HSE（健康、安全和环境）培训? | New employee orientation and HSE training新员工入门培训及健康、安全和环境培训:Yes 是[ ]  No 否[ ] Annual HSE refresher training年度健康、安全和环境温习培训: Yes 是[ ]  No 否[ ] Pre-start up process specific HSE training启动前期与工艺过程相关的HSE培训: Yes 是[ ]  No 否[ ] Employee emergency response action training员工应急响应培训: Yes 是[ ]  No 否[ ] Hazard Communication危害通识Yes 是[ ]  No 否[ ] Process Safety Management工艺过程安全管理Yes 是[ ]  No 否[ ] Environmental Practices 环保实践: Yes 是[ ]  No 否[ ] Comments:      注解 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 64\* | Provide the facility’s lost time incident rate (number of lost work day cases multiplied by 200,000 divided by the number of hours worked per year) for the last three years.请提供该设施过去三年损失工作日事故率：（总损失工时/实际总工时）\*20万。 | Last year去年     Two years ago两年前     Three years ago三年前     Do not track 未做统计      | Yes 是[ ]  No 否[ ] Comments 注解      |
| 65\* | Does the site have a program for improving safe behaviors?厂区是否有提高行为安全的流程? | Yes 是[ ]  No 否[ ] If yes, please describe 若是,请说明:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 66 | Does the facility ensure the provision of safe and potable drinking water and hygienic facilities to all employees?该设施是否确保为所有员工提供安全、便携的饮用水及保健设施? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 67 | Does the company provide adequate sanitary facilities (e.g. clean toilets, possibilities for hand-washing).该公司是否提供足够的卫生设施（例如：抽水马桶，洗手设施）? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 68 | If living accommodation (e.g. dormitories) are provided to employees or contractors, are they safe and clean, and do they meet the relevant basic requirements (e.g. fire protection and emergency)?如果员工或者供应商有生活区（例如：员工宿舍），它是否安全、洁净，是否满足相关基本要求（例如：消防和应急）? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Worker Protection劳工保护 |  |
| 69 | Does the facility have a safe work permit system for the following?该设施是否备有一套针对以下工作的安全作业许可制度? | Hot Work 动火作业Yes 是[ ]  No 否[ ] 不适用[ ] Confined Space Work 有限空间作业Yes 是[ ]  No 否[ ] 不适用[ ] Energy Isolation or Lock Out/Tag Out能源隔离或锁闭/标识: Yes 是[ ]  No 否[ ]  NA 不适用[ ] Line Breaking 开管作业：Yes 是[ ]  No 否[ ] 不适用[ ] Work at Height 登高作业：Yes 是[ ]  No 否[ ] 不适用[ ] Other 其它Yes 是[ ]  No 否[ ] 不适用[ ] Please describe:      请说明: | Yes 是[ ]  No 否[ ] Comments 注解      |
| 70 | Has the facility developed and implemented an Electrical Safety Program that includes:该设施是否制定并实施了电气安全计划，包括: | Installation of lockable disconnects interlocks, and emergency stop devices? 安装了可锁定的断路器联锁以及紧急停机装置? Yes 是[ ]  No 否[ ] Labeling of switches, outlets, breakers, panels, and disconnects? 标记了开关，插座，断路器，面板和断连器? Yes 是[ ]  No 否[ ] Installation of special electrical equipment for flammable vapors, gases, combustible dusts, and wet areas? 安装了针对易燃蒸气、气体、可燃粉尘以及潮湿区域的特殊电气设备? Yes 是[ ]  No 否[ ] Periodic testing of grounding and bonding circuits, lightning arresters, and electrical distribution equipment? 定期测试接地和联结电路、避雷器以及配电设备? Yes 是[ ]  No 否[ ] Permitting only trained and qualified employees to perform electrical work? 只允许受过培训的有资质员工进行电工作业? Yes 是[ ]  No 否[ ] Providing awareness training for all employees? 为所有员工提供了认知培训? Yes 是[ ]  No 否[ ] Designating keep clear areas around electrical equipment for safe work practices? 在电气设备周围为安全工作方式划定了隔离区域? Yes 是[ ]  No 否[ ] Electrical cabinets are locked? 电气柜保持锁闭? Yes 是[ ]  No 否[ ] Emergency power supplies for relevant equipment present? 对于现有设备提供应急电源? Yes 是[ ]  No 否[ ] Arc Flash Analysis? 弧闪分析?Yes 是[ ]  No 否[ ] Comments:      注解  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 71 | Has the facility developed and implemented machine guarding procedures? 该设施是否制定并实施了机器防护程序? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 72 | Do safety symbols indicate the different hazards in the machines?在机器设备上是否有安全标志标示出不同的危害? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 73 | Does the facility use any of the following processes for managing risks related to contractor activity onsite?该设施是否采用以下任一流程来管理涉及到在厂区内作业的合同工的风险? | Contractor pre-approval合同工的预先审批: Yes 是[ ]  No 否[ ] Training/orientation before entry准入前的培训/熟悉环境:Yes 是[ ]  No 否[ ] Electronic access control电子门禁: Yes 是[ ]  No 否[ ] Drug/alcohol testing药物/酒精检测: Yes 是[ ]  No 否[ ] On-going recurrent safety training持续的经常性安全培训: Yes 是[ ]  No 否[ ] Mandatory accident reporting强制性事故报告: Yes 是[ ]  No 否[ ] Other: Yes 是[ ]  No 否[ ] If yes, please describe:      若是，请说明: | Yes 是[ ]  No 否[ ] Comments 注解      |
| 74 | Are the facility’s pedestrian and material handling equipment aisles marked or designated?该设施是否标记或指定了行人以及材料搬运设备的通道? | Yes 是[ ]  No 否[ ] Please explain:      请说明  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 75 | Has the facility developed and implemented a formal program to provide for the selection and maintenance of Material Handling Equipment?该设施是否为材料搬运设备的选择和维护制定并实施了正规的方案? | Yes 是[ ]  No 否[ ] Does it include方案是否包括:Operation by trained persons? 由经过培训的人员操作? Yes 是[ ]  No 否[ ] Periodic inspection and preventive maintenance by qualified personnel? 由资格人员进行定期检查并采取预防性维护? Yes 是[ ]  No 否[ ] If elevated work devices are used is appropriate fall protection equipment in place and is a rescue plan in place? 如果使用升高的工作装置，适当的防坠落设备以及救援计划是否到位?Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 76 | Are the facility receiving and/or shipping docks equipped with wheel chocks, dock locking systems or other means of trailer restraint to prevent trailers from moving during loading/unloading?该设施的接收和/或装运基座是否配备了车轮轴承座，基座锁定系统或其它拖车约束手段来防止拖车在装载/卸载过程中发生移动? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 77 | Is product stored overhead in pallet racking stretch wrapped or secured by some means to prevent it from falling?架空存储在托盘货架上的产品是否进行拉伸包装或其它一些固定手段来防止其坠落? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 78 | Are conveyor systems or other overhead equipment conveying materials adequately protected (side rails, netting, emergency stops, etc.) to prevent product from falling over the sides especially in situations where conveyed product might stop or hang causing jams or pile-ups of material (curves, bends, etc.)?传送系统或其它输送材料的架空设备是否得到充分的保护（护栏、拦网、紧急制动等），以防止产品从侧面滑落，尤其是在被输送产品可能发生停止或悬挂从而造成材料堵塞或堆砌（曲线、拐弯等）的情况下? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 79 | Does the facility have practices to ensure pallet racking is maintained in good condition and regularly inspected (no obvious damages to components – especially uprights – cross beams locked in place, foot plates secured to floor, and capacity posted)?该设施是否有确保托盘货架维持在良好状态并定期得到检查的实践（没有明显的部件损坏 - 尤其是立柱 - 横梁锁定到位，脚踏板固定在地板上，张贴出容量）? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 80 | Does the facility have a system to evaluate materials stored in the warehouse to ensure that special storage requirements are identified (e.g. flammable storage, segregation of non-compatible materials, containment, etc.)? 该设施是否有一套对储存在仓库的材料进行评估的系统，以确保能够识别特殊的存储要求（例如，易燃品的存放，不兼容材料的隔离，遏制等）? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Occupational Health and Industrial Hygiene职业健康与工业卫生 |  |
| 81 | Has the facility established practices to eliminate hazards of substances using the following hierarchy of exposure control:该设施是否建立了通过采取以下的暴露分级控制来消除物质危害的实践: | Use less hazardous materials when possible? 尽可能少用有害物质?Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain 请说明:      Provide engineering controls, such as local exhaust, process isolation/containment, or interlock system?提供工程控制，例如，局部排气，过程隔离/遏制、或联锁系统?Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 82 | Does the facility perform risk assessments for chemicals handled? Please specify the types of engineering controls used to manage identified chemical exposure risks? 该设施是否对所操作的化学品进行风险评估? 请具体说明用于管理暴露于所识别的化学品的风险的工程控制类型?  | Yes 是[ ]  No 否[ ] Check those which apply 适用的打勾:Laminar flow hoods层流罩: [ ]  Down flow booths 降流间： [ ] Powder transfer systems粉末输送系统: [ ] Alpha-beta valves α-β阀: [ ] Split butterfly valve分体式蝶阀:[ ] Soft or hard wall isolators软壁或硬壁隔离器: [ ] Local exhaust ventilation局部通风排气设备: [ ] Closed processes封闭的工艺过程:[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 83 | Has the facility established occupational exposure levels for all Active Pharmaceutical Ingredients (API) and hazardous substances? 该设施是否为所有活性药物成分（API）和有害物质设定了职业暴露水平? | Yes [ ]  No [ ]  NA [ ] If yes, please explain the program to assess risk and how exposure limits are determined to set employee exposures to API, chemical, biological, and physical hazards:      Yes 是[ ]  No 否[ ] N/A 不适用[ ] 若是，请解释用于评估风险的程序，以及如何确定员工暴露于活性药物成分（API）、化学、生物和物理性危害的暴露极限值: | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 84 | Has the facility established exposure control capabilities for handling pharmaceutical compounds? Please specify the lowest control range of containment for dust/powder handling that has been achieved.该设施是否建立了针对药物化合物暴露的控制能力? 请具体指出已经实现的粉尘/粉末处理遏制的最低控制范围。 | Yes 是[ ]  No 否N/A [ ] [ ] < 1μg/m3 [ ] 1-10 μg/m3[ ] 10-100 μg/m3[ ] >100 μg/m3Comments:      注解 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 85 | Does the facility perform risk-based medical monitoring or employee health surveillance which includes recording, investigation and follow-up?该设施是否进行基于风险的医疗监护或员工健康监测，包括记录、调查报告和追踪? | Pre-employment physicals就业前体检: Yes 是[ ]  No 否[ ] Routine blood monitoring血常规监测: Yes 是[ ]  No 否[ ] Routine urinalysis尿常规分析: Yes 是[ ]  No 否[ ] Hearing test 听力测试：Yes 是[ ]  No 否[ ] Lung function testing肺功能测试: Yes 是[ ]  No 否[ ] Other其它Yes 是[ ]  No 否[ ] If yes, please describe 若是,请说明:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 86 | Has the facility developed and implemented a plan to protect First Aid Responders and Medical Professionals from exposure to body fluids?该设施是否制定并实施一项用于预防急救人员和医疗专业人员接触到体液的计划? | Yes 是[ ]  No 否[ ] Please explain 请说明：     Does the program include该计划是否包括:Training? 培训? Yes 是[ ]  No 否[ ] Exposure response kits? 接触响应试剂盒? Yes 是[ ]  No 否[ ] The offer of Hepatitis B inoculations? 提供乙肝预防接种? Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 87 | Does the facility perform exposure monitoring for the following health and safety risks?该设施是否为以下健康和安全风险进行暴露监测? | Solvent vapors溶剂蒸气: Yes 是[ ]  No 否[ ] N/A 不适用[ ] Workplace noise levels工作场所的噪音水平: Yes 是[ ]  No 否[ ] N/A 不适用[ ] Pharmaceutical powders药品粉末:Yes 是[ ]  No 否[ ] N/A 不适用[ ] Radiation levels辐射水平: Yes 是[ ]  No 否[ ] N/A 不适用[ ] Oxygen-deficient atmospheres (e.g. nitrogen, inert gases) 缺氧环境（例如，氮气、惰性气体）: Yes 是[ ]  No 否[ ] N/A 不适用[ ] Ergonomics (height lifting, clima, illumination, vibrations, ..) 人机工程（抬起重物、气候、照明、振动…） Yes 是[ ]  No 否[ ] N/A 不适用[ ] Other其它: Yes 是[ ]  No 否[ ] If yes, please describe 若是,请说明:       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 88 | Is there a site procedure to inform employees of the results of exposure evaluations and monitoring results?厂区是否有一套告知员工暴露评估结果以及监测结果的程序? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments:      注解 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 89 | Does the site provide Personal Protective Equipment (PPE) for face, eye, foot, head, and hand protection?厂区是否提供可用于面部、眼部、脚部、头部以及手部防护的个人防护装备（PPE）? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 90 | Does the facility rely primarily on respiratory protective devices and/or engineering controls to protect employees who handle chemicals to achieve exposure levels below the exposure limit?该设施是否主要依靠呼吸防护设备和/或工程控制来保护操作化学品的员工，以实现将暴露水平控制在暴露限值之下? | Respiratory protective devices呼吸防护设备Yes 是[ ]  No 否[ ] Engineering controls工程控制Yes 是[ ]  No 否[ ] Both两者兼有Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 91 | Does the facility use any of the following respiratory protection equipment for worker protection against exposure to chemicals or pharmaceutical compounds?该设施是否使用以下任何呼吸防护设备来防止员工与化学品或药物化合物的接触? | Supplied air breathing systems供气式呼吸系统Yes 是[ ]  No 否[ ] Powered air purifying respirators动力空气净化呼吸器Yes 是[ ]  No 否[ ] Full face respirators 全面罩呼吸器Yes 是[ ]  No 否[ ] Half face respirators半面罩呼吸器Yes 是[ ]  No 否[ ] Filtering face masks过滤式面罩Yes 是[ ]  No 否[ ] Other其它Yes 是[ ]  No 否[ ] If yes, describe若是，请加以描述:      What criteria are used to select respirator protection devices?      采用什么标准来选择呼吸保护装置?Respiratory Protection is not used? N/A [ ]  未采用呼吸保护? 不适用Please explain if not applicable:      若不适用，请说明: | Yes 是[ ]  No 否[ ] Comments 注解      |
| 92 | Are there provisions for fit testing, training, use, cleaning, inspecting, storing, and maintenance of respirators?是否有对呼吸器进行适用性测试、培训、使用、清洁、检查、储藏和维护的规定? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| Process Safety工艺安全 |  |
| 93\* | Please indicate the top 3 most hazardous process activities conducted at this facility (e.g. hydrogenation, handling potent compounds, handling biological agents, handling flammable materials).请指明在该设施进行的前3名最危险的工艺过程（例如加氢过程、操作活性化合物、操作生物制剂、操作易燃材料）。 | 1.      2.      3.       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 94 | Does the facility have processes to manage chemical hazards safely in order to prevent catastrophic events involving highly toxic, flammable, reactive and/or corrosive substances? 该设施是否有安全管理危险化学品的流程，以便于防止涉及到高毒性、易燃性、高反应性和/或腐蚀性物质的灾难性事故的发生?  | Yes 是[ ]  No 否[ ] N/A 不适用[ ] If yes, please explain 若是,请说明:       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 95\* | Does the facility use any of the following precautions to prevent ignition of flammable liquids, vapors, powders, and gases in processing operations (including storage, transfer and charging)?该设施是否采用任何下列预防性措施来防止（包括储存、输送和充电）的加工作业中引燃易燃液体、蒸气、粉末和气体? | Maintain temperatures below flash points保持温度低于闪点: Yes 是[ ]  No 否[ ] N/A 不适用[ ] Nitrogen as inerting gas氮气作为惰性气体: Yes 是[ ]  No 否[ ] Explosive vapor monitoring in process equipment监测工艺设备中的爆炸性气体: Yes 是[ ]  No 否[ ] Oxygen level monitoring in process equipment监测工艺设备中的氧含量: Yes 是[ ]  No 否[ ] Grounding/bonding systems接地/跨接系统: Yes 是[ ]  No 否[ ] Anti-static treated working surfaces抗静电处理过的操作台面:Yes 是[ ]  No 否[ ] Other 其它: Yes 是[ ]  No 否[ ] If yes, describe 若是,请说明:       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 96 | Does the facility have adequate mechanical integrity and safe operation of the following components including a periodic inspection of their correct operation? Does the facility include periodic evaluation of the mechanical integrity and safe operation of the following components? 该设施下列部件的机械完整性和安全操作性是否足够，包括正确操作的定期检查? | **System系统**Pressure safety relief valves/rupture disks压力安全泄压阀/防爆片Yes 是[ ]  No 否[ ] N/A 不适用[ ] Bonding/earthing systems跨接/接地系统Yes 是[ ]  No 否[ ] N/A 不适用[ ] Mass transfer systems (e.g. piping systems) 传质系统（例如，管道系统）Yes 是[ ]  No 否[ ] N/A 不适用[ ] Pressurized vessels压力容器Yes 是[ ]  No 否[ ] N/A 不适用[ ] Explosion prevention system (e.g., prevention of static electrical discharge) 防爆系统（例如，预防静电放电）Yes 是[ ]  No 否[ ] N/A 不适用[ ] Other 其它 Yes 是[ ]  No 否[ ]  If yes, please describe 若是,请说明:       | **Frequency of Inspection:** **检查的频率:** **Comments 注解：**  | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 97 | Does the facility provide a means for handling compressed gases safely that includes:该设施是否提供了一种可安全地操作压缩气体的手段，包括: | Not applicable 不适用[ ] Inspection and approval before acceptance of delivery? 验收货物前的检查和批准? Yes 是[ ]  No 否[ ] Storage in a segregated area designed for compressed gases? 储存压缩气体在专用的隔离区? Yes 是[ ]  No 否[ ] Separation or barriers to manage compatibility issues? 用于解决相容性问题的隔离或障碍? Yes 是[ ]  No 否[ ] Gas classification labeling? 气体分类标识? Yes 是[ ]  No 否[ ] Regulator, hose and flexible connection inspections? 检查调节器、软管和柔性连接? Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 98 | Has the facility developed and implemented bulk chemical handling procedures that include:该设施是否制定并实施了散装化学品的操作程序，包括: | Not applicable不适用[ ] Specific unloading and loading procedures? 特定的卸载与装载程序? Yes 是[ ]  No 否[ ] Identification sampling before unloading? 卸载前的取样鉴定? Yes 是[ ]  No 否[ ] Hose inspection? 检查软管? Yes 是[ ]  No 否[ ] Fire protection? 消防？Yes 是[ ]  No 否[ ] Spill control measures (dike or bund area)? 溢漏控制措施（设定堤防或堤岸区域）? Yes [ ]  No[ ]  Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 99 | Has the facility completed an evaluation to identify processes or operations (exothermic reactions, the use of flammable, combustible or toxic materials, and processes involving extreme temperatures or pressures) that could present a significant safety, health exposure, or environmental risk?该设施是否完成了识别可能给安全、健康或环境造成显著风险的过程或操作（放热反应、使用易燃、可燃或毒性物质、以及涉及到极端温度或压力的过程）的评估? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 100 | For operations and processes that handle highly hazardous chemicals and materials, (e.g. OSHA and/or SEVESO covered processes) has the site developed and implemented a process safety management program which includes:厂区是否针对涉及到高度危险的化学品和材料的操作和过程（例如，受OSHA和/或SEVESO管制的过程）制定并实施了一套过程安全管理方案，包括: | Not applicable 不适用[ ] Process information requirements where the collection of process safety data, design information, operating parameters, and equipment specifications are documented? 记录了过程安全数据采集、设计信息、运行参数，以及设备规格的过程信息要求? Yes 是[ ]  No 否[ ] Are hazard evaluations completed that adequately capture significant risks during process development, preliminary engineering, and upon completion of process design? 是否完成了充分反映在工艺开发期间、前期工程以及工艺设计完成后的显著风险的危险性评估? Yes 是[ ]  No 否[ ] Are the controls able to adequately mitigate the risks identified in the process hazard evaluations? 控制措施是否能够充分地降低在过程危害性评估中所确认的风险? Yes 是[ ]  No 否[ ] Has the site carried out hazardous area classification including documentation (drawing) and is the equipment appropriate for respective zoning? 厂区是否进行了危险区域分类，包括有相应的文件（图示），设备是否适合于各个划分的区域? Yes 是[ ]  No 否[ ] Have pressure vessels and relief devices been sized to appropriate codes and standards? 压力容器和释放装置的尺寸是否已按照适当的规范和标准设置? Yes 是[ ]  No 否[ ] Pre-startup review program been established to systematical review a process before new start up and after management of change?是否已建立了开车前安全审查程序，用于在新的启动之前或在完成变更之后系统地对过程进行评估?Yes 是[ ]  No 否[ ]  Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 101 | Does the facility assess the hazards (Minimum Ignition Energy, Kst classification rating, Impact sensitivity etc.) of the combustible dusts and powders they are handling?该设施是否对他们所处理的可燃性粉尘和粉末的危害性（最小着火能量、KST分类评级、撞击感度等）进行了评估? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 102 | For facilities that handle combustible powders, what types of engineering controls are used to prevent explosions or damage to personnel, equipment, or buildings?针对处理可燃性粉尘的设施，使用什么样的工程控制方法来防止爆炸，对人员的伤害，或者对设备或建筑的损坏？ | Grounding and bonding接地和跨接系统[ ]  Explosion relief panels泄爆板[ ]  Damage limiting construction 隔爆设施[ ] Other 其它[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 103 | Does the facility have engineering controls in place to provide a basis of safety (e.g. containment, absence of a flammable atmosphere [vacuum or inertion], suppression or venting)?该设施是否有合适的工程控制系统来提供基础安全（例如，遏制系统、无易燃环境[真空或惰性]，抑制或排气系统）? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 104 | Does direct fire equipment (e. g. boiler, incinerators, ovens etc.) have a burner management and combustion control system compliant with relevant insurance and/or regulatory requirements? 明火设备（例如，锅炉、焚烧炉、烘箱等）是否有符合相关的保险和/或监管规定的燃烧器管理及燃烧控制系统? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Does it include 是否包括：Prevention of boiler feed water low level 防止锅炉给水低液位的措施Yes 是[ ]  No 否[ ] Routine testing in line with regulatory and/or insurance requirements 符合法规和/或保险要求的定期测试Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 105 | Has the facility evaluated the impact of high hazard operations on the community? 该设施是否评估了高危险性操作对社区的影响? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 106 | Has the facility evaluated the impact from high hazard activities from neighboring operations that may impact the site and result in business interruption? 该设施是否评估了可能影响到该厂区并导致业务中断的、来自相邻企业的高危险性活动的影响? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| Emergency Preparedness and Response应急准备与响应 |  |
| 107 | Are the following areas of the facility equipped with fire detection/protection systems? 该设施的以下区域是否配备了火灾检测/保护系统? | Site areas厂区区域 | Fire/smoke detectors火灾/烟雾探测器 | Sprinkler or suppression systems喷淋或抑制系统 | Comments 注解      |
| Raw material warehouse原材料仓库 | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Flammable liquid storage tanks易燃性液体储罐 | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Process areas工艺区域 | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ] Comments 注解      |
| Finished product warehouse成品仓库 | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ]  | Yes 是[ ]  No 否[ ] Comments 注解      |
| 108 | Does the facility ensure that an adequate amount of fire water is maintained for fire protection?该设施如何保证存有足够量的防火用水? | Yes 是[ ]  No 否[ ] Please explain and include the source of water请说明，包括用水来源:       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 109 | Are new facilities constructed of fire resistive or non-combustible materials? 新设施的建造是采用了防火或非燃性的材料吗? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 110 | Are emergency exits and evacuation routes clearly marked, kept free of obstructions (unlocked), and illuminated with emergency backup power?紧急出口和疏散通道是否都清楚地标明，畅通无阻（未上锁），且有应急备用电源照明? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 111 | Are regular emergency evacuation drills conducted, and what is the frequency? 是否进行常规应急疏散演习，演习的频率如何?  | Yes 是[ ]  No 否[ ] Frequency 频率     Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 112 | Is the fire alarm system monitored 24 hours a day (including weekends and holidays) with prompt notification to emergency services (within 5 minutes)?是否一天24小时内（包括节假日）都有火警系统监控，并能够即时通知应急服务机构(5分钟以内)? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 113 | Does the facility provide sufficient portable fire extinguishing equipment for the hazards present?该设施是否针对可能存在的危害提供足够的便携式灭火设备? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 114 | Is the facility emergency response equipment (fire extinguisher, fire pumps, sprinkler systems) visually inspected monthly, comprehensively inspected annually, and documentation maintained for all inspections? 该设施的应急设备（灭火器、消防泵、喷淋系统）是否每个月都要进行目视检查，每年都要进行全面检查，并保存了所有的检查记录? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 115 | Does the facility properly store idle pallets (e.g.limiting the number and height, no storage in pallet racking, excess storage maintained outside of the manufacturing facility/warehouse unless proper fire suppression in place)? 该设施是否妥善存放闲置托盘（例如：限制数量和高度，不要存放在仓储货架，除非有适当的灭火设施到位，将过量的存储置于生产设施/仓库之外）? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 116 | Does the facility have communication systems to alert the local community of impacts in the event of major emergency? 该设施是否有通讯系统，以便在发生重大突发事故时，可用于提醒当地社区事故的影响? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Please explain what the communication system consists of 请说明通讯系统的组成       | Yes 是[ ]  No 否[ ] Comments 注解      |
| 117 | Are emergency response plans in place and when were the plans updated?应急计划是否到位，是什么时候更新的? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] When was the plan last updated 应急计划最近一次更新是什么时候      Have all foreseeable significant emergency scenarios been accounted for in the Emergency Response Plan?在应急响应计划里面描述了所有可预测的严重的应急场景？Yes 是[ ]  No 否[ ] N/A 不适用[ ]  | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解     Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 118 | Does the site have an on-site emergency response team that is trained for fire or other emergencies?厂区对于火灾或者其它紧急事件是否有驻厂受训的应急响应团队? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] If yes, please explain 若是，请说明       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 119\* | Does the site use off-site consequence modeling to evaluate to potential off-site impact of chemical releases?是否有针对厂区外可能的后果进行模拟，来评估化学品泄露对厂区外的潜在影响? | Yes 是[ ]  No 否[ ] N/A 不适用[ ] If yes, please explain 若是，请说明       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| Hazard Information危害信息 |  |
| 120 | Does the facility maintain Safety Data Sheets (SDSs) for all hazardous substances? 该设施是否保存了所有有害物质的安全数据表（SDSs）? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] Comments 注解      |
| 121 | Does the facility have a training program covering the properties and health effects of the hazardous substances, use of and access to SDSs, container labeling and safe handling procedures?该设施是否有一套涵盖了有害物质的属性及其对健康的影响、安全数据表（SDSs）的利用和获取、以及容器的标记和安全操作程序的培训方案? | Yes 是[ ]  No 否[ ] Please explain:      请说明  | Yes 是[ ]  No 否[ ] Comments 注解      |

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| Biological Safety – Does the facility handle biological materials[[2]](#footnote-2) Yes [ ]  No [ ]  (skip this section)生物安全 – 该设施是否涉及生物安全的物料Yes 是[ ]  No 否[ ]  （跳过该部分） | **Auditor Verification**Please provide observations, details, comments and any supporting documents**审计员核实**请提供观察结果、细节、注解以及任何支持文件 |
| 122 | Does the facility hold a regulatory permit for biological material operations? 涉及生物安全材料的操作，该设施是否持有监管许可? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 123 | Has the facility developed and implemented a Biological Safety Program? 该设施是否制定并实施了生物安全程序？ | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 124 | Does this program include procedures to perform risk assessments of biological materials?该计划是否包括了对生物安全物料进行风险评估的程序? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 125 | Does the facility have a bio-safety committee responsible for evaluating the risk associated with biological materials operations and determining control strategies?Does the facility have a bio-safety committee responsible for evaluating the risk associated with operations and determining control strategies? 该设施是否有一个生物安全管理委员会，负责对与生物安全物料操作有关的风险进行评估，并确定相应的控制策略? | Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 126 | Are engineering and/or administrative controls used to control employee exposure to biological materials? 是否采取工程和/或行政管制来控制员工与生物制剂的接触? | Administrative Controls 管理控制Yes 是[ ]  No 否[ ] Engineering Controls 工程控制Yes 是[ ]  No 否[ ] Please explain:      请说明 | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |
| 127 | Which of the following types of biological materials are stored or handled on the site (please specify the highest risk group (RG)[[3]](#footnote-3) or equivalent hazard category for each).在厂区内储存和使用下列哪类生物材料（请为每一类注明其最高的风险组别（RG）或其它同等的危险分类）。 | Human source material? 人源物质? Yes 是[ ]  No 否[ ]  Specify RG注明风险组别（RG）:      Non-human primate source material? 非人灵长类来源的物质? Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:      Bacteria? 细菌？Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:           Viruses? 病毒？Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:           Fungi? 真菌？Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:      Genetically Modified Organisms / rDNA/ recombinant nucleic acid? 转基因生物/核糖体DNA/重组核酸? Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:      Select Agents / Dual Use Agents(US only) 选择制剂/两用制剂（仅美国适用）: Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:      Other (parasites, prions)? 其它（寄生虫，朊病毒）? Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:      Biological toxins? 生物毒素? Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:      If yes, is the LD50<10 ng/kg? 若是，其LD50是否 <10 ng/kg? Yes 是[ ]  No 否[ ] If yes please explain: 若是， 请说明:       | Yes 是[ ]  No 否[ ] N/A 不适用[ ] Comments 注解      |

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This section is to only be used by the auditor

**此部分仅限审计员使用**

**Summary of Observations/Findings**

**观察项/发现项结果总结**

**Critical Findings 重要的调查结果**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Finding number调查结果编号 | PSCI Principle (Management System/Ethics/Labor/Environment/Health and Safety) and local law(give regulatory citation)PSCI原则（例如，管理体系/道德规范/劳工/环境保护/健康及安全）和地方法规（注明引用的法规） | **Description of Finding****调查结果描述** | **Objective evidence observed****发现的客观证据** | **Possible corrective action****可能的纠正措施** |
|       |  |       |       |       |
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**Other Findings其余的调查结果**

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| --- | --- | --- | --- | --- |
| Finding number调查结果编号 | PSCI Principle (Management System/Ethics/Labor/Environment/Health and Safety) and local law(give regulatory citation)PSCI原则（例如，管理体系/道德规范/劳工/环境保护/健康及安全）和地方法规（注明引用的法规） | **Description of Finding****调查结果描述** | **Objective evidence observed****发现的客观证据** | **Possible corrective action****可能的纠正措施** |
|       |  |       |       |       |
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***Note备注:***

***Critical Observations重要的调查结果::***

* *High or very high risk observations that require immediate action to protect human life, the health of employees or the environment*

*有着高或非常高风险的观察结果，需要立即采取行动，以保护人身安全、员工健康和环境安全*

* *May result in loss of license to operate, damage to reputation*

*可能导致丧失经营许可，并使声誉受损*

* *Requires immediate corrective action taken by supplier*

*需要供应商立即采取纠正行动*

* *Need to be communicated to the audit sponsor prior to audit report finalization*

*在审计报告最终定稿之前需要与审计发起者进行沟通*

***Other Observations******其余的调查结果****:*

* *Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time*

*指所有其它的严重或者轻微审计发现项，需要供应商承诺按照设定的时间表采取纠正行动*

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| --- |
| Summary of Points of Excellence / Good Examples observed观察到的卓越/良好实例点汇总 |
| Points of Excellence / Good Examples observed观察到的卓越/良好实例点 | Objective evidence observed发现的客观证据 |
|       |       |
|       |       |

**Photo Form图片格式**

**Adding Images** To help keep the size of the Report as small as possible for ease of sending and saving the document we recommend that you use Microsoft Paint to resize your photos. To do so please follow these instructions

**添加图像** 为了尽可能减小报告的大小，以便于发送和保存文件，我们建议您使用微软画图程序“Microsoft Paint”来调整照片的大小。请按以下说明操作:

1) To start Microsoft Paint, click 'Start', 'Programs', 'Accessories', then 'Paint'.

 依次点击“开始”、“程序”、“附件”、和“画图”来启动Microsoft Paint。

2) Open the image file you wish to edit.

 打开您想要编辑的图像文件。

3) Click the 'Image' Menu at the top and select "Stretch/Skew Image”.

 点击顶部的“图像”菜单，然后选择“拉伸/扭曲图像”。

4) Choose a percentage figure to resize the image: to avoid distortion, choose the same percentage for horizontal and vertical stretch. Click OK.

 选择一个百分比数字来调整图像的大小:为水平和垂直拉伸选择相同的百分比以避免失真。点击OK。

5) Once you have the desired size, click File > Save As (to prevent overwriting the original image).

 Save As jpeg (this provides compression to make the file smaller).

 一旦您有了所需的尺寸，点击“文件”>“另存为”（ 以防止覆写掉原始图像）。

 保存为JPEG格式（这导致压缩而使得文件变小）。

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| Confirmation 确认Must be signed by both parties 必须由双方共同签署 |
| **Please sign this document confirming that the above findings have been discussed with and understood by you:** (site management)**请签署这份文件，以确认您参与了上述调查结果的讨论并理解其内容:**（厂区管理人员） |
| Site Representative Signature:厂区代表签名: |       | Name:      姓名Title:      职位名称Date:      日期 |
| Auditor Signature: 审计员签名: |       | Name:      姓名Title:      职位名称Date:      日期 |
| Please indicate below if you, the site management, dispute any of the findings作为厂区管理人员，请您在下面注明，是否对任何调查结果持有异议。I dispute the following numbered findings:我对以下编号的调查结果持有异议: |
|       |
| Signed:签名 |       | Title       职位名称Date      日期 |
| Site Comments:厂区注解: |
|       |

1. Water scarcity is defined by the UN Food and Agriculture Organization as: (i) scarcity **in availability** of fresh water of acceptable quality with respect to aggregated demand, in the simple case of physical water shortage; (ii) scarcity **in access** to water services, because of the failure of institutions in place to ensure reliable supply of water to users; (iii) scarcity due to the **lack of adequate infrastructure**, irrespective of the level of water resources, due to financial constraints. In the last two cases, countries may have a relatively high level of water resources endowment, but are unable to capture and distribute them because of limited financial resources for infrastructure development or lack of institutional capacity to maintain and manage them appropriately. (UN FAO, <http://www.fao.org/nr/water/topics_scarcity.html>)

联合国粮农组织对缺水的定义是：（I）与总需求相关的合格质量的淡水资源的短缺，简单的情况是物理性水资源短缺；（II）缺乏供水资源，因为机构没有能够确保向用户提供可靠的供水；（III）由于财政紧缩，缺乏足够的基础设施引起的缺水，在此不考虑供水资源的水平。对后两种情况，国家可能有相对高的供水资源技术水平，但是对于基础设施建设仅有有限的财政资源，或者缺少制度来恰当的维护和管理，导致供水资源不能均匀分布。 [↑](#footnote-ref-1)
2. Biological Materials include pathogenic and non-pathogenic microorganisms, proteins, and nucleic acids, as well as any biological matter that may contain microorganisms, proteins, nucleic acids, or parts thereof. Examples include, but are not limited to, bacteria, viruses, fungi, prions, biological toxins, genetically modified organisms, nucleic acids, tissue samples, biomedical waste, diagnostic specimens, live vaccines, and isolates of a pathogen (e.g., pure culture, suspension, and purified spores).

生物安全材料包括病原，非病原微生物、蛋白及核酸，也包括可能包含微生物、蛋白、核酸，或其中一部分的涉及生物安全的物料。例子包括，但不局限于：细菌、病毒、真菌、感染性蛋白、生物毒素、转基因生物体、核酸、组织样本、生物医学废料、诊断试样、减毒性疫苗以及隔离病原体（例如：纯培养物、悬浮和纯化孢子）。 [↑](#footnote-ref-2)
3. As defined in the World Health Organization, Laboratory Biosafety Manual, 3rd Ed. (2004)

基于世界卫生组织，实验室生物安全手册，第三版（2004）的定义 [↑](#footnote-ref-3)