MANAGERIAL SYSTEM

管理系统

● **Administrative/Role & Responsibilities** 管理的作用和职责	***YES***	***NO***
• Current organization charts available and accurate? 当前可用的、正确的组织结构图		
• Policy/procedure that defines the responsibility and authority of QC unit. 规定 QC 部门的权力和职责的方针或程序		
• Have the responsibilities of each functional group and supervisor been clearly Defined, including testing and operational requirements, SOPs, and all other Critical functions? 每一个分工小组和管理者的职责应有明确的规定，包括测试和操作要求、SOPS 以及其他的关键要求。		
• Is an organizational structure in place and properly staffed to assure all required Testing/monitoring support activities are performed? 是否有适当的组织结构，使员工保证所有要求检验、监测支持活动必须被执行。		
• Is the span of control adequate? 控制范围是否适当、充分？		
• What is the ratio of supervision to analyst? 分析员监督比率是多少？		
• Are the roles and responsibilities for each position clearly defined? 每一个岗位（或职位）的作用与职责是否被明确的规定？		
• Are job descriptions available? 是否有职位说明？		

• Are signature authority, responsibility, and accountabilities appropriate and clearly defined? 签名权力、责任、适当的问责制是否有明确地规定？		
• Do systems exist to enhance communication, understanding, and working relationships between Laboratory and QA personnel? 在实验室与 QA 之间是否有加强信息沟通、理解以及工作关系的程序？		
• Does a personnel performance evaluation system exist which tracks Laboratory Personnel strengths and weakness and establishes corrective action procedures to Mitigate any weakness？ *是否有人员业绩评估程序，跟踪实验室人员的优势和劣势，建立矫正行动程序，减轻任何弱点？*		
• Does a master testing schedule or similar document(s) exit to insure smooth workflow, and minimize Laboratory personnel over commitment? 是否有用以保证顺利工作流程，最小化实验室人员上面的的承诺的主要试验大纲或类似的文件(s)？		
• Do current CV's and resumes exist for all personnel including consultants? 是否有所有员工包括顾问的个人简历？		
• **Training** **培训**		
• Have the educational, training and work experience requirements for each laboratory position been clearly defined and do they reflect current standards in the industry? 对于每一个实验室岗位的教育、培训和工作经验强化培训计划需求是否有明确的规定？*对于行业中的现行标准，他们是否可以反映？*		
• Are training requirements clearly documented in a SOP. (Including Managers, Supervisors, Analysts and Temporary staff)? 培训需求在 SOP 中是否有明确的规定（包括经理、管理者、分析员以及临时员工）？		
• Has a training curriculum been developed for each position which clearly identifies all required SOPs and Policies, safety, cGMPs as well as all other internal and external courses or programs? (Database or hard copy?) 每个位置需要的 SOPS、策略、安全、cGMPs 以及所有其他的内部和外部的课程或者方案(数据库或硬拷贝) 的培训课程是否被开发？		

• Is job-specific training identified? 仅限于工作的培训鉴定了吗？		
• Does each employee have a training file? 每位员工是否都有培训文件（资料）？		
• Are the training histories for each individual current? (Database or hard copy?) 当前的每位员工是否都有培训历史？（数据库或硬拷贝?）		
• Have all laboratory personnel been properly trained? 所有试验人员是否得到适当的培训？		
• Is this training documented and where do these documents reside? 是否有培训记录，并存档？		
• How is SOP training conducted? 如何实施 SOP 培训？		
• Are metrics used to determine acceptability? 是否有可接受的标准？		
• Is there a laboratory certification program? 是否有实验室认证程序？		
• Has an individual been designated as the training coordinator or manager? 是否有固定的培训协调员或经理？		
• Is there evidence or rmanagement support for training and training programs? 是否有培训和管理培训方案的程序文件？		
• Does a formal training budget exist? 是否有一个正式的培训（经费）预算？		
• Do vendor-training records exist? 是否有供应商培训记录？		

• Is there evidence that newly hired employees are evaluated for skill level and competency 是否有证据表明新聘用的员工是经过技术水平和能力的评估？		
• Is there a formal training schedule in place and is being executed? 是否有一个正式的培训计划并正在执行？		
• Is there evidence of employee re-training? 是否有员工再培训的证据？		
• Is there a positive attitude with respect to training on the part of Management and Laboratory personnel? 关于对实验室的管理和人员培训这部分是否有一个积极的态度？		
• **Change Control** **变更控制**		
• Is there a current Change Control system and written procedure for authorization, documentation and implementation of changes that may have a regulatory or quality impact? 是否有经批准的日常变更控制系统和诉讼的书面程序？是否有变更执行后的监管或对质量的可能影响？		
• Who is responsible for administration and approval of Change Control system? 谁负责管理变更控制系统？谁负责审批变更控制系统？		
• Is there a tracking system for changes? 是否有变更跟踪系统？		
• Does the Change Control system include mechanisms for planned changes to: 变更控制系统是否包括对计划的变更机制：		
Standard Operating Procedures? 标准操作规程（SOP）？		
Formulation? 处方？		
Manufacturing Process		

生产过程？		
Major Equipment? 主要设备		
Batch Size? 批量？		
Production Site? 生产地点？		
Raw Material or Packaging Material Supplier/Process? 原（辅）料和包装材料的供应商及生产过程？		
Testing Methods? 测试方法？		
Product Specifications? 产品规格？		
Raw and Packaging Material Specification? 原（辅）料和包装材料明细表？		
Changes in Regulatory Requirements? 变化的监管要求？		
Defining Major and Minor Changes? 定义主要和次要的变化？		
• How are unplanned changes made? 无计划的变更是如何发生的？		
• Who approves those changes? 谁批准这些变更？		
• **Communications/Reports**		

通信/报告		
• Does the lab conduct statistical quality control? 实验室是否进行统计质量控制？		
• How is this information communicated? 此信息是如何传达的？		
• Are lab OOS results trended? 实验室 OOS 结果的趋势如何？		
• Is there a system to inform QA of negative trends? 这个系统在通知 QA 的过程中是否有消极的趋势？		
• Is management notified in a timely manner of all laboratory rejections and negative trends? 在拒绝了所有实验室和消极的趋势后，是否及时的通知了管理人员？		
• Is the information on OOS,lot rejections,etc.supplied in a timely fashion for Annual Product Reviews? 在年度产品回顾中，是否有 OOS 的信息，包括供应商？		
• Are laboratory operations audited routinely? 是否有实验室操作常规审计？		
• What is the frequency? 频率是什么？		
• Are the results documented? 结果是否记录？		
• Are corrective actions done in a timely manner? 是否及时纠正？		
• Who receives copies of the audit reports, responses? 审计报告的副本给谁？是否有反馈？		
• Is there a self-audit program in place?		

是否有一个适当的自审程序？		
• Documented? 记录？		
• Follow-up on Corrective Actions? 对纠正措施的落实？		
• Are internal audit reports reviews with analyst? 是否有内审报告回顾与分析？		
• Are there systems for periodic review of testing programs and QA systems to remain current with industry standards? 这个系统是否有定期审查的测试程序，QA 系统是否是现行的行业标准？		
• Has this process been mapped, does it identify timelines, corresponding SOP and is the map visible to others? *这个过程是否被映射，有确定的时间表，对应的 SOP 以及被其他人看见？*		
• What laboratory committees are in place? 实验室委员会全体委员是否到位？		
• How are the laboratory committee(s) meeting minutes and actions proposed and taken communicated within the department? 实验室委员会如何实施会议纪要，并在提出和采取行动的部门内部实施沟通？		
• Are data reported in all types of reports easily traceable to raw data? 报告中的数据是否容易追踪到所有类型的原始数据？		
• **Trending-Statistical Quality Control** **趋势统计质量控制**		
• Is control charting of data performed? 数据控制图表是否被执行？		
Points to consider:		

考虑的要点		
Finished product 成品		
Raw material 原（辅）料		
Covered by an SOP 覆盖的 SOP		
Frequency of evaluation of control chart 频率控制图的评价		
Appropriateness of response to evaluations 适当的回应评价		
Stability Data 稳定的数据		
● **Complaints** **投诉**		
• Is there a formal product complaint handling system in place, including some system of complaint monitoring, and statistical review? 是否有适当的产品投诉系统，包括一些投诉监控系统，以及统计回顾？		
Points to consider: **考虑的要点：**		
Defined by SOP SOP 的定义		
Consistent with regulatory and industry practice 符合法规和行业惯例		

Laboratory Purchasing **实验室采购**		
• Are levels of approval defined and appropriate 是否规定适当的级别？		
• Are items purchased from qualified vendors (e.g. raw materials, regents, standards, instruments, etc.)? 是否有资质的供应商目录（原材料、试剂、标准品、仪器等等）？		
OPERATING PROCEDURES **操作规程**		
SOPs-General **SOPs-通则**		
• Is there a comprehensive and current laboratory Standard Operating Procedure system? 是否有一个综合的和目前实验室的标准操作规程程序？		
• Is there a list of all approved SOPs? 是否有所有批准的 SOP 目录？		
• Are the SOPs current, clearly written and accessible to all appropriate personnel? 现行的 SOPs，对与所有相关人员是否都是书面明确的和可理解的？		
• Is there a system for periodic review of all SOPs to assure that they are consistent with current Company and industry practices? 是否有所有 SOP 的定期审核制度，以确保它们与当前公司和行业惯例一致？		
• Is there an SOP governing the SOP program? 是否有一个 SOP 管理程序来管理 SOP？		
• Is there a system for controlling the issuance and revision of all SOPs? 是否有控制发放和修订所有 SOP 的系统？		

• Are policies and manuals used that supplement the units SOPs? 是否有政策和手册中使用的 SOPs 的单位补充？		
• How easily accessible are they? 他们如何容易的接受？		
• Are all SOPs reviewed and updated at least every 3 years? 所有的 SOP 回顾和更新至少每 3 年 1 次		
• **Are There Specific Standard Operating Procedures Covering:** **是否有具体的 SOP 覆盖？**		
• Change Control? 变更控制		
• Record review and release requirements? 记录审核与放行的要求？		
• Description of the requirements for performing data review? 数据审核要求的描述？		
• Laboratory records (are raw data recorded in bound notebooks or controlled worksheets?) 实验室记录（受控的原（辅）料数据记录本或者工作表）		
• Dissolution testing? 溶解测试？		
• Sample receipt, documentation, handling, storage, and control? 样品接受、登记、处理、存储和控制？		
• Laboratory investigation/OOS results? 实验室调查/OOS 结果？		
• Validation of Analytical methods? 分析方法验证？		

• Impurity policy for new impurities and/or higher levels of previously knows impurities? 新的杂质，和/或高含量的已知杂质的验证？		
• Laboratory computer validation? 实验室计算机验证？		
• Preparation, labeling, identification, expiration-dating, and storage of chemicals, Reagents and solutions? 制备、标签、标识、产品有效期和化学品储存，试剂和溶液？		
• Equipment/Instrument use, PM, calibration and qualification? 设备/仪器的使用，管理、校准和确认		
• Appropriate labeling of out of use lab equipment? 不再被使用的实验室设备的标志？		
• Glassware washing? 玻璃器皿清洗？		
• Lockers for analysts, uniforms? 分析员是否有衣帽柜，是否有工作服？		
• Practices regarding housekeeping, safety glasses, eating in labs, smoking, etc.? 实验室日常操作中关于家务活、安全眼镜、吃饭、抽烟等是否存在？		
• Waste disposal? 废物处理？		
• Laboratory Sample? 实验室样品处理？		
• Is there an SOP for defining appropriate sampling plans for all QA testing? 是否有规定所有 QA 测试的适当的取样计划？		
• Are samples randomly chosen and are they representative of all portions of the lot? 抽样是否是随机选择的样本，是否具有带表性？		

• Is there an SOP for receipt, documentation, handling, storage and distribution of laboratory samples? 实验室是否有样品接受、登记、处理、存储和分发的 SOP？		
• Is a sample log-book maintained? 是否有连续的样品登记簿？		
• Are samples tracked? 样品是否有跟踪?		
• Is sample disposition included in tracking? 样品是否有处理，包括跟踪？		
• Are areas available for sample disposition(retention, destruction) 是否有样品处理的地方（保留、销毁）？		
• Is there an authorized signature list, including persons names, initials, and responsibilities? 是否有批准的清单，包括姓名（英文名的人名、字母）、责任？		
• Are records available and are samples labeled appropriately to include: Sample description, source, quantity, date sampled, date sample received for testing? 记录是否适用，样品应该贴签，包括：样品种类、来源、数量、取样时间、测试收到样品的时间？		
• Are sample storage areas properly identified and maintained? 是否能正确识别样品的保存和维护区域？		
• Is there a sample backlog? 是否有样品积压？		
• **Laboratory Chemicals, Solutions and Reagents:** **实验室化学品、溶液和试剂**		
• Is there a written procedure for receipt/storage of chemicals and reagents? 化学品和试剂的接受和存储是否有书面的规程？		
• Are they properly labeled with date of receipt, date opened and expiration and retest dates? 瓶子上是否有接受日期、开瓶日期、有效期（或者失效期）和复验期等？		

• Are lab prepared reagents and solutions properly identified? (chemical name or symbol, concentration, date of preparation, initials of the analysts who prepared it, expiration date) 实验室配制的试剂和试液是否有适当的标识？（化学名称或符号、浓度、配置日期、配置人、有效期）		
• Are records available to document preparation and standardization of volumetric solutions? 试剂和试液是否有配制记录，滴定液是否有标化记录？		
• Is the frequency of standardization of various reagents described? 各种试剂的标化频率是否规定？		
• Is it consistent with USP? 是否符合美国药典？		
• Are standardized reagents stored to assure integrity? 标准化试剂的存储，*以保证完整性?*		
• Are procedures for preparation of laboratory reagents and cultures described? 实验室试剂和培养基的配制过程是否有规定？		
• Are procedures for maintenances of laboratory reagents/cultures described? 实验室试剂和培养基*维护*是否有规定？		
• **Laboratory Reference Standards:** **实验室参考标准**		
• Is there a written procedure for ordering and receipt of compendial standards and non-compendial reference standards? 是否有订购和接受药典标准和非药典参考标准的书面规程？		
• Are the primary standards the current lot listed in the USP? 一级标准是否是美国药典中列出的？		
• Is their receipt logged? 接受是否有记录？		

• Are all standards labeled with name, source, lot number and expiration date? 所有的标准标识是否包括：名称、来源、批号和有效期？		
• Do written procedures include provisions for prevention of contamination of Primary standards? 对污染预防的基本标准是否有书面的规程？		
• Are standards stored in a secured area under environmentally Controlled and monitored conditions? 标准是否在有环境控制和监测条件的环境中储存？		
• Are procedures for assuring standard integrity available? 是否有规程保证标准完整可用？		
• Are working or "house" standards checked against primary standards at least every Two years? 工作标准或企业标准是否至少每 2 年跟一级标准核对一次？		
• Are stock solutions appropriately identified, and are their re-use based on their stability? 储备溶液是否有适当的规定，重新使用是否建立在它们的稳定性基础上的？		
• Do procedures exist for the certification and use of non-commercially available Reference standards? 是否有认证的程序和非商业化运作方面存在的参考标准？		
• Do certificates of analysis exist for all reference standards and are these certificates stored as controlled documents? 所有参考标准是否有 COA，并作为受控文件存储？		
• Have provisions been made for handling controlled substance reference standards? 是否规定了处理受控物质的参考标准？		
• Does the reference Standard SOP address proper handling of controlled substance Reference standards? *参考标准 SOP 解决受控物质的参考标准，是否妥善处理？*		
Laboratory Test Procedures **实验室测试过程**		
• Is there an index listing the testing documents/specifications? 是否有索引列表的测试文件/明细单？		

• How is this list updated and controlled? 列表如何更新和控制？		
• Do the test procedures include sufficient instructions to conduct the testing and operate the specific lab instruments? 测试过程包括足够的管理测试的操作指南和操作具体的试验仪器？		
• Is there a system for controlling the issuance and revision of all testing related records? 是否有一个系统控制发放和修订所有的与测试相关的记录？		
• Are laboratory test procedures and specifications approved by the QA unit? 实验室的测试程序和说明是否是经 QA 部门批准的？		
• Is there a written Change Control procedure covering making methods changes? 是否有书面的变更控制程序，包括改进方法的变更？		
• Are specifications for compendial products meeting compendial requirements? *是否有满足药典要求的产品说明？*		
• How are "in-house" or tighter release specifications determined? *内控或更严格的版本的规定是如何确定的？*		
• Covered by SOP? SOP 的覆盖？		
• Are raw materials released by using validated analytical methods? 原（*辅*）料的放行，使用的是否是经验证过的分析方法检测的？		
• What methods are used to release raw materials? 用什么方法来放行原（*辅*）料		
• What methods are used to release container/closures? 用什么方法来放行容器/贴封？（包装材料）		
Laboratory Data and Results **实验室数据和结果**		

• Is data documented in bound pre-numbered logbook, notebook, or other data acquisition system? 有在预先编号的日志，笔记簿，或者其他数据采集系统记录的数据？		
• Is the use of scrap paper, "post its", or similar uncontrollable paper specifically prohibited in the laboratory? 实验室明确禁止使用便条纸、贴纸、或者类似不受控的纸张		
• Are corrective to data entry errors covered in an SOP? 是否有 SOP 规定数据输入错误的纠正？		
• Are all documents/data written in permanent ink? 记录和数据是否是用永久墨水书写的？		
• If bound notebooks are used, is there a system for control, issuance and use? 如果使用笔记簿，是否有控制、签发和使用的程序？		
• Is each page dated and signed by the analyst and second reviewing authorized individual in a timely manner? 每一页是否有分析员签名、并签署日期？及时由经批准的第二人复核？		
• Are all entries checked and approved for completeness of sample identity, reagents, standards, experimental conditions and purpose? 所有项目检查和核准，包括样品身份、标准、试验条件和目的？		
• Are chromatograms, spectra, etc. appropriately identified, stored, referenced to notebooks and readily retrievable *色谱、光谱等是否有适当的识别标志、存储、参考的笔记簿和容易获得的？*		
• Are the date, calculations and results verified by second competent individual for accuracy, completeness and compliance with specifications? 数据、计算和第二人结果复核，要求准确的、完整的和符合规范要求		
• Are the qualifications of person conducting the review acceptable? 对人的资格审查，是否可以接受？		
• Is the review documented by full signature and date? 检查是否用全签名和日期？		

• Are levels of approval described? 是否有批准的水平描述？		
• Are data review and approval activities captured in LIMS? 在 LIMS（实验室信息管理系统）系统获得的数据，是否经审查和批准？		
• Are results approved before distribution? 在放行前，结果是否经过批准？		
• If so, by whom? 如果是这样，那是谁？		
• How do you assure that the method being used in the laboratory is the current approved version method for testing this product? 如何保证实验室采用的方法是目前经批准的版本，用于测试该产品的的方法？，		
• Do you record the method used onto the laboratory testing results sheet? 实验室检测结果中使用的方法是否记录？		
• Is the laboratory method recorded into LIMS? 实验室方法是否是用 LIMS（实验室信息管理系统）？		
• Is there a written SOP for handling of reintegration of HPLC/GC data? 是否有 HPLC/GC 数据处理的书面的 SOP？		
• If a computer software package is used to calculate results, is there an example calculation included with the reported results verifying proper algorithm execution? 如果用计算机软件来计算的结果，与一个实例计算与文献报道的结果验证算法，是否在一个适当的范围内？		
• Are all correction factors used in calculations expressed with proper units? 在适当的单位计算中，所用数据的修约？		
• Are raw data defined in an SOP? SOP 中是否有原始数据的定义？		

● **Security of Data** **数据保密**		
• Is access stored data limited? 存储数据的访问是被限制的？		
• Are data protected from fire, water, and other environmental hazards? 火灾、水灾和其他的环境危害中数据的保护？		
• Is readily retrievable? 可随时检阅？		
• How is it controlled? 如何控制？		
• How long are data kept and how is documentation retention times determined? 数据可保存多久，记录保存时间是如何确定的？		
• Are backup copies of data stored at an off-site location? 备份数据是在原位置以外的地方？		
• Is there a disaster recovery plan, and has it been rehearsed? 是否有一个灾难恢复计划，并且它已经被演练？		
● **Distribution of Results** **结果放行**		
• Are results entered into a LIMS or other electronic management system? 结果输入 LIMS（实验室信息管理系统）中或者其他的电子管理系统中？		
• Do LIMS reports show results that reflect tests that have been determined to be lab errors? LIMS（实验室信息管理系统）报告是否显示测试的结果，已经被确定的实验室错误？		
• Is LIMS used to provide data for using for use in Annual reports? LIMS（实验室信息管理系统）在年度报告中是否被允许使用？		

• How are LIMS data used to support testing of Complaint samples? 如何使用 LIMS（实验室信息管理系统）的数据来支持投诉样品的测试？		
• Is data transcribed from notebooks and reports? 是否有从笔记簿和报告中转录（转抄）数据？		
• Is transcription accuracy being verified? 转录（转抄）的准确性是否被验证？		
● **Chromatography** **色谱**		
• Is system suitability performed routinely? 系统适用性是常规进行？		
• What is system suitability testing run on,e.g. HPLC,GC? 比如 HPLC、GC 中，系统适用性测试是什么？		
• How the system suitability parameters are determined (Selected)? 系统适用性参数如何设定（选择）？		
• Are there acceptance criteria and performance parameters? 是否有接受标准和性能参数？		
• Is there an SOP delineated a standard sample queue? (i.e. interspersing of standards and samples during the course of the chromatographic run) 是否有 SOP 规定标准样品序列？（即在色谱运行过程中的标准和样品）		
● **In-Process Testing** **过程测试**		
• Are established and validated methods available for in-process testing? 提供的过程测试方法是否经制定和验证？		
• Do sampling plans exist?		

是否有抽样计划？		
• Are there established acceptance criteria/ranges/specifications for the in-process tests? 过程测试中的接受标准/范围/规范是否建立？		
• How is sample integrity preserved during handling and storage? 样品处理和存储过程中，样品的完整性如何？		
• Are all in-process tests conducted?(blend samples, weight variation, hardness, thickness) 所有的过程测试都被控制？（混合样品、重量差异、硬度、厚度）		
● **Assignment of Retest/Expiry Dates** **复测工作/失效日期**		
• Are expiration/retest dates based on available in-house storage stability data or otherwise justified? 到期/复测数据是根据现有的内部存储稳定性的数据或者其他的合理依据，是这样的吗？		
• Does the SOP differentiate between retest and expiry dating? 复验和失效期在 SOP 中是否有区别？		
• Is there a limit for extending the retest life the substance evaluated? 对于延长有效期的物质重新测试评估，是否有限制？		
• Are there procedures for Handling/Storage of Reference Standard and Reference Cultures? 是否有处理/存储参考标准和标准菌株的程序？		
LABORATORY EQUIPMENT **实验室设备**		
● **Laboratory Equipment-General** **实验室设备通则**		
• Are the laboratory equipped with all of the necessary instruments for the analytical testing to be performed? 对于实验室分析测试所必需的仪器装备，是否到位？		

• Is there a written Qualification, Calibration and Preventive Maintenance program in place? 是否有书面的资格、校准和预防性维修计划？		
• Is there a master listing available and maintained for Unit's equipment / instrumentation calibration, maintenance and IQ/OQ/PQ documents? 使用和维护单位设备/仪器校准、维护和 IQ/OQ/PQ 的文件是否列出？		
• Who is responsible? 谁负责？		
• How is it administered (analyst vendor, outside contractor)? 如何管理（分析师供应商、承包商）		
• Is there a master schedule? 是否有主计划？		
• Are logbooks available documenting instrument calibration history, status and requirements? 是否有可用的日志来记录仪器校准的历史、现状和要求？		
• Is there usage logs associated with each piece of equipment? 每件设备是否有相关的使用记录？		
• Are logbooks, records, file maintained and accessible in which repairs and PM are recorded? 修理中是否有日志、记录、文件维护和访问， 设备管理记录？		
• Do labels on the instruments identify the person who performed the calibration, date of calibration and due date of next calibration? 仪器上是否有标识？校准人、校准日期和下次校准日期？		
• Are the records reviewed? 记录审核？		
• Has IQ/OQ/PQ been performed and properly documented for all relevant facilities, equipment, instrumentation and utilities?		

是否有 IQ/OQ/PQ 认证？妥善记录所有相关设施、设备、仪器仪表和公用事业？		
•		
• Does the SOP require that instruments failing calibration be removed from use? 未能校准的仪器 SOP 需要从使用中删除？		
• Does the procedure provide directions for investigations when instrumentation is found to be out of calibration? 该程序是否为当仪器被发现是标定了调查方向？		
•		
• Is calibration and preventive maintenance(PM),including tolerances, based on manufacturer's recommendation? 是否有校准和预防性维护（PM），包括根据供应商建议的偏差？		
•		
• Are balances calibrated at both upper and lower weighing capability? 天平在量程高低范围内是否校准？		
• Calibrated against NIST standards? 按照 NIST（美国国家标准和技术协会）标准校准？		
• Is calibration correction factor visible on thermometers? 各温度下的校正系数是已知的？		
• Are PH meters calibrated at two points, not differing by more that 4 PH units? pH 是采用两点校准，而不是更多的 4 点校准？		
• Are UV spectrophotometers calibrated for wavelength and photometric accuracy? 紫外分光光度计是否是波长校准和广度的准确性校正？		
• Is there a written procedure for set up, calibration, and operation of Dissolution baths? 崩解仪是否有设置、校准、和操作的书面程序？		

• Are there written procedure for calibration and maintenance of HPLC / GC, including pumps, auto sampler reproducibility, wavelength accuracy? HPLC/GC 是否有仪器校准和维护的书面规程，包括泵、自动进样的重复性、波长精确度等？		
• Do PMs include seal and valve change? 密封件和阀门的变化是否有管理？		
• Do columns undergo performance checks for resolution, retention, and efficiency? 分离度、保留时间、柱效等柱性能检查？		
● Validation (Qualification) of Laboratory Equipment **实验室设备的验证（确认）**		
• Is there a written policy or procedures for validation of computer, microprocessor controlled instrumentation using software calculations of data? 计算机验证以及微处理机控制的仪器数据处理软件计算的数据是否有书面的程序？		
• Is there a list describing instruments requirement validation and change control procedures? 是否有一个列表来描述需要验证的仪器和变更控制的程序？		
• Are there IQ, OQ, PQ requirements, suitability and availability of documentation? 是否有 IQ\OQ\PQ 的需求、系统适用性和记录的有效性？		
• Are cleaning procedures included in the SOPs for instrument qualification or calibration? 是否有清洁规程，包括仪器确认或校准的 SOP？		
• Is computer controlled laboratory equipment validated? 采用计算机控制的实验室设备的验证？		
• Is system used to install new software versions and to decide what scope of re-validation must be done? 采用新的软件版本以及再验证的范围必须确定？		
• Is there an SOP that described this system? 是否有 SOP 来说明这个系统？		
• Was an IQ and OQ performed on the system during installation?		

系统安装过程中的 IQ 和 OQ 是否做过？		
• Was computer software validation a part of the OQ process? OQ 过程是计算机软件验证的一个部分？		
• Does the vendor maintain the source code? 供应商是否保持原代码？		
• Do they provide a validation certificate? 他们是否提供验证证书？		
• Is the validation documented? 是否有验证文件？		
• Are there systems in place to prevent installation of unauthorized software? 是否有防止未经授权的软件安装系统？		
• How were integrators validated? 如何进行综合验证的？		
• Is there a validation master plan that defines timing and responsibility for qualification? 规定验证的时间和职责的验证主计划是否有？		
• What triggers re-qualification and is it integrated into the master plan? 什么情况下需要再确认，主计划中是否有说明？		
• Does the lab equipment have the correct qualification specifications? 实验室设备是否有正确的确认规程？		
• Are calibration/metrology records secure (locked up)? 校准和计量记录是否安全（被锁住）？		
• Are balances checked for *corner* loading? 天平***额角***加载是否检查过？		
• Are HPLC/GC systems qualified/calibrated first by component, then as a system?		

HPLC/GC 系统的验证/校准首先是各组件，然后是整个系统？		
• Are PH meters standardizes and calibrated? PH 计是否计量和校准？		
• Are calibration/service vendors qualified and are their training records available? 校准/服务的供应商确认以及他们的培训记录？		
LABORATORY FACILITIES **实验室设施**		
● **Laboratory Facilities-General** **实验室设施通则**		
• Is the physical contraction of the laboratory areas adequate for testing and all routine actives with respect to : 实验室区域是是否适合于测试和所有的常规活动，包括：		
Size?尺寸		
Layout and design?布局和设计		
Sample receipt?样品接收		
Appropriate tables for balances/ instruments, etc? 合适的天平和仪器台		
Location of SOPs, location of methods, safety data sheet? SOP，方法和安全性数据表的放置		
Location of reagents, standards, solutions, solvents?		

试剂，标准品，溶液，溶剂的放置		
Data entry, recording, writing areas? 数据录入，记录和书写区		
Sample storage and retention? 样品保存		
Refrigeration? 冷藏		
• Are proper system in place to minimize cross-contamination during sample preparation and laboratory testing? 是否有合适的系统用于减少样品制备和实验室测试的交叉污染？		
• Are all controlled temperature/humidity storage areas, incubators, etc. monitored to assure that proper conditions are maintained? 是否所有受控温度，湿度的贮存区，培养箱等都受监测以确保维持合适的条件？		
• Have temperature monitoring systems and equipment been properly validated? 是否温度监测系统和设备已经经过验证？		
• Is good housekeeping observed? 是否可以看到好的内务管理？		
• Are controlled substances properly segregated and controlled according to DEA requirements? 受控物品是否隔离并根据 DEA 要求控制？		
• Is the environment/temperature control correct for the areas for different types of equipment? 对于不同的设备是否有恰当的环境/温度控制？		
• Are radioisotopes in the review of proper storage areas, etc.? 放射性同位素是否放在合适的区域？		

• Are uninterruptible powder supply units (UPS) available in the case of powder surge? 当电力不足时，UPS 是否可用？		
• If an UPS exists, has it been qualified and an SOP describing its use been written? 如果存在 UPS，是否对其进行确认，及有 SOP 描述了使用方式？		
• Are piping systems specified at the correct pressure and that they have been cleaned, flushed, leak tested passivated (sanitary use) and certified? 管道系统设计是否在正确的压力下，及经过清洁，冲洗，泄漏测试，钝化和鉴定？		
• Have appropriate air filters have been installed and smoke tests performed? 是否安装了合适的空气过滤器和完成烟雾测试		
• Have facility monitoring systems been validated? 设备监控系统是否验证？		
• Have purified water and WFI systems been validated correctly? 纯水和 WFI 系统是否正确的验证了？		
• Is there an SOP for lab or engineering maintenance of the air system? 是否有空调系统的实验室或工程维护的 SOP？		
• Are appropriate controls available/specifications for handling particulate matter, microbes? 是否有合适的控制/说明用于处理微粒和微生物？		
• Is there control of HVAC in instrument rooms? Balance area, HPLC? 在器械室是否有 HVAC 的控制？天平室，HPLC 呢？		
• Where does the hood exhaust? 在哪排气？		
• where is air intake system? 空气入口在哪？		
• How are solvent, dust, microbes and chemical handled? 溶剂，灰尘，微生物喝化学品如何处理？		

• Is the HVAC for stability/retention samples adequately monitored? 就于稳定性/留样的空调系统是否监测 ？		
• Is there a distilled water system supplying the laboratory? 是否有蒸馏水系统用于实验室?		
• Is there routine monitoring to assure adequate quality of the water? 是否有常规监测以确保水的质量？		
• Are the types of water required for the lab identified-specs? 水的类型是否满足实验室要求？		
• Is lab water in site monitoring program-testing frequency? 是否经常进行实验室用水在线监测系统测试？		
• Are there action plans following water OOS? 是否有水的 OOS 的行动计划？		
• Is there a schedule for servicing the laboratory water system? 是否有维修水系统的时间表？		
• *How are appropriate quality assured-powder failures-brown outs?*		
• For testing restarted because of powder of HVAC utility failure, is there an SOP available for restarting testing, OOS etc. ? 对于由于空调电力故障造成的测试重启，是否有 SOP 用于重新开始测试和 OOS 等？		
• **Safety and Environmental Concerns** **安全和环境**		
• Is there a safety and environmental SOP? 是否有安全和环境 SOP？		
• Is there testing of Hoods? 是否有排风测试		

• Are hazardous materials identified and segregated? 有害物品是否标明并单独存放？		
• Are safety data sheets available? 安全数据表是否可用？		
• Are they updated? 是否更新？		
• By whom? 由谁更新？		
• Is there a program that describes microbes, handling and disposal of, biohazardous waste? 是否有程序描述微生物，生物有害性废物的处理？		
• Are toxic/dangerous chemicals handled and disposed of according to local regulations? 是否根据当地法规进行有毒/危险化学品处理和处置？		
• Are employees trained to handle toxic/dangerous materials? 职工是否经过处理有毒/危险化学品的培训？		
● Laboratory Glassware **实验室玻璃器具**		
• Has glassware washing/cleaning been validated? 玻璃器具的清洗是否经过验证？		
• Is there a PM program-manual/mechanical/software? 是否有 PM 程序－手动/自动/软件？		
• How has removal of chemical residues been demonstrated? 如何证明化学残留的去除？		
• Are physical imperfections checked and defective glassware discarded? 不完整和有缺陷的玻璃器具是否丢弃？		

● **Cleaning Validation** **清洁验证**		
• Is there an on-going cleaning validation program in place? 是否有正在进行的清洁验证程序？		
• Is cleaning validation conducted according to a master plan and schedule? 清洁验证是否根据主计划和时间表进行？		
• Are there validated sampling procedures developed to support cleaning validation studies? 是否有验证的取样程序以支持清洁验证研究？		
• Are there written acceptance criteria? 是否有书面可接受标准？		
• Were recovery studies conducted? 回收率测试？		
• Are there validated analytical methods developed to support cleaning validation studies? 是否有验证过的分析方法？		
• Does the cleaning validation test both rinse water and area swap samples? 清洁验证是否测试淋洗水和擦拭样品？		
LABORATORY COMPUTER SYSTEMS **实验室计算机系统**		
● **Laboratory Computer Systems-General** **实验室计算机系统通则**		
• Is there a written Qualification, Calibration and Maintenance program in place for laboratory instrument software? 是否有实验室器材软件的书面确认，较验和维护程序		

• How are spreadsheets uses in the laboratory? 如何使用电子表格？		
• Are they available on the network, or on disk? 是用于网络还是硬盘？		
• Are the spreadsheets alterable? 电子表格可修改吗？		
• Have the calculations been validated? 计算是否经过验证？		
• How do you insure that the correct and validated versions are being used? 如何确保使用了正确的经验证的版本？		
• Do you use any other special computer programs to calcute results? 是否使用其他专用计算机程序计算结果？		
• HPLC or GC data calculations? UV spectral calculations? GPLC 或 GC 数据计算？UV 光谱计算？		
• Are electronic documentation systems used? 是否使用电子文档系统		
• If yes, are they validated? 如果用，是否经过验证？		
• What is the frequency of revalidation? 再验证的周期？		
• Is there a LIMS System for data management? 是否有 LIMS 系统用于数据管理		
• What samples are included in LIMS? LIMS 包括哪些样品？		

• What decisions are made from the LIMS data? 哪些结果是 LIMS 数据得出的		
• What calculations does the LIMS perform? (min, max, averaging, etc.) LIMS 完成哪些计算（最小，最大，平均等）		
• What reports are generated by LIMS? LIMS 生成哪些报告？		
• Do these reports go into batch records? 这些报告会和批记录一起吗？		
• Have lab personnel been trained on LIMS data entry? 实验室人员是否经过 LIMS 数据输入的培训？		
• Where are data stored that has not been included in the notebook? 不存放在笔记本中的数据存放在哪？		
• Is it validated? 是否验证？		
• Is there a SOP describing the procedure for installing and validating LIMS software, including System Setup/Installation, Data Collection, System Maintenance, Data backup and Recovery, Security, Change Control? 是否有 SOP 描述了 LIMS 软件的安装和验证，包括系统安装，数据收集，系统维护，数据备份和恢复，安全，变更控制？		
• **System Setup/Installation** **系统安装**		
• Was a functional specification written for the LIMS purchase? 是否有用于 LIMS 购买的功能说明？		
• Is the LIMS a custom program or a commercial system? LIMS 是一个客户程序还是商业系统？		

• Was an IQ/OQ performed at the time that the LIMS program was installed? LIMS 程序安装时是否完成了 IQ/OQ		
• Installation Qualification IQ		
• Was the IQ purchased from the vendor? IQ 是否购自供应商？		
• What site preparation was necessary? 工厂需要准备什么		
• Did the vendor install the system or site personnel? 供应商完成安装还是工厂人员？		
• How was the installation of the system documented? 系统安装如何文件化		
• Operational Qualification OQ		
• How was the customization of the system documented? 系统的定制如何文件化？		
• How are the master copies of the software stored? 软件的主备份如何保存		
• Was the LIMS system validated to produce the reports that currently being used? LIMS 系统是否验证		
• Were the calculations currently being performed validated during the OQ? OQ 期间是否完成了计算的验证		
• Were the scheduling functions currently being used validated during the OQ? 顺序功能在 OQ 时是否经过验证		

• How was the OQ documented? OQ 如何文件化		
● **Data Collection** **数据收集**		
• Are there automated data entry and extraction points in the LIMS? LIMS 中有没有自动的数据进入和取出点？		
Have the links been validated for : 具有		
Bar code reader? 条形码读取器		
HPLC data stations? HPLC 工作站		
GC data stations? GC 工作站		
Balances? 天平		
Spreadsheets? 电子表格		
• Is there a definition of what is considered raw data? 是否有对原始数据的定义？		
• Can data entries be made by only authorized, password protected individuals? 数据输入可否仅由授权人进行，有单独密码保护？		
● **System Maintenance** **系统维护**		

• Are the versions of software used to generate, collect, maintain, and transmit data updated in the system documentation? 用于产生，收集，维护和传送数据的软件版本是否在系统文件中更新？		
• Are all system changes reviewed for their impact on the LIMS program? 是否所有的系统变更都对其影响进行回顾		
• Are new reports considered updated? 新的报告是否考虑更新？		
• Is the program re-validated on a regular basis? 程序的再验证是否有正规的依据		
• When the last time re-validation is was accomplished? 最后一次再验证是什么时候完成的		
• **Data backup and recovery** **数据备份和恢复**		
• Do you have procedures for backup and recovery? 是否有数据备份和恢复的程序？		
• Is the system backed up on a regular basis? 系统是否基于一定的规则进行备份？		
• Are the backups documented? 备份是否文件化？		
• Are recoveries documented? 恢复是否文件化？		
• **Security of Data** **数据安全**		
• Is access stored data limited?		

数据的访问是否受限		
• Are data protected from fire, water, and other environmental hazards? 数据是否受保护以免遭火，水和其他环境灾害		
• Is it readily retrievable? 是否可挽回		
• How is it controlled? 如何进行控制		
• Is there a system to assure that once data is entered, written security procedures prevent its delection, editing or alteration? 是否有一个系统确保一旦进入数据，避免其被删除，编辑或修改		
• How are data amendments authorized? 数据改正如何授权？		
• Are the original data retained? 原始数据是否保存		
• How do you control deletion of HPLC data by functions such as "abort", "restart" etc.? 如何控制 HPLC 数据通过“放弃”和“重启”进行删除		
• How long are data kept and how is documentation retention times determined? 数据保存时间和文件化的周期如何确定		
• Are backup copies of data stored at an off-site location? 备份的数据是否离线保存		
• Is there a disaster recovery plan, and has it been rehearsed? 是否有灾难恢复计划，是否进行演习？		
Software Change Control **软件变更控制**		

• Have there been updates purchased or improvements made to the software? 是否有软件的更新		
• Have the improvements been validated? 更新是否经过验证		
• Does a change control system track the changes? 是否有变更控制系统跟踪变更？		
• Are the system manager's qualifications, training, and experience documented? 是否有系统管理者的确认，培训和经历的文件？		
• Are the user's trained in operation of the system? 使用者是否经过如何操作系统的培训		
• What training materials are used? 使用的培训材料？		
• Is the training consistent with all relevant cGMPs? 培训是否和所有相关 cGMP 一致？		
• Are all monitoring programs clearly defined, including scope of the program, testing rationale, testing frequencies, action limts,etc.? 是否所有的监测程序都得到明确定义，包括范围，测试原理，频率，和行动限等。		
LABORATORY INVESTIGATIONS **实验室调查**		
● **OOS Investigations** **OOS 调查**		
• Is there a procedure that defines the minimum requirements for OOS investigations? 是否有程序规定了 OOS 调查的最低要求？		

• Are OOS investigations handled in a manner consistent with Barr decision and FDA expectations? OOS 调查是否与 FDA 期望的一致？		
• Is supervisor immediately notified of OOS result? 主管是否立即知道 OOS 调查的结果？		
• Are test material (glassware, test solutions) retained? 测试材料（玻璃器具，测试溶剂）是否保留？		
• Are informal/formal investigations performed in a timely manner? 是否有及时的正式/不正式的调查？		
• Are criteria and accountability defined for cross-functional investigation, retesting, re-sampling etc? 是否有交叉功能调查，重测，重新取样等的标准和说明？		
• Are procedures in place to eliminate release of product by continuous or re-sampling? 程序是否		
• Does a pre-defined testing regimen exist? 是否有预先确定的测试主体？		
• Are investigations/responses performed in a timely manner? 调查/反应是否及时完成？		
• Is there a procedure that defines the minimum requirements for all types of QA investigations? 是否有程序规定所有 QA 调查的最低要求？		
Deviations 偏差		
Retention Samples 留样		
• Are retention samples taken at the same time as the test sample and representative of the lot? 在取测试样品时和批次代表时是否进行留样？		

• Is retention samples appropriately labeled, stored in secure, environmentally controlled and monitored area? 留样是否有合适的标签，安全存放，环境控制和监测区域？		
• Is a current list of retention samples maintained including lot numbers and location? 是否有现行的留样清单包括批号和位置？		
● **Microbiological OOS Investigations** **微生物 OOS 调查**		
• Is there an SOP for the investigation of OOS microbiological results and subsequent retesting? 是否有微生物结果的 OOS 调查和重新测试的 SOP？		
• Is microbiological retesting compendia based? 微生物重新测试是否基于药典？		
• FDA based? 根据 FDA？		
• Other? 其他？		
• Does the SOP cover failure investigations for sterility, pyrogens, water, environment monitoring, microbial limits? SOP 是否包含灭菌，热原，水，环境监测，微生物限度的失败调查？		
• Any others? 及其他？		
• Are isolates from Total Plate Count testing identified when there are major concerns for microbial contaminations? 当怀疑是微生物污染时，从总菌落计数中分离到的菌株是否进行鉴定？		
● **Environment Monitoring Program** **环境监测程序**		

• Is there a formal program? 是否有正式的程序？		
• What is the rationale for the program elements? 程序的基本原理是什么？		
• What is the frequency of monitoring? 监测频率？		
• Have environmental recoveries been validated from hard surfaces? 环境恢复是否经过验证？		
• Critical and Non-critical? 关键的还是非关键的？		
• What are the elements of the personnel monitoring program? For sterility-hands, gowns. 人员监测程序的原理是什么？包括手消毒和更衣		
• What are the environmental monitoring air limits? 环境监测空气限度是什么？		
• Are environmental action and alert limits established? 是否制定了环境行动限和警报限？		
• Is trending of data performed? 是否对数据趋势进行统计？		
• How are operating departments notified of a problem? 操作部门如何通报问题？		
• What time frame? 时间构成？		
• How is this documented? 如何文件化？		

● **Aseptic Technique** **消毒技术**		
• Is there an SOP for aseptic technique? 是否有消毒技术的 SOP？		
• Does it require training of new analysts and reinforcement training of more experience analysts? 是否需要对新分析员的培训和有经验的分析员加强培训？		
● **Media Preparation/Sterilization** **培养基配制/灭菌**		
• Is there an SOP that governs the preparation and sterilization of media? 是否有 SOP 管理培养基的配制和灭菌？		
• Is there an SOP requiring growth promotion? 是否有要求促生长实验的 SOP？		
• Are growth promotion studies performed for each batch of media? 是否每批培养基都进行促生长实验？		
• If supplier by outside vendor, has the vendor been validate? 如果由外界供应商提供培养基，供应商是否经过验证？		
• Are media vendors qualified? 对培养基的供应商是否进行了确认？		
• Do purchased and prepared lots of media have lot numbers, expiry dates and growth promotion results? 购买和配制的培养基是否有批号，失效期和促生长实验结果？		
• Are they labeled with date received, date opened and date to be discarded? 是否有标签显示接收日期，开瓶日期和失效期？		
• Are prepared solutions and media labeled with identity, preparer, dates of preparation and expiration date? 配制的溶液和培养基是否有标签显示名称，制备人，制备日期和失效期？		

• Are media, reagents, biological indicators, etc. stored under appropriate conditions? 培养基，试剂，生物指示剂等是否存放于合适的条件下？		
● **Bioburden / Microbial Limits Testing** **生物负载/微生物限度检查**		
• What categories of samples are tested? 哪些样品被测试？		
• Is there an SOP that governs bioburden testing requirements, controls, specifications, disposition and documentation? 是否有 SOP 管理生物负载测试要求，控制，规定，部置和文件？		
• Have all bioburden methods been validated and documented? 是否所有的生物负载方法已经过验证并文件化？		
• Are bioburden data trended? 是否有生物负载数据的趋势统计？		
• Are positive controls used in all testing? 所有测试都使用阳性对照？		
• Is the identification of isolates performed when appropriate? 必要时是否对菌落进行鉴别？		
• Is microbiological stability testing performed on specified time intervals and according to stability protocols? 是否在规定时间通过稳定性方案进行微生物稳定性测试？		
● **Sterility Testing** **无菌检查**		
• Is testing in agreement with regulatory filing? 测试是否与注册文档一致？		

• Is the method validated and documented? 方法是否经过验证并写成文件？		
• Is environmental monitoring performed during sterility testing? 无菌检查的同时是否进行环境监测？		
• Are there alert and action levels with rationale? 是否具有警报限和行动限		
• Is there an SOP for cleaning, disinfection and sterilization of the sterility testing? 是否有清洁，消毒和灭菌的 SOP？		
• Are negative controls used? 是否使用阴性对照？		
● **Water Testing** **水测试**		
• Is there an SOP for sampling water, containing sampling points, frequency? 是否有水取样的 SOP，包括取样点和取样频率？		
• Is there an SOP for microbiological testing of water, specification, handling of disrepant results? 是否有水的微生物测试的 SOP，规范，差异数据处理？		
• What are the action and alert limits for : WFI-endotoxin, WFI-bacterial testing, Purified water, other? 是否有 WFI－内毒素，WFI－细菌测试，纯化水及其他的行动限和警报限？		
• Are water data trended? 是否有水数据的趋势统计		
● **Special Microbiological Testing** **特定微生物测试**		
• Is microbiological testing performed on disinfectants, lubricants, packaging components, biological indicators, complaints, and validation and/or R&D samples?		

消毒剂，润滑剂，包材，生物指示剂，投诉，样品的研发和确认是否完成微生物测试		
● **Identification Systems** **鉴别系统**		
• Is there an SOP for identifying organisms? 是否有鉴别微生物的 SOP？		
• Are manual and/or automated identification systems used? 使用的是人工的还是自动的鉴别系统？		
• Are these systems validated? 系统是否经过验证？		
• Were plant isolates and predefined acceptance criteria used? 是否使用分离培养和预先确定的接受限度？		
● **Preservative Effectiveness Testing** **防腐剂效力测试**		
• Is there an SOP for performing preservative effectiveness testing? 有完成防腐剂效力测试的 SOP 吗？		
• Is the method validated? 方法是否经过验证？		
• Is preservative effectiveness testing performed for stability samples of preserved products? 防腐剂效力测试是否用于保存的产品的稳定性样品？		
• Is analytical testing performed for this purpose? 分析方法是基于这个目的吗？		
● **Bacterial Endotoxins Testing** **细菌内毒素测试**		

• Is there an SOP for performing bacterial endotoxins testing? 是否有细菌内毒素测试的 SOP？		
• Is the test validated? 测试是否经过验证？		
Compressed Gases **压缩气体**		
• Is there an SOP for sampling compressed gases, including sampling points, frequency specifications, handling discrepant data? 有没有压缩空气取样的 SOP，包括取样点，频率，差异数据处理？		
• Is there an SOP for microbiological testing of compressed gases? 有没有压缩气体微生物测试的 SOP？		
ANY ADDITIONAL ITEMS? **其他项目？**		