# ****CHAPTER 1 PHARMACEUTICAL QUALITY SYSTEM****

# ****第1章 药品质量体系****

1.8 Good Manufacturing Practice is that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing Authorisation, Clinical Trial Authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control. The basic requirements of GMP are that:

1.8药品生产质量管理规范（GMP）是质量管理的一部分，有助于确保产品按标准持续生产和控制，以符合其预期使用的用途，并符合注册要求、临床试验要求或产品质量标准的要求。药品生产质量管理规范涉及药品生产和质量控制。GMP的基本要求是：

(i) All manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications;

(i) 所有的生产过程都有清晰的定义，并经过系统性审查，以证明能够持续生产满足质量要求并符合质量标准的药品；

(ii) Critical steps of manufacturing processes and significant changes to the process are validated;

(ii)制造工艺的关键步骤和工艺重大变更应进行验证；

All necessary facilities for GMP are provided including:

提供GMP的所有必要条件，包括：

· Appropriately qualified and trained personnel;

适当的合格和受过培训的人员；

· Adequate premises and space;

适当的场所和空间；

· Suitable equipment and services;

适当的设备和维修保障；

· Correct materials, containers and labels;

正确的物料、容器和标签；

· Approved procedures and instructions, in accordance with the Pharmaceutical Quality System;

根据药品质量体系批准的程序和操作指令；

· Suitable storage and transport.

适当的储存和运输。

(iv) Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided;

(iv) 应当使用准确、易懂的语言制定程序和操作指令，特别是设施设备的操作；

(v) Procedures are carried out correctly and operators are trained to do so;

(v) 操作人员经过培训，以正确执行操作程序；

(vi) Records are made, manually and/or by recording instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected;

(vi)在制造过程中应手动和/或仪器形成记录，以证明程序和操作指令要求的所有步骤被有效执行，且产品数量和质量符合预期；

(vii) Any significant deviations are fully recorded, investigated with the objective of determining the root cause and appropriate corrective and preventive action implemented;

(vii)任何重大偏差都要充分记录，调查以确定根本原因并采取适当的纠正和预防措施；

(viii) Records of manufacture including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form;

(viii)批记录和发运记录应当能够追溯批产品的完整历史，并妥善保存、便于查阅；

(ix) The distribution of the products minimises any risk to their quality and takes account of good distribution practice;

(ix)产品分销应降低其质量的风险，并执行GDP；

(x) A system is available to recall any batch of product, from sale or supply;

(x)建立召回系统，确保可从销售或供应中召回任何一批产品；

(xi) Complaints about products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent reoccurrence.

(xi) 调查导致药品投诉和质量缺陷的原因，并采取措施，防止类似质量缺陷再次发生

**QUALITY CONTRO**

**质量控制**

1.9 Quality Control is that part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organisation, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. The basic requirements of Quality Control are that:

1.9质量控制是药品生产质量管理规范的一部分，涉及取样、质量标准和检验以及组织、文件和放行程序，应确保在必要的和相关的检验完成，并且物料或产品质量被判定为合格前，物料不得放行使用，产品不得放行销售或供应。

(i) Adequate facilities, trained personnel and approved procedures are available for sampling and testing starting materials, packaging materials, intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;

(i) 应有足够的设施、经培训的人员和经批准的程序用于原材料、包装材料、中间品、待包装品和成品的取样和检测，和满足GMP的适当的监测环境条件（如适用）；

(ii) Samples of starting materials, packaging materials, intermediate products, bulk products and finished products are taken by approved personnel and methods;

(ii)原材料、包装材料、中间产品、散装产品、成品的取样人员和方法应经过批准；

(iii) Test methods are validated;

(iii)检验方法应经过验证；

(iv) Records are made, manually and/or by recording instruments, which demonstrate that all the required sampling, inspecting and testing procedures were actually carried out. Any deviations are fully recorded and investigated;

(iv)应有手动的和/或通过记录仪器的记录，证明所有要求的取样、检查和检验程序有效执行。任何偏差都应充分记录和调查；

(v) The finished products contain active ingredients complying with the qualitative and quantitative composition of the Marketing Authorisation or Clinical Trial Authorisation, are of the purity required, and are enclosed within their proper containers and correctly labelled;

(v)含有的活性成分符合注册或临床试验的定性和定量要求的成品，应符合纯度要求，用适当的容器包装，并正确标识；

(vi) Records are made of the results of inspection and that testing of materials, intermediate, bulk, and finished products is formally assessed against specification. Product assessment includes a review and evaluation of relevant production documentation and an assessment of deviations from specified procedures;

(vi)应当记录检验结果和根据质量标准对物料、中间、散装和成品的正式评估。产品评估包括对相关生产文件的审查和评估以及不符合规定程序的偏差的评估；

(vii) No batch of product is released for sale or supply prior to certification by an Authorised Person that it is in accordance with the requirements of the relevant authorisations;

(vii)在质量受权人（QP）证明其符合相关授权要求之前，任何一批产品都不得放行供销售或供应；

(viii) Sufficient reference samples of starting materials and products are retained in accordance with Annex 19 to permit future examination of the product if necessary and that the sample is retained in the final pack.

(viii)根据附录19保留足够的原材料和产品留样，以便必要时产品检查，并且样品应保留在最终包装相同的包装中。

**PRODUCT QUALITY REVIEW**

**产品质量回顾**

1.10 Regular periodic or rolling quality reviews of all authorised medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements. Such reviews should normally be conducted and documented annually, taking into account previous reviews, and should include at least:

1.10对所有注册药品（包括仅出口产品）进行定期或滚动质量回顾，以确认工艺稳定可靠，以及原辅料、成品现行质量标准的适用性，及时发现不良趋势，并确定产品和工艺改进。此类回顾通常应每年进行一次并记录，同时应考虑到以前的回顾，并至少应包括：

(i) A review of starting materials including packaging materials used in the product, especially those from new sources and in particular the review of supply chain traceability of active substances;

(i) 对产品中使用的原材料包括包装材料进行回顾，特别是新供应商的包装材料，以及贵活性物质的供应链追溯性的回顾；

(ii) A review of critical in-process controls and finished product results;

(ii)对关键过程控制和成品检验结果进行回顾；

(iii) A review of all batches that failed to meet established specification(s) and their investigation;

(iii)对不符合既定质量标准的所有批次及其调查进行回顾；

(iv) A review of all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventive actions taken;

(iv)对所有重大偏差或不符合的情况、相关调查以及由此采取的纠正和预防措施的有效性进行回顾；

(v) A review of all changes carried out to the processes or analytical methods;

(v)对工艺或分析方法的所有变更进行回顾；

(vi) A review of Marketing Authorisation variations submitted, granted or refused, including those for third country (export only) dossiers;

(vi)对提交、批准或拒绝的注册变更，包括第三国（仅出口）的资料进行回顾；

(vii) A review of the results of the stability monitoring programme and any adverse trends;

(vii)对稳定性考察方案的结果和任何不利趋势进行回顾；

(viii) A review of all quality-related returns, complaints and recalls and the investigations performed at the time;

(viii)对所有与质量相关的退货、投诉和召回以及当时进行的调查进行回顾；

(ix) A review of adequacy of any other previous product process or equipment corrective actions;

(ix)对任何以前产品工艺或设备纠正措施的充分性进行回顾；

(x) For new Marketing Authorisations and variations to Marketing Authorisations, a review of post-marketing commitments;

(x)对于新的注册和注册的变更，需回顾上市后的承诺执行情况；

(xi) The qualification status of relevant equipment and utilities, e.g. HVAC, water, compressed gases, etc;

(xi)对相关设备和公用设施的确认状态，例如暖通空调、水、压缩气体等进行回顾

(xii) A review of any contractual arrangements as defined in Chapter 7 to ensure that they are up to date.

(xii) 回顾第7章中规定的任何合同安排，确保它们是最新的。

1.11 The manufacturer and, where different, Marketing Authorisation holder should evaluate the results of the review and an assessment made as to whether corrective and preventive action or any revalidation should be undertaken, under the Pharmaceutical Quality System. There should be management procedures for the ongoing management and review of these actions and the effectiveness of these procedures verified during self-inspection. Quality reviews may be grouped by product type, e.g. solid dosage forms, liquid dosage forms, sterile products, etc. where scientifically justified.

1.11制造商和不同的上市许可持有人（MAH）应对回顾结果进行评估，确定是否需要采取纠正和预防措施或进行再验证。应有持续管理和回顾这些行动的管理程序，并在自检过程中验证这些程序的有效性。当有合理的科学依据时，质量回顾可按产品类型分组，如固体剂型、液体剂型、无菌产品等。

Where the Marketing Authorisation holder is not the manufacturer, there should be a technical agreement in place between the various parties that defines their respective responsibilities in producing the product quality review. The Authorised Person responsible for final batch certification together with the Marketing Authorisation holder should ensure that the quality review is performed in a timely manner and is accurate.

如果上市许可持有人（MAH）不是制造商，则双方之间应达成技术协议，确定他们各自在生产产品质量回顾方面的责任。最终批放行的授权人员（AP）与上市许可持有人(MAH)应确保及时进行质量回顾和回顾准确性。