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Title	Quality Management System & QA Responsibilities	
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Prepared By	[Name / Title]	Date: [Date]
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质量管理体系与QA职责

Revision History / 修订历史

Rev.	Date	Description of Change	Approved By
01	[Date]	Initial Release	[Name]

Table of Contents / 目录

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1. Purpose / 目的

This SOP defines the organizational structure, roles, responsibilities, and authority of the Quality Assurance (QA) unit as required by 21 CFR 211.22 and 21 CFR 1271.150. It establishes the QA unit's independent authority for product release, batch disposition, and quality system oversight.

- Define the QA organizational structure and reporting relationships
- Establish clear roles and responsibilities for all QA functions
- Ensure QA independence from production and commercial pressures
- Define authority for product release, rejection, and batch disposition

2. Scope / 范围

This SOP applies to all Quality Assurance personnel and all departments that interact with the QA function. It covers:

- QA organizational structure and reporting lines
- QA responsibilities for product quality oversight, batch disposition, and release
- QA authority over production operations, laboratory controls, and document control
- Interfaces between QA and other departments (Production, QC, Engineering, Regulatory, Supply Chain)
- QA responsibilities specific to GMP (21 CFR 211) and GTP (21 CFR 1271) compliance

3. Responsibilities / 职责

Role	Responsibility
VP Quality / Quality Director	Provide strategic leadership for QA; report to executive management; serve as management representative for quality; authorize final product release for commercial distribution
QA Manager	Manage day-to-day QA operations; supervise QA staff; manage document control, deviations, CAPA, and change control programs; prepare quality metrics
QA Supervisor(s)	Supervise QA analysts and specialists; coordinate batch record review; manage on-floor QA support; conduct in-process inspections
QA Specialists / Analysts	Execute batch record review; perform in-process audits; manage deviation documentation; support CAPA investigations; maintain training records
QA Document Control Specialist	Manage document lifecycle; maintain document control system; distribute and retrieve controlled documents; maintain master document index
Production Management	Cooperate with QA; implement QA-approved procedures; report deviations; support investigations
QC Laboratory Management	Provide analytical data for batch release; report OOS/OOT results; maintain laboratory compliance

4. Definitions / 定义

Term	Definition
Quality Unit	The organizational unit responsible for all QA and QC functions, as defined in 21 CFR 211.22
Batch Disposition	The formal decision to release, reject, or quarantine a batch/lot based on review of all manufacturing and testing records
Product Release	The authorization to distribute a batch/lot for its intended use after confirming compliance with all specifications
Quality Oversight	The systematic monitoring and evaluation of all quality-related activities to ensure compliance with GMP/GTP
Independence	The organizational separation of QA from production to prevent conflicts of interest in quality decisions
Responsible Person	The designated individual with authority and responsibility for ensuring compliance with applicable regulations (per 21 CFR 1271.150)
Material Disposition	The decision to accept, reject, or quarantine incoming materials, components, and containers/closures

5. Procedure / 程序

5.1 QA Organizational Structure / QA组织架构

The QA unit shall be organized to ensure independence from production and commercial functions, with a direct reporting line to senior executive management.

Organizational Reporting Structure:

- The VP Quality / Quality Director shall report directly to the CEO / General Manager
- The QA Manager shall report to the VP Quality / Quality Director
- QA Supervisors, Specialists, and Analysts shall report to the QA Manager
- The QC Laboratory Manager shall report to the VP Quality / Quality Director (maintaining independence from production)

> **Implementation Note:** *Per 21 CFR 211.22, the quality control unit shall have the authority to approve or reject all procedures or specifications impacting the identity, strength, quality, and purity of the drug product.*

The QA unit shall be adequately staffed with qualified personnel to fulfill all responsibilities defined in this SOP. Staffing levels shall be assessed annually during management review.

5.2 QA Core Responsibilities / QA核心职责

5.2.1 Product Quality Oversight

- Review and approve all production batch records, packaging records, and associated documentation prior to batch disposition
- Monitor in-process controls and critical process parameters during manufacturing
- Ensure all deviations are properly investigated and resolved before batch release
- Oversee environmental monitoring programs and review results

5.2.2 Document and Record Control

- Manage the document control system for all GMP/GTP documents
- Ensure all SOPs, work instructions, and forms are current, approved, and accessible
- Maintain the master document index and controlled copy distribution
- Manage record retention and archival per regulatory requirements

5.2.3 Deviation and CAPA Management

- Receive, classify, and track all deviations
- Ensure thorough root cause investigations are conducted
- Approve CAPA plans and verify effectiveness of implemented actions
- Report deviation and CAPA metrics to management

5.2.4 Change Control

- Manage the change control system and ensure all changes are properly evaluated
- Coordinate cross-functional impact assessments
- Approve or reject change requests based on quality and regulatory impact
- Ensure post-implementation reviews are completed

5.2.5 Training Program Oversight

- Develop and maintain the GMP/GTP training curriculum
- Ensure all personnel are trained on applicable SOPs before performing GMP/GTP activities
- Track training compliance and report deficiencies

5.3 Batch Disposition and Product Release / 批次处置与产品放行

The QA unit has sole authority for batch disposition decisions. No batch shall be released for distribution without QA approval.

Batch Release Checklist (minimum requirements):

1. Batch production record reviewed and all entries complete, accurate, and signed
2. All in-process controls within specification
3. All analytical testing completed and results meet acceptance criteria
4. All deviations investigated and impact on batch quality assessed
5. Environmental monitoring data reviewed and within limits
6. Component/material COAs verified and accepted
7. Labeling reconciliation completed and acceptable
8. Yield calculations within expected range
9. Stability program enrollment confirmed (if applicable)
10. QA final review and disposition signature

Disposition Decision	Criteria	Authority
Release	All specifications met; all deviations resolved; no open critical issues	QA Manager or VP Quality
Reject	Failure to meet specifications; unresolvable deviation; adulteration or contamination	QA Manager or VP Quality
Quarantine / Hold	Pending investigation; awaiting additional testing; under review	QA Supervisor or above
Reprocess	Defined reprocessing procedure available and approved; reprocessed batch meets all specs	VP Quality

5.4 QA Authority Matrix / QA权限矩阵

The following matrix defines QA approval authority for key quality system actions:

Action	QA Analyst	QA Supervisor	QA Manager	VP Quality
Deviation initiation	Execute	Approve	Approve	Approve
Minor deviation closure		Approve	Approve	Approve
Major/Critical deviation closure			Approve	Approve
CAPA approval			Approve	Approve
Batch release			Approve	Approve
Batch rejection			Approve	Approve
SOP approval			Approve	Approve
Change control approval		Review	Approve	Approve
Supplier qualification			Approve	Approve
Product recall decision				Approve
Regulatory filing quality review			Review	Approve

5.5 GTP-Specific QA Responsibilities / GTP特定QA职责

For HCT/P operations regulated under 21 CFR Part 1271, the QA unit shall additionally:

11. Designate a Responsible Person per 21 CFR 1271.150(a) who has authority and responsibility for ensuring compliance with applicable GTP requirements
12. Review and approve donor eligibility determinations per 21 CFR 1271 Subpart C
13. Oversee tissue processing, storage, and distribution records for CGTP compliance
14. Manage tracking and traceability systems per 21 CFR 1271.290
15. Ensure proper adverse reaction reporting per 21 CFR 1271.350
16. Maintain registration and product listing with FDA per 21 CFR 1271 Subpart B

Implementation Note: *The Responsible Person for GTP compliance may be the VP Quality or a designated senior QA professional who meets the education and experience requirements.*

5.6 Interfaces with Other Departments / 与其他部门的接口

Department	Interface Activities	Key QA Touchpoints
Production	Batch record issuance, in-process monitoring, deviation management, line clearance	Batch release, deviation review, process change approval
Quality Control	Test method approval, OOS/OOT investigation, specification review, stability program	Results review, method validation approval, lab audit

Engineering	Equipment qualification, calibration, facility modifications	IQ/OQ/PQ approval, change control, maintenance oversight
Regulatory Affairs	Filing support, inspection preparation, regulatory intelligence	Dossier quality review, commitment tracking
Supply Chain	Supplier qualification, material receipt, CoA review	Supplier approval, material release, vendor audit
R&D / Tech Transfer	Technology transfer, process development, validation	Protocol approval, report review, scale-up support
Human Resources	Training records, qualification documentation	Training curriculum, competency assessment

6. Documentation & Records / 文件与记录

Document / Record	Retention Period	Storage Location
QA Organizational Chart	Current + 5 years	QA Document Control / HR
QA Authority Matrix	Current version + all prior versions	QA Document Control
Batch Disposition Records	1 year beyond product expiry or 3 years (whichever longer)	QA Document Control
QA Personnel Qualification Records	Duration of employment + 3 years	HR / QA
Responsible Person Designation (GTP)	Current + 5 years	QA Document Control

7. References / 参考文献

17. 21 CFR 211.22 - Responsibilities of Quality Control Unit
18. 21 CFR 211.25 - Personnel Qualifications
19. 21 CFR 1271.150 - Current Good Tissue Practice Requirements
20. ICH Q10 - Pharmaceutical Quality System
21. QP-SOP-001 - QMS Quality Program / Pharmaceutical Quality System
22. QA-SOP-002 - Document & Record Control
23. QA-SOP-003 - Deviation, Investigation & CAPA Management

8. Training Requirements / 培训要求

Training Topic	Target Audience	Frequency	Method
QA Roles & Responsibilities	All QA Personnel	New Hire + Annual	Classroom
Batch Record Review Process	QA Reviewers	Initial + Annual	OJT / Workshop
Batch Disposition Authority	QA Manager, VP Quality	Initial + Major Revision	Classroom

GTP-Specific QA Requirements	QA Staff (GTP operations)	Initial + Annual	Classroom
QA Interface Procedures	QA and Cross-Functional Staff	New Hire + As Needed	Classroom / OJT
21 CFR 211.22 Requirements	All QA Personnel	Annual	eLearning

Appendices / 附录

Appendix A: QA Batch Release Checklist / QA批次放行检查表

Product Name:	
Batch/Lot Number:	
Batch Size:	
Manufacturing Date:	
Expiration Date:	
Reviewer Name:	
Review Date:	

#	Checklist Item	Status (Y/N/NA)	Comments
1	Batch production record complete and signed by all operators/supervisors		
2	All critical process parameters within specification		
3	In-process testing results within acceptance criteria		
4	Finished product analytical results meet release specifications		
5	Environmental monitoring data reviewed and within limits		
6	All deviations documented, investigated, and assessed for batch impact		
7	Component/raw material COAs verified and accepted		
8	Packaging and labeling reconciliation completed		
9	Yield within expected range		
10	Stability enrollment confirmed (if applicable)		
11	No open CAPA or hold affecting this batch		
12	All applicable change controls implemented		

Disposition Decision:	[ ] Release [ ] Reject [ ] Quarantine [ ] Reprocess
Justification (if not Release):	
Approved By (Print Name):	
Approved By (Signature):	
Date:	

Approval Signatures / 审批签名

Role	Signature	Date
Prepared By:		
Reviewed By:		
Approved By:		

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