Change Control Procedure

Document Approval

	Prepared By	Reviewed By	Authorized By
Name:			
Title:			
Date:			

Contents

1. Purpose & Scope

This procedure establishes a robust, risk-based change control process for regulated operations. It ensures that changes to procedures, specifications, analytical methods, manufacturing or laboratory equipment, computerized systems (including eQMS, LIMS, ERP, MES), facilities, utilities, materials, labeling, artwork, and records are initiated, assessed, reviewed, approved, implemented, verified, and closed in a controlled, traceable manner. The procedure supports regulatory compliance, protects product quality and patient safety, and preserves data integrity in line with ALCOA+ principles.

Scope includes all regulated documented information and operational changes across manufacturing, QC/QA, warehousing, logistics, validation, supplier management, and computerized systems. Exclusions: non-GxP administrative changes (e.g., internal HR forms) unless they affect GxP workflows; such changes may follow a simplified internal process.

2. Regulatory & Guidance Context

This procedure is designed to be compatible with commonly adopted regulatory and quality frameworks. Applicable requirements depend on organizational scope and regulatory obligations.

Data integrity expectations follow ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, and Available).

3. Definitions

- **Change**: Any planned or unplanned modification to regulated documents, systems, equipment, facilities, or processes.
- **Change Control**: Formal process ensuring changes are documented, risk-assessed, reviewed, approved, implemented, verified, and archived.
- **Impact Assessment**: Structured evaluation of regulatory, quality, validation, supply, training, and data integrity effects of the change.
- **Risk Matrix**: Tool combining Severity, Probability, and Detectability to determine risk level and required mitigations.
- **Temporary Instruction**: Time-limited, controlled guidance issued to address urgent situations pending a permanent change.
- **Computerized System**: Any GxP-relevant system (e.g., LIMS, MES, ERP, eQMS) subject to validation and Part 11 controls.
- **ALCOA+**: Data integrity principles: Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, Available.

4. Roles & Responsibilities

- Procedure Owner / Quality Function: Maintains this SOP; ensures impartial reviews; approves high-risk changes; oversees effectiveness checks.
- Change Owner (Process Owner/Author): Initiates CR, drafts rationale/plan, performs preliminary impact assessment, coordinates implementation.
- Independent Reviewer: Evaluates clarity, completeness, regulatory alignment, and risk; records objective evidence of review.
- IT/Systems Administrator: Implements technical controls, manages user roles, audit trails, backups, and e-signatures in validated repositories.
- Training Coordinator: Plans and records training for impacted personnel; ensures competency before effective date.
- All Personnel: Use only current controlled documents; report issues and propose changes using the approved form.

5. Procedure

5.1 Initiation

1. Submit Change Request (CR) using [QMSP-CC-002] including purpose, scope, rationale, impacted processes, and proposed timelines.
2. Classify change type: Environment, Equipment, Facility/Utility, Analytical Method, Labeling/Artwork, Computerized System, Supplier Change, Other.
3. Indicate urgency and whether a temporary instruction is required. Temporary instructions must include an expiry date and control markings.
4. Attach preliminary risk hypothesis and proposed acceptance criteria for post-implementation verification.

See **Appendix E** for an example of a completed Change Request form, including rationale, risk level, and mitigation actions.

5.2 Impact Assessment – Detailed Criteria

- **Regulatory**: Identify applicable sections of EU GMP (Ch1, Ch3, Ch5, Ch6, Ch7, Annex 15), determine if regulatory filing/notification may be required (e.g., prior approval supplement).
- **Quality/Product**: Assess potential impact on CQAs, CPPs, batch release criteria, stability protocols, and shelf life.
- **Validation**: Determine need for re-validation/re-qualification (process, cleaning, equipment, methods, computerized systems) and outline protocol references.
- **Data Integrity**: Evaluate ALCOA+ adherence, audit trails, user access, e-signature meaning, confirm repository integrity and backup/restore readiness.
- **Supply Chain**: Review supplier changes, material attributes, certificates of analysis, lead times, and qualification status (e.g., audit reports).
- **Training**: Define roles requiring training and objective evidence, schedule training before the effective date, include comprehension checks.

Retention: Maintain for defined retention periods based on regulatory, contractual, and business requirements (adjust per market/legal requirements); ensure records remain legible, retrievable, and protected against loss or unauthorized change.

[illegible]

[illegible]

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]			

[illegible]

[illegible]

[illegible]	[illegible]

[illegible]

[illegible]

[illegible]	[illegible]

[illegible]

Appendix A: Risk Matrix & Scoring Guidance

Severity (S): 1–5. Probability (P): 1–5. Detectability (D): 1–5. RPN = S × P × D. Justify scores with objective evidence. Define actions per band.

- RPN ≤ 20 (Low): Implement with routine monitoring.
- RPN 21–40 (Medium): Implement with mitigations and verification. QA oversight required.
- RPN > 40 (High): Escalate to QA Management; consider additional validation, phased implementation, or rejection.

Appendix B: Text-Based Workflow Diagram

Initiation → Impact Assessment → Risk Evaluation → Review → Approval → Implementation → Verification → Closure → Effectiveness Review (30–90 days)

Appendix C: Example Completed Change Request (Excerpt)

Change Type: Computerized System configuration update (MES release).

Rationale: Improve batch record clarity and reduce manual entry.

Risk Level: Medium (RPN 18).

Mitigations: UAT protocol executed; role-based access review; SOP updates; targeted audit 30 days post-go-live; training completion ≥95% before effective date.

[DOCUMENT END]