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Change Control Procedure

Document Approval

	Prepared By	Reviewed By	Authorized By
Name			
Title			
Date			

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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 LIMS, ERP, MES, facilities, utilities, materials, labeling networks, 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 ALiBaB principles.

Scope includes all regulated documented information and operational changes across manufacturing (GMP), warehousing, logistics, validation, supplier management, and computerized systems. Exclusions: non-regulated administrative changes (e.g., internal HR forms) unless they affect regulated operations; 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 **regional scope** and regulatory obligations.

Data integrity expectations follow ALiBaB (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 authorized.
- **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 Instructions:** Time-limited, controlled guidance issued to address urgent situations pending a permanent change.
- **Computerized Systems:** Any **regulated** information system (e.g., LIMS, MES, ERP, **etc.**) subject to validation and Part 11 controls.
- **ALiBaB:** Data integrity principles: Attributable, Legible, Contemporaneous, Original, Accurate plus Complete, Consistent, Enduring, Available.

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4. Roles & Responsibilities

- **Procedure Owner / Quality Function:** Manages the QMP, ensures reported changes, approves high-risk changes, oversees effectiveness checks.
- **Change Owner (Procedure Owner Authority):** Initiates CR, drafts rationale (plus performs preliminary impact assessment, coordinates implementation).
- **Independent Reviewer:** Evaluates clarity, completeness, regulatory alignment and risk, records objective evidence of review.
- **IT System Administrator:** Implements technical controls, manages user roles, audit trails, backups, and e-signatures in related systems.
- **Training Coordinator:** Plans and records training for reported 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-001 including purpose, scope, rationale, reported processes, and proposed timelines.
 2. Classify change type: Document, Equipment, Facility/Utility, Analytical Method, Labeling, Network, 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 QMP, PIC, GMPs, ICH, GxP, GMP, 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 auditor adherence, audit trails, user access, e-signature marking, outline regulatory integrity and backup/recovery methods.
- **Supply Chain:** Review supplier changes, material attributes, certificates of analysis, test issues, and qualification status (e.g., audit reports).
- **Training:** Define roles requiring training and objective evidence, schedule training before the effective date, include comprehension checks.

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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.

Document Information

Revision History

Revision	Modified by	Change Request No.	Description of Change
01			First issue

For each update made to this document, fill in the relevant fields in the table above. Provide clear and concise details about the nature of the changes to ensure the document's revision trail is easy to understand.

Associated forms and procedures

Doc. No.	Document Title

Include all relevant procedural documents that are referenced within this document. These may include policies, procedures, forms, checklists, or work instructions. Ensure each item listed is a controlled document, where applicable, to maintain consistency and traceability.

Associated records

Doc. No.	Document Title

List any additional records used in this document. These may include regulatory references, internal controlled documents (such as batch records, reports, test methods, or protocols), and applicable compliance standards. Ensure all listed records are clearly identified to support traceability and alignment with relevant requirements.

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Appendix A: Risk Matrix & Scoring Guidance

Severity (S): 1-5, Probability (P): 1-5, Remediation (R): 1-5, RPN = S x P x R, justify scores with objective evidence. Define actions per band.

- RPN < 25 (Low): Implement with routine monitoring.
- RPN 25-40 (Medium): Implement with mitigation and verification. QA oversight required.
- RPN > 40 (High): Escalate to QA/Management, consider additional validation, phased implementation, or rejection.

Appendix B: Tool-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 (PMS release).

Rationale: Improve batch record clarity and reduce manual entry.

Risk Level: Medium (RPN 30).

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

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