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Deviation Control Procedure

Document Approval

	Prepared By	Reviewed By	Authorized By
Name			
Title			
Date			

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Document Preparation Notes (To Be Reviewed Before Issue)

- All red text is instructional and must be removed or replaced.
- Example content (black text) should be removed and customized.
- Apply your company's style guide (font, formatting, etc.).
- This procedure should be altered to suit your company's actual approach to deviation management.
- The footer should be updated or deleted as per with company policy.
- Editable fields (grey background) auto-update via document properties or by pressing F9.
- Assign a document number per your site's documentation control procedure.
- Use the correct QMS template if available.
- Complete the **Change History** section with a valid change control reference.
- Maintain consistency in terminology throughout the document.

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1. Purpose

To establish a standardized, risk-based process for identifying, documenting, investigating, evaluating, and resolving deviations in regulated operations to ensure product quality, user/patient safety, data integrity, and regulatory compliance.

2. Scope

Applies to all planned and unplanned deviations occurring in regulated activities and systems, including but not limited to:

- Manufacturing (batch records, equipment, materials)
- Packaging and labeling
- In-process and finished product testing
- Environmental monitoring
- Utilities (HVAC, water, compressed gases)
- Cleaning and sanitation
- Warehouse and distribution (if inspecting stock)

Exclusions:

- Deviations in R&D (non-GMP)
- Supplier deviations (handled via Supplier Quality Mgmt)
- Issues managed directly through CAPA without a deviation record

3. Regulatory & Guidance References

- EU GMP Guide (Annex 1); Chapter 1: Pharmaceutical Quality System; Chapter 2: Documentation
- FDA 21 CFR 312.62 (GMP Guide to GMP)
- FDA 21 CFR Part 312.62 (Drug: Subpart C – Records & Reports; Part 312.62 – Electronic Records / Electronic Signatures)
- ICH Q10 Pharmaceutical Quality System; ICH Q10 Quality Risk Management
- GAMP 5 (Good Automated Manufacturing Practice)
- FDA/EMA/WHO Data Integrity Guidelines (Guidance)

4. Definitions

Deviation:

Departure from an approved instruction, procedure, specification, or standard.

Planned Deviation:

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5.5 Categorization

Category	Criteria	Approval	Investigation Depth
Minor (3-4)	No impact, procedural only	QI	Justification, no RCA
Major (5-6)	Potential impact	QI + Dept Head	Full RCA
Critical (7)	Actual impact / reportable	Management Review / Quality Management	Full RCA + effectiveness check

5.6 Corrective and Preventive Actions (CAPA)

1. Propose CAPA(s) in deviation report
2. Link to CAPA Module (separate SOP)
3. Target closure
 - a. Minor: 30 days
 - a. Major: 45 days
 - a. Critical: 90 days (with justified extension)

5.7 Closure and Release

1. QI review
 - a. Investigation completeness
 - a. Risk mitigated
 - a. CAPA effective
2. Disposition of Material
 - a. Release – if no impact
 - a. Rework/Reprocess – per approved protocol
 - a. Reject/Destroy – with justification
3. Final approval
 - a. Minor/Major: QI
 - a. Critical: Head of Quality
4. Close record in system

5.8 Extensions

- a. Request Extension Form (Appendix C) all steps before due date
- a. Max 2 extension (30 days) for Major, 3 extensions for Critical (with QI approval)

5.9 Reporting

Regulatory reporting requirements (if applicable) shall be assessed and executed in accordance with applicable regulatory obligations and organizational procedures.

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6. DOCUMENTATION

Record	Retention	Location
Deviation Report (electronic)	Product lifecycle + 20 years	QMS
Investigation attachments	Same	QMS
CCRs linkage	Same	CCRs System
Trend Reports	5 years	QMS Server

7. TRAINING

- All staff staff receive training on this SOP
- QA Investigators: advanced this training (Quality, Policy)
- Record in job.

8. DEVIATION TRENDS & REVIEW

1. QA compile quarterly deviation trend report
 - a. By category, department, root cause
 - a. Pareto analysis
2. Present to Management Review / Quality Governance
3. Escalate recurring issues to CCRs

9. CHANGE CONTROL

- Any change to this SOP requires Change Control (PMS-CC-001)
- Impact assessment on existing deviations

10. REFERENCES

- IS-OP-001, 002, 003, 004
- IS-OP-Chapter 1, Annex 1
- IS-OP (Quality Risk Management)