Deviation Control Procedure

Document Approval

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Date:			

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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 impacting GMP)

Exclusions:

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

3. Regulatory & Guidance References

- EU GMP (Eudralex Vol 4): Chapter 1: Pharmaceutical Quality System, Chapter 4: Documentation

- PIC/S PE 009 Guide to GMP

- FDA 21 CFR Part 210/211 (Drugs): Subpart J – Records & Reports, Part 11 – Electronic Records / Electronic Signatures

- ICH Q10 Pharmaceutical Quality System, ICH Q9 Quality Risk Management

- GAMP® 5 (Good Automated Manufacturing Practice)

- MHRA/WHO/PIC/S Data Integrity guidance (ALCOA+)

4. Definitions

Deviation:

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

Planned Deviation:

5.5 Categorization

Category	Criteria	Approval	Investigation Depth
Minor (1-4)	No impact, procedural only	QA	Justification, no RCA
Major (5-8)	Potential impact	QA + Dept Head	Full RCA
Critical (9)	Actual impact / reportable	Management Review / Quality Management	Full RCA + effectiveness check

5.6 Corrective and Preventive Actions (CAPA)

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

5.7 Closure and Release

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

5.8 Extensions

- Request **Extension Form** (Appendix D) **≥5 days before due date**.
- Max **1 extension** (15 days) for Major, **2 extensions** for Critical (with QE approval).

5.9 Reporting

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

6. DOCUMENTATION

Record	Retention	Location
Deviation Report (electronic)	Product lifecycle + 10 years	EDMS
Investigation attachments	Same	EDMS
CAPA linkage	Same	CAPA System
Trend Reports	5 years	QA Server

7. TRAINING

- All GMP staff: biennial training on this SOP.
- QA Investigators: advanced RCA training (5-Why, FMEA).
- Record in LMS.

8. DEVIATION TRENDING & REVIEW

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

9. CHANGE CONTROL

- Any change to this SOP requires **Change Control (PHM-QUA-01-003)**.
- Impact assessment on existing deviations.

10. REFERENCES

- 21 CFR 211.100, 211.192
- EU GMP Chapter 1, Annex 1
- ICH Q9 (Quality Risk Management)