File	**QUALITY MANAGEMENT SYSTEM RMT**
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Purpose and goal:

This document is a part of the QUALITY MANAGEMENT SYSTEM folder of REVIVE MEDITECH PVT LTD. compiled for compliance of ISO 13485:2016 requirements.

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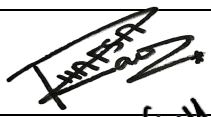
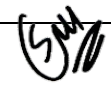
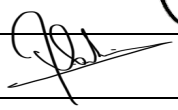
CREATOR	Assistant Manager Quality Assurance	Hafsa Inam Rao	**15-01-2025**	
REVIEWER	Quality Manager	Suhail	**04-02-2025**	
REVIEWER	Chief Technology Officer	Ibraheem Raza	**78-02-2025**	
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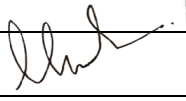
APPROVER	Chief Executive Officer	Dr. Murtaza Najabat Ali	**19-02-2025**	

REVISION HISTORY

Revision	Status	Date	Description of Change
1.0	Obsolete	19-02-2025	Initial version

NOTE:

Document Status	Description	Marking Type	Document Type
DRAFT	Documents under creation, revision or review	In document background	Electronic
APPROVED	Approved documents in electronic Document Management System	In revision history table	Electronic
MASTER COPY	Approved documents in Quality Manager office	Stamped	Physical
CONTROLLED COPY	Approved documents sent to concerned department for reference	Stamped	Physical
OBSOLETE	Documents replaced by new revisions	Stamped/Moved to archive	Physical/Electronic

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1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish a systematic and standardized approach for identifying, documenting, evaluating, investigating, and resolving both planned and unplanned deviations from approved procedures, specifications, or processes during the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)"** at **Revive Meditech Pvt Ltd. (RMT)**. This SOP ensures that all deviations are effectively controlled in accordance with the requirements of ISO 13485:2016.

2. SCOPE

This SOP applies to all departments and personnel involved in the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)"** at **Revive Meditech Pvt Ltd. (RMT)**.

It covers the management of both **planned** and **unplanned deviations** from approved procedures, work instructions, validated processes, product specifications, quality standards, or regulatory requirements that may occur during:

- Production processes (e.g., mixing, filling, sealing)
- Quality control and microbiology testing (e.g., analytical, and sterility tests etc.)
- Environmental monitoring
- Equipment operation and maintenance
- Materials handling and storage
- Process validations
- Documentation and recordkeeping activities
- Supply chain, including receipt and handling of raw materials and packaging components

This SOP includes the classification of deviations (minor, major, critical), investigation and root cause analysis, implementation of corrective and preventive actions (CAPA), documentation, tracking, closure, and trending of deviations.

3. NORMATIVE REFERENCES

- **ISO 13485:2016** – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

4. DEFINITIONS AND ABBREVIATIONS

Deviation refers to any departure from an approved procedure, instruction, specification, or standard that occurs during the execution of activities related to the "**Design, Development and Manufacturing of Intravascular Devices (Microspheres)"**.

Planned Deviation is a temporary, intentional, and pre-approved departure from an established procedure or requirement. Such deviations are justified in advance and controlled to minimize any risk to product quality or patient safety.

Unplanned Deviation is an unintended and unauthorized variation from established procedures, specifications, or standards. These deviations typically occur due to human error, equipment malfunction, environmental conditions, or unforeseen circumstances.

Minor Deviation is a deviation that does not significantly impact product quality, patient safety, or regulatory compliance. These are usually low-risk and may not require extensive investigation or CAPA.

Major Deviation is a deviation that could potentially impact product quality, regulatory compliance, or safety. Such deviations require thorough investigation, root cause analysis, and implementation of appropriate corrective and preventive actions.

Critical Deviation is a serious deviation that has a direct or immediate impact on patient safety, product performance, or results in a significant regulatory noncompliance. These require urgent attention and immediate corrective measures.

Nonconforming Product refers to a product that fails to meet its predefined acceptance criteria, specifications, or quality requirements.

Corrective and Preventive Action (CAPA) is a systematic approach used to investigate the root cause of a deviation or nonconformance, implement corrective actions to resolve the issue, and preventive actions to avoid recurrence.

Root Cause Analysis (RCA) is the process of identifying the underlying cause(s) of a deviation or problem in order to develop effective corrective and preventive actions.

Quality Management System (QMS) refers to the structured framework of policies, processes, and procedures implemented to ensure consistent product quality, regulatory compliance, and continuous improvement within the organization.

Risk-Based Approach is the method of identifying, assessing, and prioritizing risks associated with deviations, focusing efforts on issues that have the greatest potential to impact product quality, safety, or compliance.

RMT: Revive Meditech Pvt Ltd.

QA: Quality Assurance

QC: Quality Control

CPO: Chief Production Manager

AM: Assistant Manager

HR: Human Resources

5. ROLES AND RESPONSIBILITIES

Role	Key Responsibilities	Designation/Department
Initiator	Identify any deviation from approved procedures, specifications, or environmental requirements during operations. Immediately notify the Supervisor and QA about the deviation and document initial details in the deviation log. Ensure all critical information (e.g., time, date, process step, affected materials/equipment) is accurately recorded at the point of occurrence. Stop the affected process if the deviation poses a potential risk to product quality or patient safety. Cooperate with QA during preliminary impact assessment and provide supporting documents (lot records, logs, inspection logs, PTC, etc.). Participate in root cause analysis as required. In case of planned deviation prepare the Planned Deviation Request Form with detailed justification, proposed duration, and risk assessment.	Anyone involved in QMS
Supervisor	Review the deviation details submitted by the Initiator for completeness and accuracy. Assess whether the deviation is critical, major, or minor and escalate accordingly.	Production Manager

	Support QA in determining immediate corrective actions to contain the deviation and prevent further impact. Ensure affected processes, materials, or equipment are quarantined if needed. Facilitate collection of data and records for deviation investigation. Guide the Initiator in completing deviation documentation correctly. Participate in root cause analysis and recommend preventive measures. Monitor recurring deviations in production and recommend process improvements to minimize future occurrences. For planned deviations review the necessity of the planned deviation, verifies feasibility, and ensures alternate controls are proposed.	
Microbiologist	Investigate and report deviations related to microbiological contamination or excursions. Analyze environmental monitoring trends for potential deviations. Support QA in assessing contamination-related impact on product/process. Provide recommendations for preventive actions linked to aseptic practices or environmental control. Evaluate and document microbiological risks for aseptic or controlled areas during the planned deviation period.	Assistant Manager Microbiologist
Procurement Officer	Maintain vendor communication and documentation trail for quality-impacting procurement deviations. Coordinate with QA to initiate Supplier Complaint Forms Assist in root cause analysis for externally sourced material deviations. Ensure supplier changes or delivery delays related to the deviation are documented and approved, with QA awareness.	AM Supply Chain
Quality Assurance	Receive deviation reports and assign deviation numbers for tracking and traceability. Perform initial assessment to determine the deviation classification (Critical/Major/Minor) and potential impact on product quality, safety, and compliance. Coordinate with relevant departments to conduct a thorough root cause investigation using appropriate tools Review and approve corrective and preventive action (CAPA) plans to address the deviation and prevent recurrence. Monitor timely closure of deviations within the defined timeline. Maintain the deviation log and prepare periodic deviation trend reports for management review. Ensure deviation documentation complies for audit readiness. Evaluate the impact of the planned deviation on product quality; ensures risk mitigation is adequate before approval.	AM Quality Assurance
Quality Control	Assist QA in evaluating potential impact of deviations on product testing, release specifications, and analytical results. Review test data to assess whether any retesting or additional sampling is required.	AM QC

	Support investigation of laboratory-related deviations such as OOS (Out of Specification), or equipment malfunctions. Provide QC raw data, calibration logs, and observations to aid in root cause analysis. Ensure quarantined or impacted samples are properly labelled and segregated until QA disposition. Implement CAPAs in laboratory processes as directed by QA. Confirms that analytical controls are sufficient to detect any quality impact during the planned deviation period.	
Manager	Ensure personnel are aware of deviation reporting procedures and requirements. Oversee production-related deviations and ensure prompt communication with QA. Provide required resources, records, and personnel for deviation investigations. Approve proposed CAPAs related to production processes and ensure their implementation. Review and approve deviation closure reports from the department's perspective. Monitor recurring deviations and recommend process improvements to minimize future occurrences. Ensure all impacted team members are informed and trained about the deviation procedure; supervise implementation if approved.	Relevant Manager
Engineering/ Maintenance	Investigate deviations related to equipment failure, utility breakdowns, or calibration issues. Provide maintenance logs, calibration records, and incident reports to support root cause analysis. Implement immediate containment measures and corrective actions for equipment-related deviations. Support QA and Production in validating the effectiveness of corrective actions. Maintain updated equipment maintenance and calibration schedules to minimize future deviations. Provide technical input for risk assessments related to engineering controls. Assess technical feasibility if equipment or facility is involved; confirm that the requested deviation will not compromise operational safety	Assistant Manager Admin Relevant Department Head
Store Keeper	Report deviations related to raw material or packaging material handling, such as incorrect storage, expired material usage, or material mix-ups. Cooperate with QA in investigating deviations linked to material movement or inventory control. Quarantine affected materials promptly and label them until QA disposition. Ensure traceability of materials to enable effective root cause analysis and prevent recurrence. Maintain proper documentation of material issuance and storage conditions.	Assistant Manager Store

	Verify and record any material-handling deviations; ensure material segregation and labeling during known deviations.	
Training Coordinator	Coordinate training for all staff on deviation reporting, investigation procedures. Maintain training records for deviation control SOP and CAPA management. Schedule refresher training sessions for employees in case of recurring deviations caused by human error. Support QA in assessing staff competency and implementing retraining as part of preventive actions. Ensure training records are available for internal and external audits. Confirm that involved personnel are trained on revised procedures or temporary instructions linked to the deviation.	Manager HR/Admin
Admin	Ensure utilities (e.g., power supply, HVAC) are maintained to prevent environmental deviations. Assist with logistical arrangements for urgent corrective actions or third-party vendor investigations, if required. Coordinate with facility teams to ensure deviations linked to infrastructure are investigated and resolved. Coordinate facility access/logistics if deviation involves infrastructure, documentation, or support service changes.	Manager HR/Admin
Approving Authority	Grant final written approval after confirming that all risk assessments, controls, and justifications are acceptable and documented in case of a requested deviation.	Quality Manager/ CEO

6. PROCEDURE

6.1 Identification and Reporting

6.1.1 Employee Responsibility

All employees of **Revive Meditech Pvt Ltd.** shall remain vigilant during the execution of their duties and shall immediately report any observed deviation from approved procedures, instructions, specifications, or processes.

Deviations may include, but are not limited to:

- Manufacturing or production process deviations
- Equipment malfunctions or performance inconsistencies
- Testing and analytical method discrepancies
- Improper material handling or storage
- Documentation errors
- Deviations in environmental parameters (e.g., temperature or humidity excursions)

6.1.2 Reporting Process

Upon identification of a deviation, the employee shall:

- Immediately inform their immediate supervisor or designated Quality Assurance (QA) representative
- AM QA shall log the deviation details in the **Deviation Log** accurately.

6.1.3 QA Review

After logging the deviation details, AM QA shall:

- Review the reported deviation
- Categorize it as minor, major, or critical based on risk to product quality, safety, or regulatory compliance
- Initiate further investigation and risk assessment (if applicable) as per SOP

All employees shall be encouraged to report deviations honestly and without fear of reprisal. A culture of transparency and open communication shall be promoted to ensure continuous improvement and proactive quality assurance.

6.2 Classification of Deviations

All reported deviations shall be reviewed and classified by the Quality department based on the potential or actual risk they pose to product quality, patient safety, regulatory compliance, and process integrity. Classification shall help prioritize the urgency of investigation, corrective actions, and escalation requirements.

Deviations shall be categorized into the following levels:

6.2.1 Minor Deviation

A Minor Deviation shall be defined as:

- A deviation with no or limited impact on the product, process, or quality system
- One that does not compromise product specifications, function, or patient safety
- A deviation that is unlikely to result in regulatory noncompliance

Examples include minor delays in process steps without consequence, or equipment calibration out-of-tolerance but within backup verification.

Action:
Minor deviations shall be documented and investigated. Justification for the continued use of the affected product or material (if applicable) shall be recorded. CAPA may be implemented if the recurrence or trend is observed. Minor deviations shall be closed based on Quality Department's review and approval.

6.2.2 Major Deviation

A Major Deviation shall be defined as:

- A deviation that may have an impact on process, product quality, validation, or regulatory expectations
- One that may affect critical quality attributes (CQAs) or key process parameters but does not cause serious harm if controlled
- A deviation that may result in a nonconforming product or a regulatory gap

Examples include deviation from validated sterilization cycles, failed in-process controls, or mislabeling of non-critical product attributes.

Action:
Major deviations shall require immediate containment and thorough investigation with a documented risk assessment by the Quality Department. Appropriate corrective and/or preventive actions (CAPA) shall be implemented to prevent recurrence. A Nonconformance Report shall be initiated if any product impact or specification failure is identified.

6.2.3 Critical Deviation

A Critical Deviation shall be defined as:

- A deviation that has direct or potential impact on patient safety or product efficacy

- A deviation that results in noncompliance with regulatory requirements or product release specifications
- A deviation requiring immediate corrective action and possible regulatory reporting

Examples include incorrect product released to market, sterility breach, use of unapproved material, or significant GMP violations.

Action:
A nonconformance report shall be initiated for critical deviations and escalated immediately to senior management and Quality leadership. A comprehensive investigation, formal CAPA, and regulatory notification shall be initiated where applicable. Affected product shall be quarantined and dispositioned as per **SOP-Nonconformance of Product**.

6.3 Investigation and Root Cause Analysis

Upon receipt of a reported deviation, the Quality department in RMT shall initiate a formal investigation to determine the underlying cause and assess the impact on product quality, patient safety, and regulatory compliance.

6.3.1 Investigation Initiation

- QA shall initiate the deviation investigation and evaluate potential impact on product quality and compliance.
- The investigation shall be proportionate to the severity classification (Minor, Major, or Critical) and the associated risk level.

6.3.2 Root Cause Analysis (RCA)

- QA or the designated personnel shall perform a structured root cause analysis using appropriate methods to identify the true cause(s) of the deviation.
- The team conducting the RCA shall include cross-functional representation where appropriate (e.g., Production, QC, QA and MBL for Critical or Major Deviations) to ensure diverse input and accurate conclusions.

The summary of all investigation activities and findings shall be recorded in the **Deviation Log.**

Deviations with potential significant impact shall trigger a Nonconformance Register as per **SOP Nonconformance of Product**.

6.4 Planned Deviations

6.4.1 Initiation of Planned Deviation

Any department requiring a deviation from approved processes or documentation shall initiate a formal request using the **Planned Deviation Request Form**.

The initiating department shall:

- Clearly describe the deviation being requested
- Provide justification for why the deviation is necessary (e.g., equipment downtime, raw material unavailability, facility maintenance)
- Define the start and end date/time or expected duration
- Identify affected products, processes, equipment, or areas

6.4.2 Risk Assessment for Planned Deviations

A documented risk assessment shall accompany the planned deviation request if the deviation is Major or Critical to evaluate the impact of the deviation on:

- Product quality and performance
- Patient safety
- Process validation or regulatory compliance

The risk assessment shall be performed using the approved HATM

Propose risk mitigation measures to ensure continued compliance and control

6.4.3 Execution and Monitoring

- Once approved, the deviation shall be implemented exactly as described in the request.
- QA shall monitor the execution of the deviation to ensure it remains within the defined parameters and timeframes.
- Any unexpected events occurring during a planned deviation shall be reported as unplanned deviations and handled accordingly.

6.5 Risk Assessment

A formal risk assessment shall be conducted for each Major and Critical deviation to evaluate its potential impact on product quality, patient safety, and regulatory compliance.

6.5.1 Purpose of Risk Assessment

The purpose of the risk assessment shall be to:

- Determine the severity and likelihood of harm or failure associated with the deviation
- Identify the need for immediate containment actions
- Support decisions related to product disposition, escalation, and CAPA

6.5.1.1 Containment Measures

Where applicable, immediate containment actions shall be taken to isolate affected product, halt processes, or prevent distribution.

Containment actions shall be supported by:

- Product identification and traceability
- Location of affected material (e.g., warehouse, production line)
- QA will be responsible for implementing the containment

High-risk deviations shall be escalated to Quality management and may trigger regulatory notifications, internal audits, or management review.

6.6 CAPA Implementation

Based on the investigation and risk assessment outcomes, appropriate Corrective and Preventive Actions (CAPA) shall be identified, implemented, and monitored to ensure resolution of the deviation and prevention of recurrence. The CAPA actions shall be taken following the procedure defined in **SOP-CAPA.**

REFERENCE:

- SOP-Corrective Actions & Preventive Actions

6.7 Deviation Closure

All deviations, whether planned or unplanned, shall be formally closed in a timely, documented, and controlled manner to ensure regulatory compliance, traceability, and continuous improvement of the Quality Management System (QMS).

If closure cannot be completed within defined timeframe, a justification shall be provided, and an extension request must be approved by the Quality Manager and CEO.

Justifications for delay shall include the reason, revised expected closure date, and risk control measures in place during the extension period.

6.7.1 Closure Requirements

Before a deviation can be formally closed, the following conditions shall be met:

6.7.1.1 Complete Documentation

- All related documents, including the original deviation report, investigation findings, root cause analysis, risk assessment, CAPA plan, and evidence of containment or corrections, shall be reviewed for completeness and accuracy.
- Any supporting attachments such as logs, lot records, photos, videos, or interview notes shall be included in the deviation file.

6.7.1.2 Verified CAPA Effectiveness

- All corrective and preventive actions outlined in the approved CAPA plan shall be implemented and verified for effectiveness by QA.
- Verification may involve:
  - Review of updated records or procedures
  - Audit or inspection of affected process areas
  - Review of product quality metrics or complaint trends
- If the CAPA is found to be ineffective, the deviation shall remain open, and additional actions shall be initiated.

6.7.1.3 Final QA Approval

- The Quality department shall review the full deviation file to ensure that:
  - All required steps have been completed
  - Risks have been addressed
  - No further actions are pending
- Once confirmed, Quality Manager shall approve the deviation closure by signing and dating the deviation report.

Closed deviation records shall be maintained in accordance with RMT's **SOP-Document Control** and **SOP-Control of Records.** Deviations shall be indexed and archived for audit readiness and future reference, with clear traceability to affected products, lots, equipment, or processes.

6.7.2 Trending and Metrics

A structured trending and metrics review process shall be maintained to proactively identify recurring deviations, assess process performance, and support continuous improvement and regulatory compliance.

6.7.2.1 Deviation Record Maintenance

The Quality department shall maintain a centralized and up-to-date Deviation Log**.**

6.7.2.2 Quarterly Trending and Analysis

QA shall perform trend analysis of all recorded deviations using data from the Deviation Record. This trend analysis shall aim to:

- Identify recurring deviations, common root causes, or areas of non-compliance
- Detect emerging risks or process weaknesses
- Assess the effectiveness of implemented CAPAs

Statistical or graphical tools may be used to visualize and interpret trends.

6.7.2.3 Escalation and Corrective Action

If trends indicate a systemic issue or significant risk, QA shall escalate the matter to management and relevant department heads. Escalated issues may warrant:

- Review of existing CAPAs
- Initiation of new CAPAs
- Process redesign or revalidation
- Internal audit or training refreshers

6.7.2.4 Management Review Inclusion

A summary of deviation trends and key metrics shall be compiled by QA and presented during the scheduled Management Review meetings as per the QMS requirements. The summary shall include:

- Total deviations reported
- Deviation types and classifications
- Open vs. closed status
- Top root causes and affected areas
- Recurrence data
- CAPA effectiveness observations

This information shall be used by management to make informed decisions regarding resource allocation, training needs, risk prioritization, and overall system improvement

7. Records and Documentation

Proper documentation and retention of deviation-related records shall be maintained as per **SOP Document Control** and **SOP Control of Records** to ensure traceability, compliance with applicable regulatory requirements, and support for continuous improvement. All records generated during the deviation management process shall be considered part of the Quality Management System (QMS) and maintained in accordance with RMT's **SOP-Document Control** and **SOP-Control of Records**.

7.1 Mandatory Deviation Records

The following records shall be maintained for each deviation:

- Planned Deviation Request Form
- Investigation and Root Cause Analysis Records
- CAPA Forms and Effectiveness Checks
- Deviation Log
- Training Records

REFERENCE:

- SOP-Document Control
- SOP-Control of Records