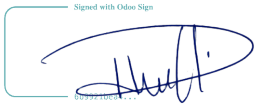
APPROVAL

Role	Name	Function	Signature & Date
Author	Evmorfia Kilimtzidi	QA	 2024/08/27
Review	Mauro Rinaldi	RAQM	 2024/8/27
Approval	Mathieu Horras	CEO	 8/27/2024

PURPOSE

This procedure aims to establish a systematic approach for managing deviations from standards or procedures within Aspivix's organization. This ensures that all deviations are controlled and have minimal impact on the products or the Quality Management System (QMS).

SCOPE

This procedure applies to QMS and Product Deviations.

RESPONSIBILITIES

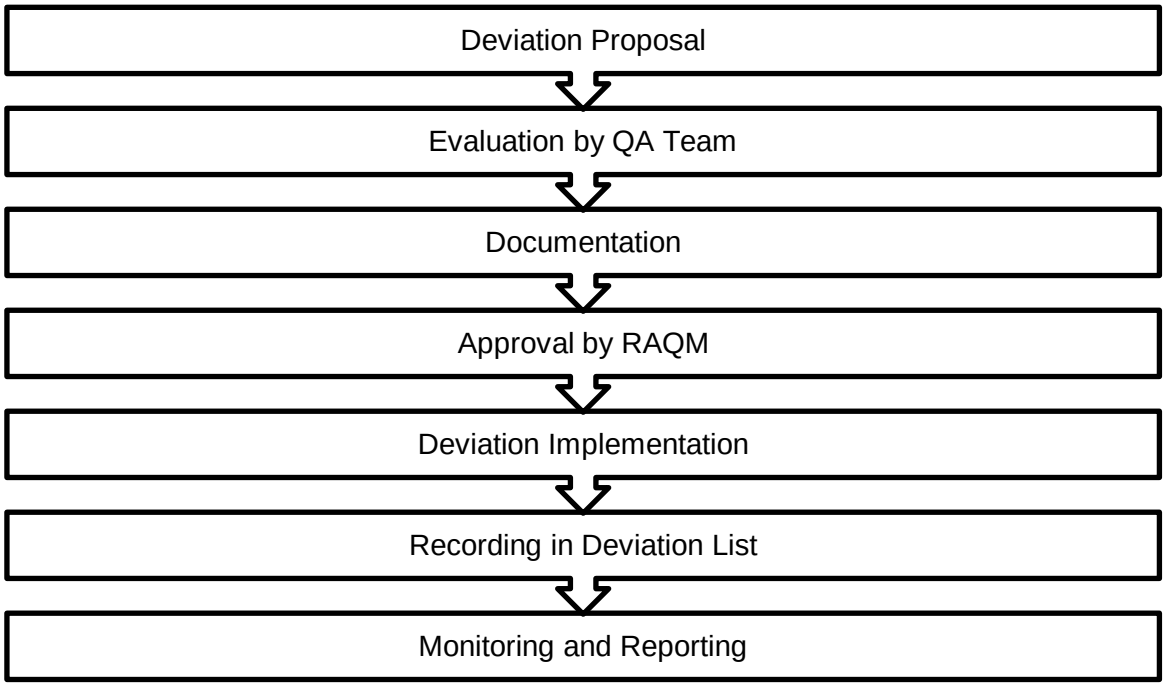
- **QA:** Responsible for evaluating, documenting, and monitoring deviations. Additionally, the QA team ensures that deviations are properly managed and controlled.
- **RAQM**: Responsible for approving deviations and ensuring they do not compromise quality or regulatory compliance.

DOCUMENT HISTORY

Description of Changes	Version
Initial version	A

TABLE OF CONTENT

1 PROCEDURE FLOWCHART



2 PROCEDURE DESCRIPTION

2.1 PROPOSAL OF DEVIATION

Any department within the organization may propose a deviation, which should be communicated to the QA team for initial review.

2.2 Evaluation by QA Team

Upon receiving the proposed deviation, the QA team and/or the Subject Matter Expert for specific topics will evaluate its appropriateness and potential impact. This evaluation ensures that the deviation is justified, temporary, and controlled.

2.3 Documentation

If the QA team deems the proposed deviation appropriate, it will document it using the template T-106-3 (Handling Deviations). The documentation should include:

- Description of the deviation
- Origin of the deviation
- Justification for the deviation
- Estimated financial impact of the deviation
- Actions and due date to handle the deviation
- Potential impact on the product or QMS

2.4 Approval by RAQM

The documented deviation is then submitted to the RAQM for approval. The RAQM is responsible for ensuring that the deviation does not compromise the quality or regulatory compliance of the product or QMS.

2.5 Implementation

Once the RAQM approves the proposed deviation, a decision will be made on whether the deviation should remain an exceptional, non-recurring change or if it is sufficiently valuable to drive a process change. The necessary changes or adjustments outlined in the deviation will then be implemented, and the corresponding actions will be carried out.

2.6 Recording in Deviation List

The QA records the deviation in the deviation list T-106-4 (Deviation List). This list is used to track all deviations and their statuses.

2.7 Monitoring and Reporting

The QA team is responsible for monitoring all deviations to ensure they are managed and controlled effectively. The status and impact of each deviation is monitored through the Deviation List and reviewed during the management review meetings.

3 REFERENCES

3.1 Procedures, Instructions and Guidelines

N/A

3.2 Templates and Forms

[1] T-106-3 Deviation Handling
[2] T-106-4 Deviation List

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Certificate of Completion

INS-106-1-rev.A_Handling Deviations_clean.pdf

Printed on 2024-08-27 - 17:21:09 UTC

Document Details

Created by: Eva Kilimtzidi
Created on: 08/27/2024 13:34:12 (UTC)
Creation IP Address: 178.192.223.103
Signers: 3

Document ID: 330
Signature: 53f30ecce0e799d3a99cd56b17984bb1c69f03bb8b5e661f0c121ddeb9f19e95

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