

EVI Policies

EVI Risk Management Policy

1. Context

EVI acknowledges that risk management is a fundamental element of good governance in a product development organisation. Integration of risk management into the operations of EVI is therefore important for the strategic objectives of the organisation. This Policy establishes the main principles with respect to identifying, managing and mitigating present and potential risks within EVI.

2. Scope of this policy

This EVI Risk Management Policy applies to all Staff Members, including in-house consultants.

3. Risk Management Framework

EVI applies a simple and well-defined framework for risk management in order to promote risk awareness among all staff and throughout the operations of EVI. The Risk Management Framework consists of three key components:

- Risk Management Policy defining how strategic and operational risks affecting EVI will be identified, assessed and managed;
- Risk Register listing strategic and operational risks, their estimated likelihood and severity and identifying any mitigation measures in place (see Annex 1);
- Crisis management process in case an incident or issue escalates to a crisis.

4. Implementation

EVI's Risk Management Framework is integrated into the existing management and operational structures to induce awareness and understanding of risks to EVI and EVI's risk tolerances at all levels of management and operation.

- Operational and strategic risks shall be identified and captured using best practice methodology for biomedical product development organisations, allowing identification of risks and ranking them in a consistent manner in the risk register;
- Operational risks shall be continuously tracked and reviewed by project teams during operational project meetings. If the impact or likelihood of a risk increases significantly, then it shall be escalated to the relevant head of department and senior management.
- Strategic risks shall be identified by reviewing the totality of EVI's activities and how they align with EVI's strategic priorities;

- New and emerging risks, operational as well as strategic shall be included in the risk registers as they are encountered
- Mitigating measures shall, insofar possible, be proposed for all identified risks, including methods to assess their effectiveness.
- The risk register shall be reviewed regularly by the senior management team to assure that it remains relevant and updated.

5. Responsibilities

5.1 Staff Members Responsibilities:

All Staff Members are required to inform their project leader and/or line managers of any strategic or operational risk they become aware of. The project leader or line manager will inform EVI's senior management about the identified risk and propose whether the risk is sufficiently real to justify inclusion in the Risk Register.

5.2 Line managers and project leader responsibilities:

Line managers and project leaders are responsible for escalating any risk that they have become aware of to EVI's senior management. In doing so, the line manager/project leader should estimate the likelihood and potential impact of the risk, together with a recommendation whether to include the risk in the risk register.

5.3 Senior management Responsibilities:

EVI senior management is responsible for creating, maintaining and reviewing the Risk Register at regular intervals (at least quarterly), as well as reviewing the appropriateness of the mitigating measures for each risk.

EVI senior management is also responsible for providing updates on strategic and key operational risks to the EVI Board.

5.4 EVI Board Responsibilities:

The EVI Board will review the strategic and operational risks, as well as the risk mitigation strategy at ordinary Board meetings.

6. Policy Review

This Policy will be maintained by EVI's Finance Director, subject to regular review by EVI's Board and senior management, and approval by EVI's Executive Director and Finance Director.

7. Communication

This Policy is available for all staff members on EVI's internal SharePoint document sharing system on will be regularly highlighted at staff meetings and to new employees.

ANNEX 1:

We have our own Template that we are using – can we please insert here as Annex 1 (instead of the example below)

Annex A

Risk Register Template

Risk no.	Risk description	Risk owner	Causes	Consequences	Likelihood (score)	Impact (score)	Risk rating (likelihood x impact)	Controls in place	Evidence to assess effectiveness of controls