INEGMA-E2

Quality Assurance, Risk Assessment and Evaluation Plan

Version 1.0

Project summary

In the context of civil protection exercises, well-considered and extensive evaluation plays a crucial role in documenting best practices and shortcomings happening during those exercises. By noting lessons learnt evaluation is essential for a constant improvement in training efforts, thus promoting the capacities of response units in the European Union and its neighboring countries for dealing with real disaster scenarios. INEGMA-E² is building upon an upcoming approach of independent evaluation and aims for a new level of exercise evaluation, which will meet high standards concerning documentation, replicability, and goal orientation. The three pillars of the project are:
1) The development of an adequate and versatile evaluation methodology, addressing the different types of existing exercises. Each of those has different needs and goals, thus requiring diverse evaluation approaches.
2) Exploring the great number of existing tools, which can facilitate the data collection throughout the exercise process. Software solutions and technical tools like databases and handhelds empower the evaluators to collect a great amount of data even under difficult circumstances often part of the training reality.
3) The creation of an international pool of evaluators, which will be accessible by all institutions managing those kinds of exercises, to ensure the availability of highly skilled experts when needed. Those invited to this pool of evaluators will have to meet a certain skill set developed during the project. A strong interconnection of all three essential fields - methods, tools and network – is crucial for setting new standards in exercise evaluation. By ensuring the provision of results for future exercises INEGMA-E² will significantly contribute to a continuous improvement of exercise outcomes. In addition, it will connect experts in exercise evaluation, will create a mechanism to share knowledge and good practices and will be designed for further grow and scale up.

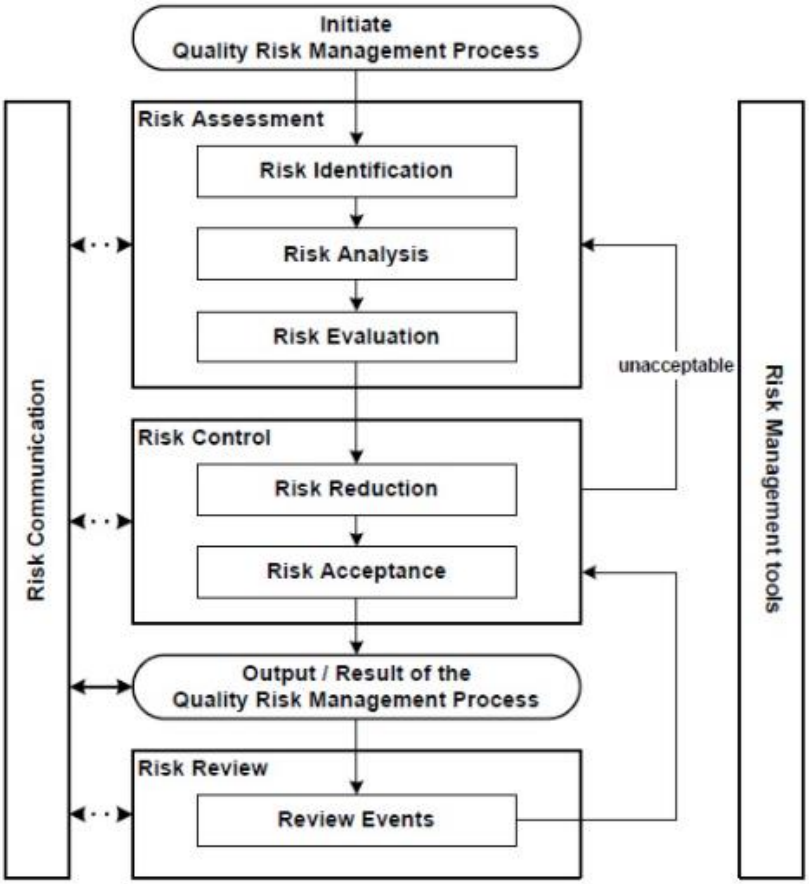
Quality Risk Management Plan

For the whole duration of the INEGMA-E2 - project a special Quality Risk Management (QRM) is necessary. It should provide a rationale to understand risk and mitigate it through appropriate and stable controls.
Quality risk management is the overall and continuing process of appropriately managing risks including assessment, control, communication, and review of risks. The responsibility is to guarantee best quality during the whole duration of the project as well as observing and evaluating situations within the project, identifying risks in timely, material or financial matters and to make the right corrections and improvements together with the Project Teams.

At the beginning of the project a Project handbook must be prepared, analysing, and evaluating the findings and report them to the Project Coordinator with suitable suggestions and conclusions. In the different task descriptions of this proposal the reporting intervals are arranged always according to the different issues and the timetable. With these measures it is possible to react immediately to complications and difficulties, finding the best solution for the project.

In exceedingly difficult and important cases, the QRM has the possibility to inform the Project Coordinator directly. These cases are such where the project must be re-organised because of false development in the project. The main results of QRM will also be part of the reports to the EC.

Overview of a Quality Risk Management process



Quality and Risk Management

After setup of the QRM structure and fixing the reporting and decision-making lines quality management will be defined and implemented. Quality management is a method for ensuring that all the activities necessary to design, develop and implement the INEGMA-E2- project are effective and efficient with respect to the system and its performance. Quality management consists therefore of quality control, quality assurance and quality improvement. By quality control the ongoing effort is to maintain the integrity of all processes and the reliability of achieving the implementation of INEGMA-E2.

The QRM Manager also must provide the project team with quality assurance which means that planned or systematic actions are necessary to provide enough confidence that INEGMA-E2 will satisfy the given requirements for quality. Whenever something goes into the wrong direction and is seen by the QRM Manager, quality improvement is necessary as a purposeful change of the process to improve the reliability of achieving our project objectives.

Risk Management is the process of planning, organising, leading, and controlling the activities of the INEGMA-E2 - project in order to minimise the effects of possible risks and uncertainties. By

providing Risk Management during the different phases of the project, problems that could become a risk for the project, will be reduced or minimised. For example, using only one special gear that is only available in one country could be a risk if it is not delivered in time. In this case e.g. it would be good to prepare an alternative already in advance. The QRM Manager as the responsible person for this action has to check all planned actions to find possible risks and to be prepared for improvement.

QRM will be subcontracted for transparency reasons.

The personnel appointed for the QRM should be able to:

- conduct a risk analysis
- identify and analyse potential risks
- evaluate risks and determine which ones should be controlled and which ones can be accepted
- recommend and implement adequate risk control measures
- devise procedures for risk review, monitoring and verification
- consider the impact of risk findings on related or similar products and/or processes.

All QRM activities are based on reports from the project partners and should be defined and documented accurate.

Reporting

To be prepared already for the final report it is necessary that QRM will start collecting all necessary information from the very first beginning. A special form for this gathering of information will be developed. In this way no detail should be forgotten or lost. Within this

project the manager has to provide the relevant information to QRM manager for the quarterly reports and the Final Report. At the end of the project all inputs must be analysed and prepared for this report.
The Project Director has to transfer the final report to the EC after the end of project.

1. **Purpose**

   This plan defines how our Quality Risk Management (QRM) program will be conducted through integration of knowledge gained from formal risk assessments, operational alerts, change controls and inspections. Information on higher risks will be communicated to management and the quality unit through a risk register intended to increase visibility and provide focus in discussions on risk control and mitigation.

2. **Scope**

   This plan applies to all personnel involved in the delivery of results in the evaluation of quality. Risk management will also be applied to the systems used to enable testing, including instruments and equipment qualification and to the design of analytical methods for use in support commercial manufacturing. The following risk management programs are not in scope of this plan and are addressed by other guidance:

   - Risk management for the project
   - Risk management of spongiform encephalopathies to our API and products
   - Safety risk assessments
   - Testing activities conducted at contract facilities
   - Testing of research materials.

Roles and Responsibilities

Roles	Responsibilities
Management	• Provide the resources necessary to support the implementation of this Master Plan for Quality Risk Management according to the GA • Ensure that related Project Manuals Procedures are aligned with this Master Plan. • Ensure periodic assessments are conducted to verify that related activities are in compliance. • Review risk assessments.
Subcontractor	• Assist in identifying and evaluating sources of risk and in establishing appropriate controls. • Ensure risk assessments, when they are appropriate, are performed, and that they are properly documented and approved by the Quality Unit as needed. • Review and approve risk assessments on activities governed by procedures. • Perform periodic review of risk register.

Roles	Responsibilities
QRM Expert	• Utilize risk tools and perform risk assessments where appropriate. • If in the role of risk assessment facilitator: - study the features of the tool to use. - identify subject matter experts to participate in the assessment. - document the assessment. • Submit formal risk assessments to Functional Area Management and Quality Unit for review and approval. • Comply with this management plan.

Risk Assessment

Risk assessment is a systematic process of organising information to support a risk decision to be made within a risk management process. It consists of the identification and the evaluation of risk.

2.1. Risk Identification

The systematic use of information to identify potential sources of hazards referring to the risk question or problem description.

2.1.1. This QRM intends to both address potential of harm to people and uncertainty in objectives. The primary focus of risk management is to control the risk to data on product attributes, as this data is used to both determine suitability of products for clinical programs and to propose specifications utilized in evaluation of manufacturing process control. Other objectives include accurate data for proposal of labelling information; development and validation of robust methods, and testing in support of manufacturing activities (e.g., water testing).

2.1.2. Risks are proactively identified in deliverables by conducting risk assessments to the type of tests that evaluate product quality attributes used in the decision for batch release. Failure modes are identified by experts in the technique and ranked. Multiple sources are used for further identification of risks to be evaluated as well as to trigger review of processes for risk assessment. These sources include: Quality Unit and regulatory inspections, benchmarking, internal self-inspections, investigations on operational alerts, and trend evaluations. These risks are analysed and evaluated for inclusion in the Risk Register.

2.1.3. Typically, a list of the potential risks which may be introduced, increased or controlled in each area should be drawn up. In the risk assessment the following basic questions should be addressed:

- What problems/difficulties might occur?
- What is the origin of possible risks?
- What is the probability of their occurrence and how easy is it to detect them?
- What are the consequences?

2.2. Risk Analysis

It is the estimation of the risk associated with the identified hazards.

2.2.1. Qualitative Risk Analysis

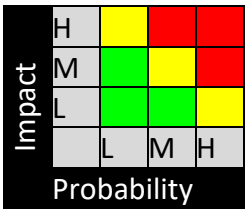
The probability and impact of occurrence for each identified risk will be assessed by the project manager, with input from the project team using the following approach:

Probability

- High – Greater than <70%> probability of occurrence
- Medium – Between <30%> and <70%> probability of occurrence
- Low – Below <30%> probability of occurrence

Impact

- High – Risk that has the potential to greatly impact project cost, project schedule or performance
- Medium – Risk that has the potential to slightly impact project cost, project schedule or performance
- Low – Risk that has relatively little impact on cost, schedule or performance



Risks that fall within the RED and YELLOW zones will have risk response planning which may include both a risk mitigation and a risk contingency plan.

3. Risk Control

The sharing of information about risk and risk management between the decision maker and the project partners.

3.1. The purpose of a risk management program is to decide, for the hazards identified, what controls are possible and when they should be sought and implemented. Evaluation of risk controls will consider the following questions:

- Is the risk currently managed at an acceptable level?
- What can be done to reduce or eliminate the risk?
- Is there other data that helps manage the process, evaluation and can be used in lieu of a control?
- What is the appropriate balance among benefits, risks, and resources?
- Does implementation of the control introduce new risks?

Risk control is the process in which the team will identify, evaluate, and implement measures to bring risks down to acceptable levels or avoid them altogether. Risks that require a mitigation or avoidance strategy will be assigned to a risk owner. The risk owner is responsible for providing risk status and all documentation associated with such in a manner consistent with the control strategy guideline below.

Risk control can include:

- ➢ not proceeding with the risky activity
- ➢ taking the risk

- removing the risk source
- changing the likelihood of the risk
- changing the consequences of the risk
- sharing the risk with another party
- retaining the risk by informed decision

Probability Impact Score	Control Strategy
High	Risk will be statused on a daily basis. The risk owner will document all avoidance and mitigation efforts. As mitigation and avoidance actions occur the risk will be assessed daily until the risk level is acceptable or has been avoided altogether
Medium	Risk will be statused on a weekly basis. The risk owner will document all avoidance and mitigation efforts. As mitigation and avoidance actions occur the risk will be assessed weekly until the risk level is acceptable or has been avoided altogether
Low	Risk will be statused weekly. No mitigation or avoidance efforts are necessary unless risk becomes elevated

The risk owners for all high and medium risks must consider each of the following options for controlling risk:

- Alternative courses of action or workarounds
- Mitigation steps to reduce the probability or impact of the risk
- Changing project requirements to eliminate or reduce the probability or impact of the risk
- Risk acknowledgement which accepts the risk without taking any action

4. Risk Communication

4.1. The goal of a risk communication is to, by way of sharing information on risks identified and their controls, increase risk awareness and promote controls that support quality. This means that personnel in different roles have different needs regarding communication of risk.

4.2. Personnel conducting activities will need to be informed of risks so that they maintain behaviours that support best practices sustain vigilance and understand process so as to help control risk. This communication is achieved through training, method details, formal procedures, and aides such as check lists to enhance their ability to control risk.

4.3. Management is responsible to allocate resources for activities; therefore, they must support identification of risk and stay informed of risks that require additional controls. Management is also responsible to commit resources to the development of those controls or accept residual risk. This communication will be achieved and documented

through their approval of plans, procedures, formal change controls and of the risk register.

4.4. All risk assessments performed by an organisation should be documented. The documentation should list and track all key risks as perceived by the organisation and summarize how the risks have been mitigated.

5. Risk Review

Review or monitoring of output or results of the risk management process considering new knowledge and experience about the risk.

To remain effective, the risk register review will consider the impact of trends in quality events, change controls and lessons learned from audits and inspections and its review documented at a minimum once every 3 years. This review will also document removal of a risk from the register due to risk reassessment.

Evaluation

INEGMA-E2 project will be monitored and evaluated in line with EC corporate standards. Project monitoring will be characterised by a gender-sensitive approach. The main tools for organizing the project monitoring system encompass:
(a) The gender-sensitive Results Framework and its indicators as described in the WP (milestones, progress reports);
(b) The Project risk analysis;
The project will be subject to a mid-term participatory review engaging all relevant stakeholders and beneficiaries, so as to assess progress, achievements, relevance of the intervention and its approaches and if needed, identify suggestions for adjustments to the project to be considered by the Project Management Board.
DCNA will support DSU in WP1 to evaluate and monitor as well as undertake a mid-term internal quality assurance, while the results and its recommendations will be presented to the Project Management Board. For the whole duration of the project a special Quality Insurance Management System will be installed and linked with the risk management procedures. The responsibility for taking actions with regards to this monitoring and evaluation activities are with DSU. Furthermore, key performance indicators will be developed at highest and best relevant quality, DCNA is to guarantee best quality during the whole project as well as ensuring that all the activities necessary to design, develop and implement are effective and efficient with respect to the team and its performance. DSU and DCNA will establish additional quality control, quality assurance and quality improvement. (a) By quality control the ongoing effort is to maintain the integrity of all processes and the reliability of achieving the implementation of the project. (b) The quality assurance measures include cost control measures as well as systematic actions that are necessary to provide enough confidence that INEGMA E2 will satisfy the requirements. These requirements will be set up in the Project Management Board. (c) Whenever something goes into a wrong direction, quality improvement is necessary to change processes to improve the reliability to achieve project objectives. The results of the quality management will be on one

hand a combined quality and risk management status report to monitor the development of the project and will also support to keep the activities according to the timeline and track the project activities and their relevant reports. The following table describes the indicators in the monitoring plan:

Monitoring Activity	Purpose	Frequency	Expected Action
Track results progress	Progress data against the results it will be collected and analysed to assess the progress of the project in achieving the agreed outputs	Quarterly	Slower than expected progress will be addressed by project management.
Monitor and Manage Risk	Identify specific risks that may threaten achievement of intended results. Identify and monitor risk management actions using a risk log.	Quarterly	Risks are identified by project management and actions are taken to manage risk. The risk log is actively maintained to keep track of identified risks and actions taken.
Learn	Knowledge, good practices and lessons will be captured regularly, as well as actively sourced from other projects and partners and integrated back into the project.	At beginning and end of project	Relevant lessons are captured by the project team and used to inform management decisions.
Project Report	A progress report will be presented to the Project Management Board and key stakeholders, consisting of progress data showing the results achieved against predefined annual targets at the output level	Annually, and at the end of the project (final report)	

Project Review **(Project Board)**	The project's governance mechanism (i.e., Project Management Board) will hold regular project reviews to assess the performance of the project and review the Work Plan to ensure realistic budgeting over the life of the project.	Quarterly	Any quality concerns or slower than expected progress should be discussed by the project board and management actions agreed to address the issues identified.

Project Risk Analysis and Mitigation Actions

Main risk	Description	Mitigation actions to correct the problem or to avoid the risk
Lack of support	• Inadequate support from stakeholders	• Close project monitoring should indicate inadequate support early enough to start corrective actions
Incorrect assumptions at planning	• Incorrect assumptions may cause additional planning and updated scenarios	• Injects can be re-dimensioned • Injects can be started at a later time or phase of the scenario • Some injects can be deleted if the workflow indicates this
Logistical problems	• economic crisis, badly planned arrangements • time delays	• precise advance planning • making arrangements in advance
Poor planning of exercise	• exercise goal not clearly defined • exercise objective not met	• precise planning • clear definition of the exercise goal
Financial underfunding	• Some costs may arise over the estimation of the project proposal	• Close financial monitoring is a necessity to be able to react on short notice • To hold the balance maybe cutbacks at other positions are needed
Conflicts of scheduled events	• Predefined events may overlap with local activities and be a problem for participation	• Early announcement of meetings, workshops and seminars should avoid or reduce an overlapping • If the conflict cannot be fixed early a postponing or a shift to an earlier date may be a solution

Resignation of a partner within the consortium	• Internal problems in a partner`s organization can occur and can lead to an exit	• Solutions are sought to redistribute the working packages and tasks
Missing reports or deadlines	• lack of communication between partners • time management is not appropriate • time delay in transmission of reports	• Completion of the reports is checked at an early stage
Data collection not feasible	• Insufficient data access • Not enough data to be exploited	• Precise planning and arrangement in advance

Risk Portfolio