

Quality Management Plan for the “PureCell Project: Towards Precision Medicine” Project

1. Purpose and Scope

This Quality Management Plan (QMP) is designed to ensure the success of the "PureCell - Towards Precision Medicine: Advanced Cellular Analytics in Biomedical Research" project. The scope includes leveraging institutional capacities at INAB|CERTH, enhancing advanced cellular analytics, and establishing a National Open Infrastructure for biomedical research. The QMP will address quality standards, procedures, roles, and responsibilities to meet project goals effectively.

2. Quality Objectives

1. To ensure that project deliverables meet the highest standards of scientific and technological excellence.
2. To promote innovation in advanced cellular analytics and its applications in Precision Medicine.
3. To maintain compliance with regulatory, ethical, and safety standards for research and infrastructure.
4. To establish mechanisms for stakeholder collaboration and feedback.
5. To equip researchers and technicians with the skills needed for effective use of advanced equipment.

3. Roles and Responsibilities

- **Project Manager:** Oversees the implementation of quality standards and ensures compliance across all phases.
- **Quality Assurance (QA) Team:** Monitors adherence to established protocols and standards.
- **Research Teams:** Ensure precision and reliability in scientific outputs, data collection, and analysis.
- **Stakeholders:** Provide feedback for continuous improvement of processes and deliverables.

4. Quality Standards

- **Scientific Excellence:** Ensure state-of-the-art methods in cellular analytics and data interpretation.
- **Operational Standards:** Adhere to protocols for the use of research equipment.
- **Regulatory Compliance:** Align with EU and national guidelines for biomedical research, including ethical practices.
- **Data Management:** Utilize robust systems for data storage, access, and analysis, ensuring data integrity and security.

5. Quality Control Processes

1. Research Protocols:

- Standardize experimental procedures.
- Regularly update protocols to reflect technological advancements.

2. Infrastructure Maintenance:

- Schedule routine checks for instruments and computational systems.
- Document and address any equipment malfunctions or discrepancies.

3. Data Verification:

- Conduct peer reviews of collected data and analysis.
- Implement error-checking algorithms for automated data processing.

4. Training:

- Provide workshops and seminars for researchers and technicians.
- Ensure competency in using advanced tools like the Seahorse analyzer.

6. Quality Assurance Processes

• Internal Audits:

- Periodic reviews of laboratory operations, data quality, and compliance.
- Reports to identify gaps and recommend corrective actions.

- **Stakeholder Feedback:**
 - Regular surveys and meetings to gather insights from collaborators, industry partners, and academic institutions.
- **Risk Management:**
 - Identify potential risks in equipment procurement, research, and data security.
 - Develop mitigation strategies for identified risks.

7. Deliverable Review and Acceptance Criteria

All deliverables will undergo a rigorous review process to ensure:

- Alignment with project goals.
- Compliance with international research standards.
- Applicability to both academic and industry needs.

8. Communication and Reporting

- **Documentation:**
 - Maintain logs for experimental processes, results, and equipment usage.
 - Share findings in reports aligned with stakeholder needs and project milestones.
- **Stakeholder Engagement:**
 - Disseminate progress through regular newsletters, workshops, and the PureCell website.
 - Organize thematic Open Days for collaboration and knowledge sharing.

9. Continuous Improvement

- Feedback loops to refine research methods and infrastructure usage.
- Updates with technological and methodological advancements in cellular analytics.
- Close monitoring of emerging needs in biomedical research to adapt infrastructure capabilities.

10. Evaluation Metrics

- **Scientific Impact:** Number and quality of publications, patents, and methodologies developed.
- **Infrastructure Utilization:** Percentage of capacity used by internal and external stakeholders.
- **Stakeholder Satisfaction:** Feedback from partners, collaborators, and researchers.
- **Compliance:** Successful audits and adherence to safety, ethical, and regulatory standards.

11. Conclusion

This Quality Management Plan will be revisited periodically to incorporate new insights and evolving project requirements, ensuring the PureCell initiative achieves its ambitious goals in advancing biomedical research and Precision Medicine.