

Topics in Microbiology Quality Assurance Project Plan Essentials

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Key Elements to Consider

- Who will be involved with the plan?
- What is the problem definition for the plan?
- What is the summary of the task descriptions?
- What are my quality objectives and criteria to follow?
- What special training or certifications are required?
- What kinds of documentation is required for the plan?

Roles and Responsibilities

- Project Supervisor: Who is the lead contact for the project?
- Other Participants:
 - Quality Assurance Officer
 - Analysts
 - Sampling Coordinator
- Who are the points of contact for the project and how can they be reached?
- What is the overall organization for the project as defined in an organization chart?

What is my objective/problem definition for the plan?

- What is the reason for this project?
- What question(s) are we trying to answer?
- What is not known that is driving the need for the project?
- What is the benefit in performing the project?
- Is there existing background information that supports the need for the project?
- Where can this background information be found?
- Who will use my data from the project?

What is the summary of the task descriptions?

- Which locations will be sampled?
- How many samples per location?
- What parameters will be tested?
- What final products do I need to include, i.e. reports generated? Raw data and quality control records, etc.
- What is the schedule that we are trying to follow?
- How will my data be evaluated and by whom?

What are my quality objectives and criteria to follow?

- What are my target performance criteria?
 - Precision?
 - Accuracy or bias?
 - Are my samples and study results representative and comparable to past projects?
 - How much data do I need to demonstrate my project objectives?
 - Are the methods that I propose to use sensitive/specific enough to meet my needs?
- What data quality indicators will I use?

Quality Control Measures for Microbiology

- Testing of materials to be used for sterility
 - Equipment (including all sampling and testing apparatus) and media
- Testing of materials to be used for viability
 - Media
- Replicate sample testing to assess precision
 - Laboratory developed criteria based on sample duplicates
- Spiking with known densities to assess recovery
 - Bioballs or other approved sources of QC samples or lab-developed controls
- What is the acceptance criteria for all of the above?

What procedures will we follow if my QC fails?

- Plans for root cause analysis of failed data
- Corrective Actions (CAs) to be followed
- Targets for measuring the effectiveness of my CAs
- Plans for testing of materials or equipment to avoid future issues
- Resampling plans for affected samples
- Qualification of any unacceptable data

Additional Concerns

- What SOP(s) will be used?
 - SOPs must define in detail the procedures to be followed from start to finish and the interpretation of the results
 - SOPs need to address critical elements for the whole project
 - Sampling SOPs are as important as the testing SOPs
 - References must be included
 - Safety concerns in the field and at the analytical bench need to be addressed
 - Waste management and pollution prevention need to be addressed
 - Quality control measurements must be defined (type and frequency and acceptance)
 - Equipment and supplies

Summary

- Proper planning is a great tool
- Expedites the approval process
- Helps with troubleshooting problem data
- Defines the process so that the project can proceed as intended
- Allows for a defined plan that all can follow
- Makes for sound and defined science

Helpful Links

<https://www.epa.gov/quality/quality-assurance-project-plan-development-tool>

<https://www.epa.gov/quality/template-developing-generic-quality-assurance-project-plan-or-plan-elements-model>

https://www.state.nj.us/dep/dwq/pdf/WWFTDDP_QAAP.pdf

Check your state's websites for local projects in your area