Quality Control, Monitoring & Deviations — Service Segment

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Service Segment · Quality Control, Monitoring & Deviations
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We help you convert your protocol into a practical quality control and monitoring approach that fits PhD realities. You get simple but defensible QC checks, monitoring routines, deviation logs, and corrective and preventive action (CAPA) notes that make your study look organised and auditable to guides, ethics committees, and examiners.

- List of critical data and process points that need explicit quality control
- Source document verification and data check plan at realistic intervals
- Basic study monitoring outline, including what is checked, how often, and by whom
- Deviation and violation categorisation with simple documentation templates

- Corrective and preventive action (CAPA) notes linked to typical deviations
- Protocol ready text describing QC, monitoring, and deviation handling sections

Workflow — How Quality Control, Monitoring & Deviations Runs

1. **Review of protocol, SOPs, and CRF/EDC**
   We scan your study design, variables, visit schedules, and operational documents to identify where errors or drift would seriously impact validity.
2. **Identification of critical quality points**
   Together we list critical data fields, processes, and timings that must be correct for your primary endpoints and key safety or ethical requirements.
3. **Design of simple QC checks**
   Practical checks are proposed, such as source document comparisons, range checks, re measurements, or second signatures, scaled for a PhD project.
4. **Monitoring plan outline**
   We outline how often QC checks happen, who performs them, and how findings are summarised, whether by the scholar, guide, or a small internal team.
5. **Deviation and violation framework**
   A simple framework is drafted to distinguish minor deviations, major deviations, and protocol violations, with criteria relevant to your context.
6. **Log and template creation**
   Templates or log outlines are created for documenting deviations, QC findings, and follow up actions, suitable for use in spreadsheets or paper logs.
7. **CAPA note drafting**
   For common or anticipated deviations, suggested corrective and

preventive actions are written in language that shows reviewers you have thought ahead.

8. **Integration with SOPs and visit schedules**
   QC and monitoring steps are cross checked with SOPs, lab manuals, and visit schedules so they are naturally embedded in day to day work.
9. **Protocol and ethics wording**
   Concise text is assembled for protocol sections describing quality control, monitoring, and how deviations will be recorded and handled.
10. **Delivery and refinement cycle**
    You receive the plan, logs, and text blocks. One refinement cycle is included after guide or internal review feedback.

What You Get in Your Quality Control & Monitoring Pack

- **Critical quality point list** highlighting which data items and procedures deserve extra checks.
- **QC and monitoring outline** specifying what is checked, by whom, and at what approximate frequency.
- **Deviation and violation framework** with basic definitions adapted to your project and setting.
- **Log and template outlines** for recording QC checks, deviations, and CAPA actions in editable formats.
- **Short CAPA guidance notes** tied to likely deviations such as missed visits, late samples, or incomplete forms.
- **Protocol ready text blocks** covering quality control, monitoring, and deviation handling for ethics and protocol documents.

The intention is to provide enough structure to reassure reviewers and examiners that your study is under control, without creating a monitoring burden that is unrealistic for a single scholar.

Detailed Deliverables, Formats, and Service Boundaries

Deliverables and formats

- One **QC and monitoring summary document** in DOCX or similar editable format.
- **Critical quality point table** linking fields or procedures to checks and frequencies.
- **Deviation and violation log templates** for tracking issues and actions over time.
- **Short CAPA guidance sheet** listing typical problems and suggested responses.
- **Protocol wording snippets** suitable for Methods, Quality Control, and Monitoring sections.

What is included

- Identification of practical QC points based on your protocol and CRFs or EDC.
- Design of a simple, feasible monitoring outline suited to PhD level resources.
- Creation of deviation and violation definitions and log templates.
- Basic CAPA guidance for common data collection and protocol issues.
- One refinement cycle to align with guide or departmental feedback.

What is not included

- Formal sponsor style monitoring visits or full GCP compliant audit programmes.
- On site monitoring execution, verification visits, or continuous oversight.
- Institution level quality system design, accreditation, or certification work.
- Complex electronic audit trail configuration beyond simple log templates.

When to Use This Service and What You Should Have

Ready

Best time to book

- After your protocol blueprint, variables, and SOP or visit schedule are in place or nearly final.
- Before starting recruitment or main data collection, so QC is built in from day one.
- When guides, ethics committees, or institutional reviewers ask about monitoring and deviation handling.
- When you are worried that errors, missed visits, or staff turnover might compromise data quality.

Helpful inputs from your side

- Your latest protocol draft and any existing SOPs or visit schedules.
- Information about staff support, lab technicians, or collaborators who will help run the study.
- Any departmental or institutional guidance on quality control or monitoring, if available.
- Examples of typical problems seen in similar projects in your department or setting.
- Constraints on how often QC checks can realistically be performed.

FAQs — Quality Control, Monitoring & Deviations

1. Is a formal monitoring plan really needed for a PhD?
Many committees and examiners now look for at least basic QC and monitoring descriptions. A simple, honest plan signals that you take data quality seriously.

2. Who usually does the monitoring in a PhD level project?
In most cases, monitoring is shared between the scholar, guide, and sometimes a departmental coordinator. The plan we create assumes this realistic structure.

3. What is the difference between a deviation and a violation?
A deviation is a departure from the protocol that may or may not be major. A violation is usually a more serious or repeated breach that could threaten safety or validity. We help you define these simply for your context.

4. Does this service include statistical monitoring or interim analyses?
No. We focus on operational QC and basic monitoring. Statistical monitoring, if relevant, is addressed in conjunction with your analysis plan.

5. Will the QC plan create too much extra work?
The plan is intentionally kept light and focused on what really matters for a PhD scale study, so checks are manageable and high value.

6. Can this be adapted for lab only or bench work?
Yes. For lab projects, QC often focuses on sample identification, instrument runs, calibration logs, and repeat measurements; wording is tuned accordingly.

7. Is this compatible with GCP concepts?
While not a full GCP monitoring programme, concepts such as source verification, deviation logging, and CAPA are aligned with good practice and can be expanded if needed.

8. What if my department already has a QC template?
We work within existing templates, focusing on filling them with content that is coherent with your protocol and realistic for you to execute.

9. Will these logs and plans help during viva or audits?
Well documented QC and deviation records can be very useful during viva, departmental scrutiny, and any external audits, as they show transparent handling of issues.

10. Can the QC plan be updated later?
Yes. The documents are provided in editable formats so you can adjust frequencies, checks, or CAPA details as your project evolves.