Guideline number	**Guideline 51.016A**	Version	**2.0**
Title	**Quality Control of Trial Master File**		

1. Introduction

The intention of carrying out Quality Control checks of the content of the Trial Master File (TMF) is to ensure that the information contained within the TMF is accurate, complete and up to date to meet the requirements of GCP and those set out in the Medicines for Human Use (Clinical Trials) Regulations.

2. Quality Control Checks

2.1 Responsibility

The QC of information within the TMF is the responsibility of the owner of the documentation, this may be delegated to another individual who may carry out the task of printing and filing documentation within the TMF.

2.2 Timeline

The QC checks should be performed at minimum every 6 months from the creation of the relevant sections of the TMF, which in turn should take place as soon as possible after MHRA approval. The earlier an issue is identified, the easier it will be rectify. If the QC is left until the end of the trial, issues identified may relate to activity that took place months or years prior and may no longer be possible to correct.

2.3 Content

The content of a QC check is most often a straight forward activity, it relates to confirming that the output of required processes are completed as expected as well as confirming some routine areas of common issues.

- Ensure all controlled documents have appropriate titles, versions and page numbers.
- Ensure all areas which require signatures are completed with appropriate signature.
- Ensure there are no missing pages from a document.
- Ensure the document is legible.
- If the document in question supersedes another, ensure the superseded document is marked as superseded and moved to appropriate section if required.
    - In continuation of this, ensure previous versions of documents are present.
- Ensure the presence of all required documents, for example of filing details related to a regulatory submission ensure all the associated documents are present.
- Ensure all filed documents are clean copies with no track changes or comments, unless required. For example, in the instance a track change copy was a required submission for MHRA/REC etc.
- Ensure when filing a document that the same document has not already been filed.
- If there is any associated correspondence relevant to a document being filed, ensure it is filed in the relevant correspondence section.

2.4 Documenting Checks

When a QC check has been completed, complete the QC log on the index page for the relevant section. Adding the name of the individual who completed the checks, the date, the subsection applicable and some basic details of the checks. This can reference a specific document or the complete section. Additional space can be added using Appendix 1 if the table is filled.

2.5 Updates to TMF

If any issues are identified as a result of carrying out a QC check, the issue must be resolved and the corrected and updated documentation filed with the TMF. If it is required to explain a correction or update, a file note may be generated.

Guideline signatories

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Document history

Version	Date	Description
1.0	24/07/2023	First Release
2.0	08/05/2025	Frequency of QC checks added