Quality Management System

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1 OBJECTIVE

The Quality Management System package has the purpose to ensure all TriTiCon ApS's (TTC) work and services are conducted in a lawful manner, adhering to relevant regulations, industry standards and are carried out with high quality and ethical standards.
This Standard Operating Procedure (SOP) defines the overall structure of TTC's Quality Management System (QMS) and guidance documents, as well as the procedures for writing, reviewing, approving, and filing all Policies, SOPs, templates, etc. (jointly called Quality Management System (QMS) Documents). An overview and index of currently applicable QMS documents is maintained in Appendix 1.

1.1 CHANGES SINCE LAST REVISION

No changes, this is a new SOP.

2 APPLICABILITY AND RESPONSIBILITIES

This SOP applies to all GxP work conducted in TriTiCon ApS. It is the responsibility of all TriTiCon ApS's employees to keep up to date with and follow this SOP.

3 DEFINITIONS

TriTiCon QMS documents and guidance consists of three groups of documents.

3.1 POLICIES

Policies are formal, brief, and high-level statements or plans that embraces the organization's general beliefs, goals, objectives, and acceptable procedures for a specified subject area. Policies are created with the intent to be in place for several years and regularly reviewed with approved changes made as needed.

3.2 STANDARD OPERATING PROCEDURES (SOPS)

SOPs are detailed, written instructions that document a routine or activity, to ensure that it is perform a reliably and consistently.

3.3 TEMPLATES, CHECKLISTS AND OTHER CONTROLLED DOCUMENTS

Templates, checklists, and other controlled documents are tools or instructions to users, designed to streamline certain processes according to what the best practices are. Guidelines should to greatest possible extent be adhered to but are still open to interpretation and do not need to be followed to the letter. Hence, they provide flexibility for unforeseen circumstances.

4 CREATION OF NEW DOCUMENTS, THEIR APPROVAL AND STORAGE

The Board of Directors is responsible for identifying needs for new or revised QMS documents; with the purpose of adequately support lawful and ethical behaviour, regulatory compliance, and harmonizing company practices.

The Board of Directors are responsible for producing (or delegating the production of) QMS documents. Approval of QMS Documents should be made by two Board members. All QMS documents are version-controlled. Version history is maintained in SOP-01 Index of TTC Policies, SOPs, Guidelines and Checklists Documents.

A complete package of all QMS documents, should be made available for all employees in pdf format in a shared area. An electronic archive of all QMS documents and guidelines, including prior document versions, Word-versions and documents under development should be maintained. See SOP-01 Index of TTC Policies, SOPs, Guidelines and Checklists Documents for electronic storage locations.

5 RESPONSIBILITIES

5.1 A DESIGNATED DIRECTOR

The Designated Director (Magnus Värendh) is responsible for, but may delegate tasks to other relevant operational experts:

- Development or generation of draft new QMS documents and guidelines.
- Update/revision of existing documents, whenever required.
- After the completion of drafts, send to the appointed person from the Board of Directors for review and comments, and make satisfactory corrective changes. Finalise and store QMS documents.
- Maintain SOP-01 Appendix 1 up to date.

5.2 EACH EMPLOYEE

Each employee is responsible for:

- Keep themselves informed and comply with and use of TTC’s QMS Documents. Train (read and understand) annually.
- Document the training in a training log, collected by the designated director annually.
- Act in accordance with the policies, procedures and guidelines provided. In addition, make sure client requests and trainings are conducted prior to start of individual projects, and that also these guidance documents are adhered to.

6 REVIEW AND REVISIONS

All QMS Documents will be reviewed bi-annually by at least one board member and the designated director.

7 VALIDITY

All new and/or amended QMS documents become valid from the date signed by board members, given on the last page on the document.

8 ARCHIVING

Records will be signed electronically and retained electronically for a period of 10 years.

9 REFERENCES

SOP-01 Index of TTC Policies, SOPs, Guidelines and Checklists Documents

10 DOCUMENT HISTORY

Version	Date	Author	Comment
1.0	2024-03-01	Magnus Värendh	New SOP