viedoc™

Quality Policy

Version Date 2024-06-14

Document History

Version	Author	Date	Change
1	Alan Yeomans	2016-03-22	Replaces earlier SOP ”QSSOP06-08 Quality Assurance”. Redefines the Viedoc Technologies Quality Management System.
2	Alan Yeomans	2017-06-27	Updated section 3.4 Risk Management with information about the risk assessments performed. Updated to new template.
3	Alan Yeomans	2017-12-14	Added a description of the Quality System document architecture at the end of chapter 3.1
4	Alan Yeomans	2019-05-08	Renamed COMPOL04, information added about archiving, review of efficiency of CAs and PAs and information about Medical Devices.
5	Alan Yeomans	2020-11-30	Updated to new company name Added a diagram showing the Management System document hierarchy Updated reference to IT Infrastructure Overview
6	Alan Yeomans	2021-12-01	Updated to new Viedoc branding. Changed location of safe in 3.10. Added the audit plan. Defined signature responsibility for all the documents in 3.9. Updated 3.8 and 3.9.3 with the metrics from the annual Quality Report.
7	Alan Yeomans	2022-02-18	Updated §3.1 with information about the Company Process Map and the process groups. Updated to the new company template.
8	Claes Aspman	2023-04-05	Updated with new template. Re-worded the beginning of chapter 3. Updated chapter 3.4, elaborated on processes to identify and/or mitigate risks
9	Claes Aspman	2023-09-25	Updated chapter 3.9 to reflect what is now covered in the Quality Manual. Added chapter 4 with reference to the Quality Manual.

10	Claes Aspman	2024-06-14	Updated with latest SOP template. Added reference to COMSOP24 Company Process Map. Added chapter 3.1.1 Electronic signatures.

Contents

1 OBJECTIVE 4
2 FOUNDATIONS FOR THE QUALITY MANAGEMENT SYSTEM 5
2.1 The Context 5
2.1.1 Internal Context 5
2.1.2 External Context 5
2.2 Leadership Commitment to Quality 5
2.3 Organisational Commitment to Quality 5
2.4 Continual Improvement 5
3 ELEMENTS OF THE QUALITY MANAGEMENT SYSTEM 6
3.1 Processes 6
3.1.1 Electronic Signatures 7
3.2 Resources, Roles and Responsibilities 7
3.3 Partnering 8
3.4 Risk Management 8
3.5 Issue Management 9
3.6 Knowledge Management 9
3.7 Documentation Supporting Achievement of Quality 9
3.8 Measuring Quality 9
3.9 Management Review 9
3.9.1 Quality Plan 9
3.9.2 Audit Plan 9
3.9.3 Quality Report 10
3.9.4 Escalation of Issues 10
3.10 Archival 10
4 REFERENCES 10

1 OBJECTIVE

The Viedoc Technologies quality management system (QMS) is an integrated framework through which the company can systematically plan and achieve our quality objectives. Viedoc Technologies has therefore decided to standardise on the Clinical QMS Conceptual Framework proposed by the Transcelerate[1] project.

The Clinical QMS at Viedoc Technologies is defined as senior management development and visible support for quality and compliance standards, understanding customer requirements, maintaining policies and procedures, providing adequate training, implementing quality control and quality assurance, developing risk-based monitoring and auditing, conducting trend analysis, reviewing metrics, having a robust corrective and preventative action (CAPA) process, and ensuring continual process improvements.

The Quality Management System (QMS) is that part of our overall business system which implements our Quality Policy and satisfies both internal and external quality system requirements. The QMS includes the policies, procedures, organizational structure, requirements and responsibilities for achieving our quality policy.

The Viedoc Technologies QMS is based on the Clinical QMS Conceptual Framework proposed by the Transcelerate project, see the figure below:

Figure 1 Foundations and elements of a clinical QMS conceptual framework.

[1] TransCelerate BioPharma's mission is to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines. Through partnerships with Health Authorities and other industry stakeholders, the Quality Management System (QMS) Initiative aims to explore ways to improve quality across the industry. See the transcelerate website for more information - http://www.transceleratebiopharmainc.com/

2 FOUNDATIONS FOR THE QUALITY MANAGEMENT SYSTEM

The foundations for the Clinical QMS at Viedoc Technologies are:

2.1 The Context

The first foundation is a clear understanding of both the internal and external context within which Viedoc Technologies operates so that the QMS can be properly applied:

2.1.1 Internal Context

Viedoc Technologies is a software vendor to the Clinical Research sector and are bound to fulfil all regulatory requirements for software used in that sector, e.g. ICH GCP. This includes regulatory requirements and guidelines in all countries where Viedoc Technologies products are used.

2.1.2 External Context

Pharmaceutical companies, Medical Device companies, CROs and Academic institutions are all important customers for Viedoc Technologies. Viedoc Technologies must have a clear understanding of their expectations for quality.

2.2 Leadership Commitment to Quality

Viedoc Technologies management shall be committed to quality and the actions important to establishing and maintaining the company culture that supports this Quality Policy. The management serve as visible quality advocates; assure adequately trained staff is available to support all functions with a role in ensuring clinical quality; and reward proactive mitigation of risks to quality. Leaders shall promote the importance of a collaborative approach to quality within Viedoc Technologies, as well as the role of each employee in ensuring quality objectives are met.

2.3 Organisational Commitment to Quality

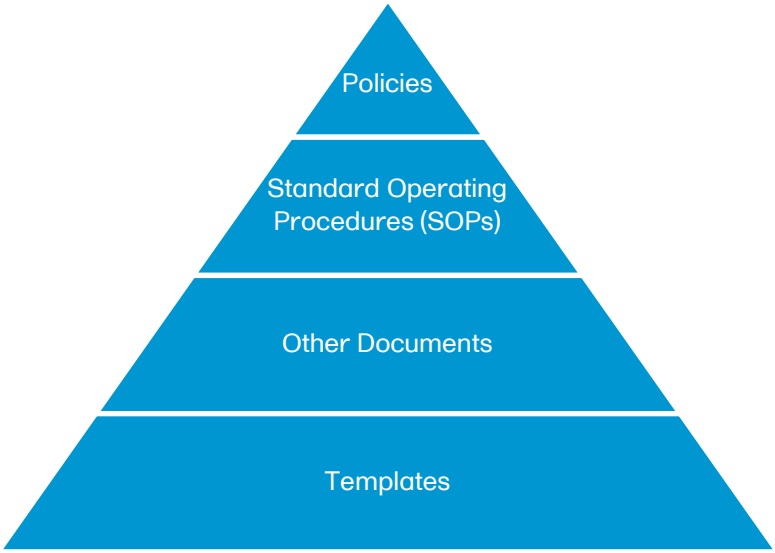
Every employee at Viedoc Technologies takes individual ownership for quality in their role and is empowered to drive quality in their work.

2.4 Continual Improvement

Continual evaluation and improvement of the framework ensuring that the framework will be responsive to change and able to meet evolving customer requirements for clinical quality.

3 ELEMENTS OF THE QUALITY MANAGEMENT SYSTEM

The elements of the Clinical QMS at Viedoc Technologies are:



Company policies have been defined at the overall company level, including this Quality Policy. These are the overarching rules and directions which the Viedoc Technologies QMS is based on.

3.1 Processes

Company processes have been defined at the overall company level and the company process groups are shown in the Company Process Map[1].

Each process group contains the company processes used for the services and functions defined within that group. All departments within Viedoc Technologies are responsible for identifying and developing Standard Operating Procedures (SOPs) within their area of responsibility. Procedural documentation should be created or modified only as necessary to address customer requirements and risks to quality objectives. For any new or revised procedural document, the organisation should consider the burden of implementation and sustaining the process relative to the risk or requirement being addressed by the procedure.

Each department shall identify the appropriate level and detail of procedural documentation needed to support clinical quality. Procedural documents should be clear and concise, such that individuals can

readily identify their roles and associated responsibilities and the context of their roles within the broader process as well as conduct their activities consistently. Training on procedural documents should be similarly focused and streamlined.

A separate SOP on the development and release of SOPs describes these actions in more detail. All SOPs are stored in the /SOP area in the electronic SOP system used at Viedoc Technologies.

The departments are responsible for all other quality system documents as well. These include templates (stored in the /Templates area in the electronic SOP system) and other documents (stored in the /Other Documents area). Other documents contain information about the company that is not expressed in terms of procedures or templates, and include (but are not limited to):

- Guidelines
- Plans
- Organisation Charts
- Strategy Documents
- IT Security Reports
- IT Infrastructure Diagrams
- The Role Description and Training Matrix
- Viedoc Compliance to Regulatory Expectations

3.1.1 Electronic Signatures

Electronic signatures are applied to all documents within the quality system. These signatures require username and password for the initial sign-in to the system and subsequent signings require the password to be re-entered, and are 21 CFR part 11 compliant. The audit trail linked to each document captures the name, date and time, and reason for signature.

The use of 21 CFR part 11 compliant electronic signatures also apply to other documents kept in SharePoint, including (but are not limited to):

- Viedoc release documentation
- Documentation related to Viedoc study build projects where applicable, excluding contracts
- Quality Assurance documentation such as annual Quality Plan, Audit Plan, Quality Report, and audit certificates
- SOP deviation requests

3.2 Resources, Roles and Responsibilities

Viedoc Technologies shall prospectively evaluate the required resources and skillsets for sustaining its clinical quality framework. The Viedoc Technologies management shall ensure that there is clarity in roles, responsibilities, and accountability for quality at all levels throughout the organisation, including with its partners.

A separate Roles, Responsibilities and Training matrix describes these aspects in more detail.

3.3 Partnering

Viedoc Technologies shall prospectively consider the needs, expectations, and limitations of all parties involved in a partnership as well as the risks posed by the activities to be carried out in such partnerships. A common understanding should be established among all parties regarding their specific role in the overall quality of the partnered activities and how oversight of quality will be maintained. The level of oversight of partnered activities should be commensurate with the risks of the activities. The parties should develop and maintain a prospective plan for preventing and/or mitigating key risks, addressing known limitations, providing appropriate oversight, and ensuring a robust communication strategy regarding quality, including escalation where necessary.

A number of SOPs and other documents exist that address the different aspects of partnering.

3.4 Risk Management

Viedoc Technologies shall identify, evaluate, and appropriately address risks to achieving its quality objectives. The risk management procedures are defined in "COMSOP17 Risk Assessment and Risk Treatment Methodology". Risk management is performed on a company level as part of the annual ISMS activities.

Risk management of risks that require continuous attention, such as high-level information security risks of being a software development company with a cloud service offering, is integrated in our processes, either by promotion of continuous risk awareness, identification or mitigation:

- The Business Continuity Plan (BCP) describing anticipated business interruption scenarios and their mitigation. The annual testing of the BCP contribute to identifying new risks to be mitigated.
- As part of the Viedoc Continuity Qualification SOP, vulnerability scans of the development and production environments of Viedoc are performed twice a month, to identify security risks in the Viedoc product. Security meetings are held monthly to risk assess new security updates.
- As part of the Secure Development Policy, penetration testing performed at least annually to identify security risks in the Viedoc product.
- The Viedoc Disaster Recovery Plan (DRP) describing anticipated interruptions of service and their mitigation. The annual testing of the DRP contribute to identifying new risks to be mitigated.
- The risk assessment as part of the refinement of Viedoc requirements during the development process, described in the development SOPs.
- The validation of Viedoc for regulatory compliance in a risk-based manner, outlined in the Viedoc Regulatory Compliance document.
- A risk assessment documenting internal audits and audits of suppliers of GxP services required during the year as part of the Audit Plan for that year. In general supplier review as part of the Supplier Management SOP performed by supplier owners.
- Monthly access review by system owners, as defined in the Access Management SOP.

3.5 Issue Management

Viedoc Technologies has an efficient and sustainable framework for identifying and managing quality issues. The framework supports root cause assessment and corrective and preventive actions commensurate with the risk posed by the issue. Effectiveness of corrective/preventive actions and any mitigation should be measured where warranted. Some quality issues may require expedited action by and/or notification to relevant stakeholders.

A separate SOP describes the CAPA tool support and issue management at Viedoc Technologies.

3.6 Knowledge Management

Viedoc Technologies encourages sharing and transfer of knowledge in real-time to promote consistency and to facilitate sustained development and success of the organization.

3.7 Documentation Supporting Achievement of Quality

The level of documentation for any clinical development–related process should be commensurate with the risks of the activity and the significance of the activity to achieving quality objectives and meeting customer requirements.

All Viedoc Technologies QMS documents are made available to staff using QS (Quality System), the Viedoc Technologies proprietary eSOP solution available via the Viedoc Technologies portal PT (Project Terminal).

3.8 Measuring Quality

Viedoc Technologies maintains ongoing surveillance of data, metrics, and other information across clinical activities and processes to proactively verify that quality objectives are consistently met and to identify any trends or issues requiring follow-up. This evaluation is used to determine whether proactively defined risk controls are effective and efficient and if new or emerging risks to quality merit attention.

Metrics are published in the annual Quality Report.

3.9 Management Review

The Quality Manager reports to the Viedoc Technologies management team periodically, presenting the quality measured and issues that require management attention.

3.9.1 Quality Plan

An annual quality plan will be drawn up, describing quality goals, KPIs, and activities for the year. The quality plan is approved by the Quality Manager and the CEO. Further details are outlined in the Quality Manual [2].

3.9.2 Audit Plan

An annual audit plan will be drawn up, describing which internal and supplier audits shall be held during the year. The audit plan is approved by the Quality Manager and the CEO. Further details are outlined in the Quality Manual [2].

3.9.3 Quality Report

At the beginning of each year a report shall be written summarising the quality activities performed during the previous year. The quality report is approved by the Quality Manager and the CEO. Further details are outlined in the Quality Manual [2].

3.9.4 Escalation of Issues

If a quality issue remains unaddressed despite reminders of required action by the Quality Manager, then the issue will be escalated to the Viedoc Technologies Management Team. If a conflict of interest arises then it is the responsibility of the Management Team to mediate.

3.10 Archival

All documents are archived electronically in SharePoint. This includes electronically scanned copies of paper original documents (the scanning procedure is described in a separate SOP).

Some customers still insist on paper original contracts, the originals of these are stored at the relevant local office.

4 REFERENCES

[1] COMSOP24 Company Process Map

[2] QSSOP18 Quality Manual