

### Understanding Documented Information in Quality Management Systems

In a quality management system, documented information refers to any information that must be **controlled and maintained**. This includes:

- **Maintained information:** e.g. procedures, policies, and manuals that evolve over time
- **Retained information:** e.g. records that provide evidence of activities performed, such as meeting minutes, research data, methodologies, and findings

### Why Is Documented Information Important?

There are four key reasons documented information is essential:

1. **Ensures consistent communication** across the organisation
2. **Provides evidence** that processes meet requirements
3. **Preserves knowledge**, even as staff change roles or leave
4. **Demonstrates planning and control**, especially for certification or regulatory purposes

Documentation ensures reproducibility, safeguards data integrity, and supports future discoveries. Good documentation also prevents redundant work, reduces errors, and maximises the long-term value of research.

### How Much Documentation Do You Need?

The answer: **It depends**. Documentation requirements vary based on:

- Organisational size
- Process complexity
- Risk levels
- Staff competence

**Example:** A small materials testing lab may need only 20 core procedures, while a large clinical lab or medical device manufacturing organisation may require over 100. ISO 9001 promotes a **risk-based approach**: more documentation for high-risk processes, less for low-risk ones.

### Document Control Properties

When creating or updating documents, ensure they include:

- Clear titles and descriptions
- Author names and version numbers
- Document numbers and approval dates

**Example:** At SmartBio, the code SMB-CHEM-001 indicates their first SOP in the Chemistry department. The version number appears in the footer so users always know they're referencing the latest version.

### Controlling Documented Information

Effective document control includes:

1. Review and approval before release
2. Ensuring documents are accessible where and when needed
3. Protection from unauthorised use or changes
4. Controlled distribution, storage, access, and retention

**Example:** At SmartBio, staff access secured PDFs via tablets in each areas, ensuring quick, reliable access while preventing unauthorised edits.

### Managing Document Changes

Controlling changes is critical for maintaining integrity. A strong change control process includes:

- Version control
- Clear identification of changes
- Review and approval of updates
- Retention of revision history

**Example:** SmartBio highlights document changes in yellow during reviews, includes a revision history table, and requires department head approval for updates, ensuring visibility and traceability.

### Retention and Protection

Proper safeguards prevent unauthorised changes and data loss. Your document control system should:

- Define appropriate **retention periods** (based on legal or business needs)
- Ensure **secure storage** and backup
- Outline procedures for **archival or disposal**

**Example:** Professor Smith's R&D Team, under a government grant, must retain all research records, including data, methods, and findings, for at least five years post-publication.

### Building an Effective Documentation System

Focus on **right-sizing** your documentation. Just enough to ensure clarity and control without creating unnecessary burden.

1. Start by documenting **processes** – what is done, by whom, how and why.
2. Then document **procedures** – how tasks are carried out, step-by-step.
3. Involve the people who actually perform the work as they bring practical insight.
4. Apply good practices: clear formatting, plain language, and version control.

Remember: the best documentation is **used documentation**. Prioritise **clarity**, **accessibility**, and **relevance** over volume.

### Key Takeaways

1. Documentation should support your work, not create red tape.
2. Use a **risk-based approach**. Document more where risk is higher.
3. Focus on **quality over quantity**. A few well-crafted documents are more useful than many unclear ones.
4. Ensure your documentation reflects reality and that your team works according to it.

Explore the templates and examples provided to help you get started. Think of good documentation like a great map – it guides you clearly and efficiently, without overwhelming you.