



White Paper

# How to implement a Quality Management System

This whitepaper will help you to implement a Quality Management System (QMS), based on Good Manufacturing Practice (GMP), ISO 9001 or ISO 13485 within your organisation.

## Introduction

This whitepaper is intended as a guide to implementing a Quality Management System (QMS) within your organisation. As the size, type and nature of organisations vary, this whitepaper may not cover all circumstances unique to your company. It does however detail the typical process that PharmOut consultants use when implementing a QMS at a client site.

The QMS discussed in this whitepaper is based on the ISO 9001 framework as it provides an excellent and practical QMS model. Specific Good Manufacturing Practice (GMP) requirements for a pharmaceutical organisation (ICH Q10 and/or PIC/s) can easily be integrated with this model, as can ISO 13485. PharmOut recommends careful consideration of the relevant compliance standards to ensure all requirements are included.

## Managing the change

Migrating an organisation from a pre-QMS state to one that operates with the rigors of quality and control necessary for an ISO-based QMS is not a casual task. There is a tightening of how processes are managed, and often changes in staff interactions, responsibilities and accountability. Such a change is unlikely to succeed without the dedicated support of both the executive and operational management.

The greatest resource of a quality company are its people, so strategies for managing both real and perceived change, or concerns and attitudes, should be addressed during the initial planning of the QMS.

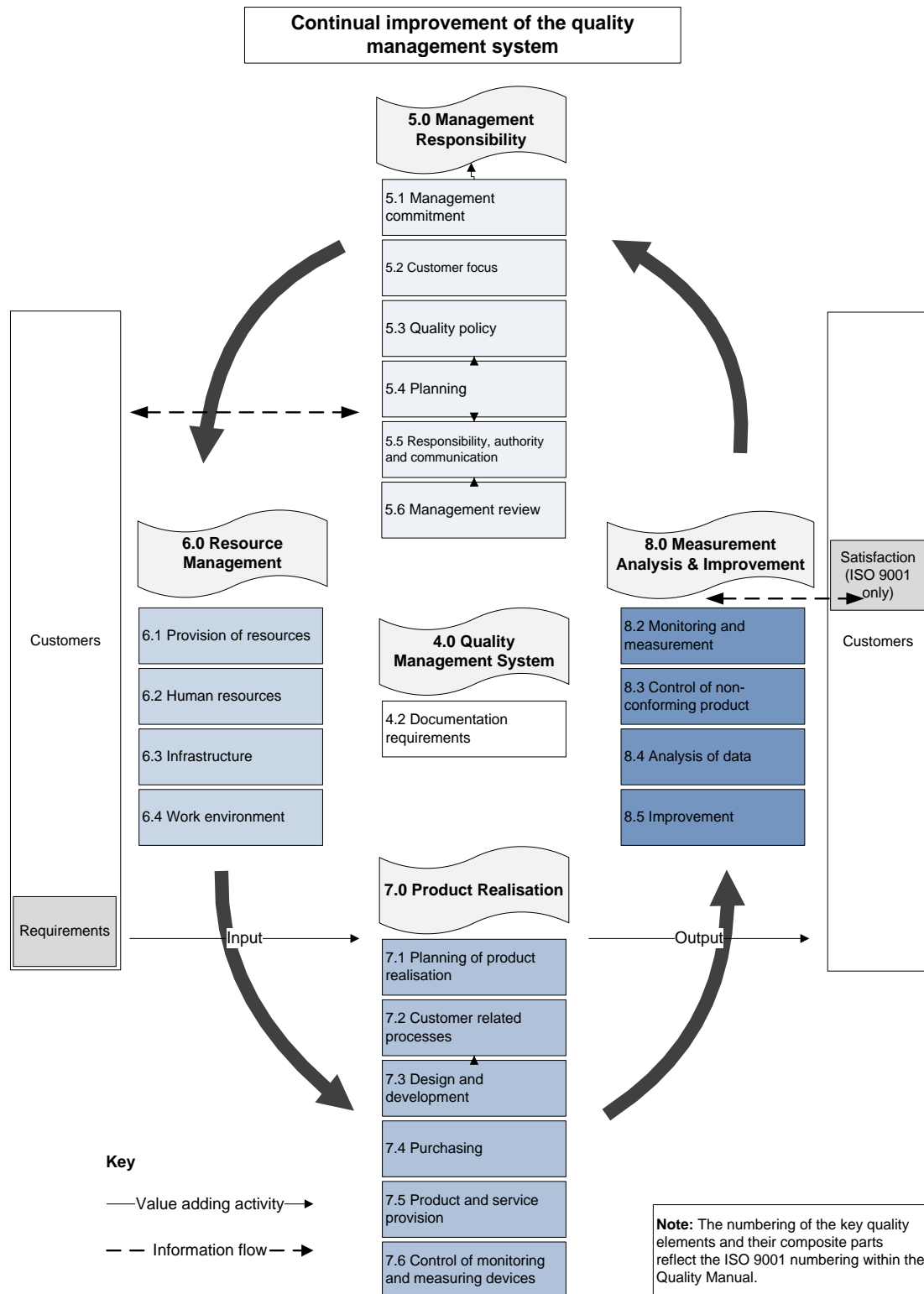
It is likely that during the first 6 to 12 months, executive management will need to positively reinforce the QMS requirements on a routine basis to ensure that staff maintain motivation and do not lapse back into old habits.

Tweaking of the QMS documents should also be expected as staff become accustomed to the requirements and begin to suggest improvements in usability. Instant business or quality improvements may be initially observed, however PharmOut's experience suggests that there is a lag phase before consistent improvements become the norm.

The benefits to the organisation of a properly functioning QMS are not just restricted to the knowledge that it complies with regulatory requirements, but that it has the discipline to manage customer requirements effectively.

## The quality management framework

The QMS is structured on the following ISO 9001 lifecycle framework. All quality, safety and customer requirements are included showing their interaction to continually improve the QMS.



## QMS requirements

A company requiring GMP and/or ISO compliance must establish, document, implement and maintain a QMS, as well as maintain its effectiveness in accordance with the required compliance standard.

A QMS requires:

- documented statements of a quality policy and quality objectives
- a Quality Manual that includes:
  - the scope of the QMS and justification for exclusions
  - documented procedures for the QMS or reference to them
  - a description of the interactions between the processes of the QMS
- documented procedures required by the compliance standard (if not located within the Quality Manual)
- documents needed by the company to ensure effective planning, operation and control of its processes
- records required by the compliance standard such as evidence of conformity to requirements and the effective operation of the QMS.

## Defining 'controlled'

Documents should detail QMS processes to ensure that they meet the compliance standard.

Using a documented procedure ensures that:

- all staff perform the same duty in the same way, every time
- all data is recorded in a similar manner
- new staff are trained to a consistent standard.

Records, including monitoring data, batch records, audit findings, labels, QC testing results, non-conformance reports, corrective actions, etc. are evidence that the QMS is being used and that processes are effective.

Both documents and records should be controlled, typically by the Quality Assurance (QA) department.

## **Controlled documents**

Documents within the QMS must be controlled so that only the current version is available to staff while performing their duties. Procedures must be in place to reflect the day-to-day management of all controlled documents.

Documents must have the following key elements to be compliant:

- a unique identifier, typically a letter code for the type of document (for example, SOP, WI, FRM, LST) and a sequential number.
- version control where each update to the document must result in an incremental increase in the version (revision, edition etc.) number
- a change history that summarises the changes made to a document each time it is updated
- signatures from the preparer and authoriser (or approver) of the document. A verifier signature is also usually required to confirm that the contents of the document is accurate, whereas the authoriser gives general approval for the document and confirms that compliance requirements are met
- the date of revision, if not updated before a specified review period.

## **Controlled records**

Records should be controlled and managed by assigning unique identifiers to individual record types. This ensures that they are traceable and retrievable. Appropriate systems must be in place and documented to manage records.

## QMS controlled document hierarchy

Controlled documents are typically organised and written according to a hierarchy.

Document Type	Description
Quality Manual	<p>A high level document that provides policy on the QMS. It details:</p> <ul style="list-style-type: none"><li>▪ QMS requirements</li><li>▪ management responsibilities</li><li>▪ management of resources for all aspects of the company</li><li>▪ how manufacture will be designed, validated and conducted</li><li>▪ customer-related processes</li><li>▪ Quality Assurance processes.</li></ul>
Policies	<p>A high level document that details overall business decisions or strategy. Policies are usually shorter documents without detailed description. They describe why something is done or high level rules required for all staff.</p> <p>It is acceptable to document policy-type material in either the Quality Manual or a procedure if preferred.</p>
Procedures	<p>Details all procedures required by the company to plan, operate and control its product and processes.</p> <p>Smaller procedures or simpler QMS may prefer to incorporate some procedures into the Quality Manual or to combine multiple, related procedures (as appropriate).</p>
Work instructions	<p>Details all instructions required to perform a section of a procedure.</p>
Lists	<p>Used to list information as required. Lists can also be incorporated into the back of a procedure as additional information (Appendix, Attachments etc).</p>
Forms	<p>Captures records for all data/information required to support or confirm processes.</p> <p>You may prefer to capture forms either as separate controlled documents and/or within the appropriate procedure.</p> <p>Note: Multiple page forms at the end of a procedure must ensure that form page numbering is separate to the procedure page numbering.</p>

Additional controlled document types may also be used at the discretion of the company depending on requirements or preferences. These may include:

- manuals
- training assessments (or other training documents)
- engineering drawings or plans
- logbooks
- templates.

## Where do I start?

The following sections outline a general approach for installing a QMS. You may also use the [QMS Preparation Checklist](#) at the end of this whitepaper to ensure that the documentation requirements have been met.

### 1. Generate templates for the controlled documents

Templates should be written for all the controlling document types intended to be used. All templates should have consistent styles and formats so that the documents are easy to navigate and to read.

Each template must meet controlled document requirements (unique identifier, version control etc). Procedures and instructions should have Purpose, Scope and Responsibilities sections (or equivalent).

A company logo can be included with the document header details if required. This is optional depending on preference or concerns regarding logo size, colour, file size or whether the documents will be primarily used online or hardcopy.

**Important:** Templates can be generated at any time before starting to write the QMS documents. You may choose to map the company processes first to better understand what types of controlled templates will be required.

### 2. Identify current procedures

Most companies already have written policies and/or procedures of some kind. However, these may be incomplete, lacking specific detail, out of date, or not integrated with other business processes.

Make a list of all these documents, including procedures, work instructions, forms and lists and include their status (such as current, out of date, inaccurate etc).

There may be some areas of the business which you decide are out of scope for the QMS, such as finance, billing or business strategy documents. Areas deemed out of scope must not have an impact on product quality or safety as this is controlled by the QMS. However, be careful when assigning documents as out of scope because you want to avoid creating two document systems.

Do not include out of scope processes in any further drafting of the QMS and ensure that these areas are listed in the exclusions in the Quality Manual.

### 3. Map your processes

Map the processes used to manage the quality framework, including their sequence and interaction with each other. Mapping typically looks like a flow chart. Ensure that all stakeholders are included in this process; consider running a brainstorming session with multidisciplinary team members (recommended).

Highlight gaps where documents are missing or where a process needs to be updated to meet an aspect of the quality standard.

Determine where changes may be required. For example, you may need to develop a procedure for controlling non-conforming product or monitoring customer satisfaction or performing management reviews.

### 4. Map the QMS structure and your documents

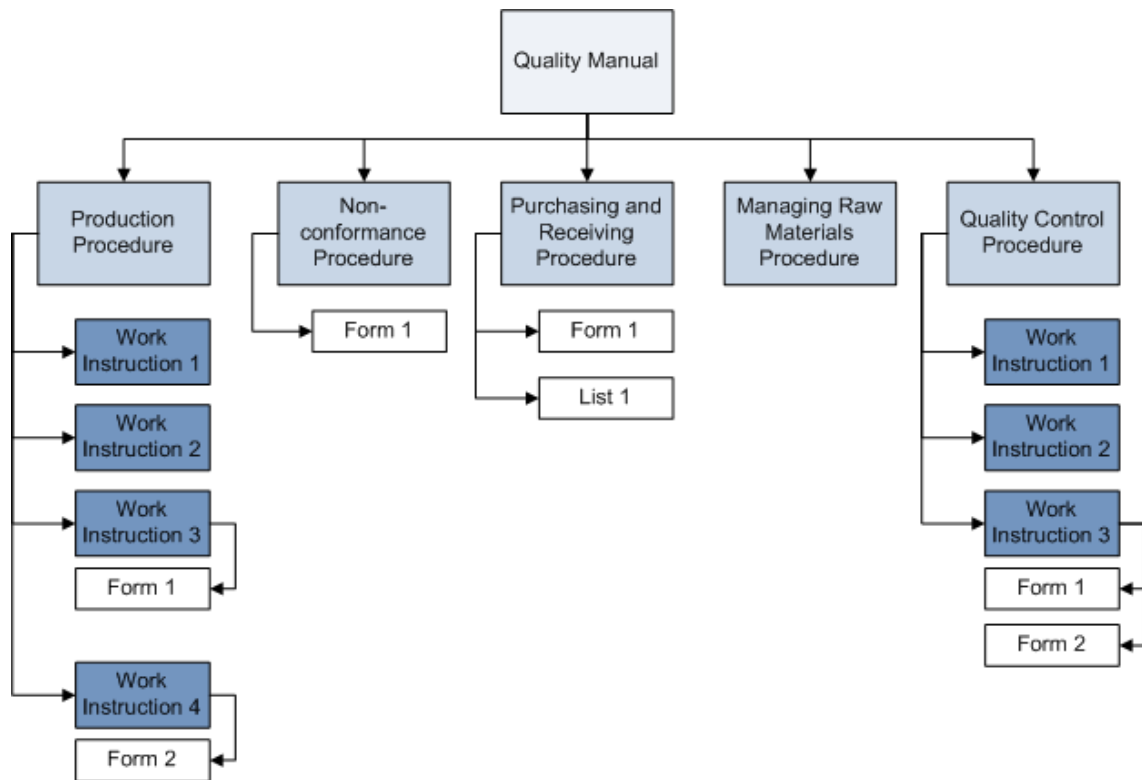
Organise the information types that are represented on the process map.

Document Type	Information Type Requirements
Procedures	Make a list of all the procedural information from the process map. A procedure is usually a series of stages performed in order over time often by different people (who, what, when, and sometime why). Define the top level steps within each procedure from the process map; these will form the main headings of each procedure.
Work instructions	Define any information that belongs in a work instruction, where detailed instructions are required for a single task (describing how something is done). Work instructions usually hang off a parent procedure and include specific details for a single stage of the procedure. Break this information down into a series of sections (if not already in the process map); these will form the main headings of each work instruction.  There may be multiple work instructions for a single procedure. As a general guide, where the instructions are less than a page or comprise only one section, then consider placing this information in the procedure instead of having a work instruction.
Forms	Once the procedures and work instructions are mapped, make a list of all forms and logs that will be needed to support the procedures and work instructions. Note the type of data required for each form (if known).  Forms are usually referenced from the controlled document that requires their use (Quality Manual, procedure, work instruction).
Lists	Make a list of all lists that will be required. Determine whether the information is dynamic or static and how regularly it will need to be updated. Consider generating a register or spreadsheet for capturing dynamic lists (controlled record) instead of having to formally issue a new version of a controlled list each time a change is required.
Quality Manual	Refer to the relevant quality standard for details for section requirements.



It is very helpful to map the controlled documents in their hierarchy, in a similar fashion to an organisation chart. Assign document numbering; this can be based on the hierarchy so that work instructions, forms and list numbering reflects the parent procedure numbering. Alternate document numbering conventions are also acceptable.

Note: Document names in the following figure are not intended to be document examples nor represent the total number of controlled documents required.



## 5. Draft the documents

Draft all the controlled documents according to the document maps.

Consider the primary audience for the document and use language and vocabulary that are both appropriate for the company and for the users. For example, if the company has a significant number of bilingual staff in one area, then write documents that they will need to use in a manner that reflects their level of literacy.

A plain English style is always best. As a general rule:

- if you stumble over a sentence when reading it aloud, then it is probably too complicated or poorly worded.
- ensure that the size/type of fonts and page layouts are appropriate for how the documents will be predominantly used (electronic or hardcopy).
- avoid using colours or backgrounds that can make it difficult for staff with vision or reading difficulties.
- consider what type of writing style is appropriate. For example, work instructions lend themselves to very structured, numbered steps whereas procedures may be more appropriate in a paragraph style.
- don't mix information types. Keep theory, such as technical background etc., procedural steps and rules/warnings separate. Mixing information types can create confusion or misunderstanding, and lead to a task being performed incorrectly.

## **6. Manage electronic drafts**

PharmOut suggests saving your files with a document identifier in the file name. This ensures that versions and review changes can be tracked and managed.

Possible identifiers may include:

- tracking the draft version - QM001 Quality Manual\_v01a, b, c etc.
- tracking the date of draft review (1<sup>st</sup> Jan 2010) – QM001 Quality Manual\_010110
- tracking a reviewer – QM001 Quality Manual\_JBloggs
- a combination of the above.

It is important to maintain consistency in the document control mechanism used during the drafting process.

Make a list (spreadsheet) of all documents with the document number, title, version number, and status of review. This document can also then easily be amended to form the Master Document List when the QMS is ready to go-live.

## **7. Review the documents**

Ensure that all documents are reviewed by subject matter experts (SMEs) from all areas that are affected by the scope of the document. Issuing a controlled document that affects an area where staff have not had the opportunity to review may cause unnecessary friction, reduce compliance and increase the risk of deviation.

## **8. Issue the documents**

Prepare hard copies of all documents and obtain the appropriate approval as dictated by the compliance standard. Issued original hardcopies (and usually MS Word versions) must be filed in a secure location.

Once the QMS documents are approved and are ready to be implemented (issued), save the electronic files according to your document control procedure using the document revision number in the file name. Publish the controlled documents (hardcopy or pdf) according to the document control procedure so that staff can be trained and use the documents.

## **Additional PharmOut QMS support**

PharmOut offers two options to support you in implementing a QMS.

### **Off the shelf QMS document packages**

These standard-specific packages have been designed for use with ISO9001, ISO13485 or GMP and may be purchased and then adapted by you for your specific company requirements.

These packages include:

- a Quality Manual, all procedures, work instructions and forms, including instructional text that defines the requirements of the quality elements (approx. 30 documents)
- MS Word templates for all procedures, work instructions and forms
- an information guide to help with specific document and drafting requirements.

Two hours free phone or email support is included within 12 months of the purchase date of the QMS document packages.

### **Tailored QMS implementation**

PharmOut has expert quality management system consultants who can implement a QMS in your company or organisation. This option is a fast and effective way to ensure your compliance with regulatory requirements.

Additional support is also available upon request. Please contact us using the contact details in the company bio section at the end of this whitepaper.

## QMS Preparation Checklist

The following checklist may be used during the preparation of QMS documents.

Step	Description	Completed? (* / ✓)
1	Generate templates for the controlled documents.	
2	Identify your company's key processes, existing procedures, and management and control systems needed for the QMS.	
3	Map the key processes and procedures so that their sequence and interaction is clear. Highlight any area that is missing a document that is required as part of the QMS.	
4	Map the document hierarchy structure and high level document contents for all controlled documents.	
5	Draft the controlled documents based on the document maps.	
6	Manage electronic drafts and draft a Master Document List.	
7	Review the content of all QMS documents with subject matter experts (SMEs).	
8	Finalise the QMS documents for approval and issuing.	
9	Go-live! Train all staff on appropriate documents with respect to their training matrix.	

## About PharmOut

PharmOut is a professional consultancy offering product registration, engineering, validation and regulatory compliance solutions to the Medical Device, Pharmaceutical and Veterinary drug manufacturing industry from concept development, feasibility studies, scale up, engineering design, project management to the final product regulatory approval and GMP compliance certification.

## How PharmOut can help

We offer the following range of services:

### ISO, GMP & APVMA compliance consulting

Policies, SOP, and Forms. We can also help you obtain approval from the following international regulatory authorities (APVMA, FDA, MHRA, and TGA).

### Engineering

Our experienced industry engineers can develop concept and detailed designs, around your production process ensuring full GMP compliance by careful project management and verification (validation) to ensure that the exacting GEP standards are met.

### GMP Compliance

We can visit your site before or after a FDA or TGA GMP audit to assess and improve your quality management systems and/or validation documentation, business processes and physical operations.

### Quality Management Systems

We can help you create a Quality Management System from scratch, or bring your current system into compliance.

### Technical Document Writing

We can help you write procedures and work instructions that your staff will actually use and can follow.

### ISO & GMP consulting

We can provide practical recommendations and advice on the implementation of ISO 9001 for Pharmaceuticals or ISO 13485 for Medical Device Quality Management Systems, Policies, SOP, and Forms. We can also help you obtain approval from the following international regulatory authorities (FDA, MHRA, and TGA). This includes Part 11 and Annex 11 compliance to FDA and TGA requirements.

### Training

We run on-site or in-the-city classroom training on GLP, GMP compliance, validation and documentation writing. We also develop e-learning modules on topics such as Good Record Keeping that you can use for your ongoing training needs.

### Validation

Our validation engineers / specialists can write validation plans, specifications and qualification protocols for i.e. cleaning validation, equipment validation, computers systems validation, analytical method validation or process validation.

