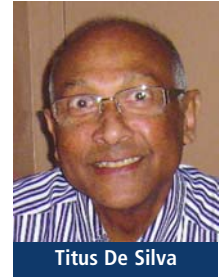


# A Quality Management System For Pharmacy Practice

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## Summary

This paper:

- outlines the benefits of a good Quality Management System (QMS)
- summarises key quality assurance programmes, codes of practice and standards that are available
- outlines quality initiatives within health services in the UK
- explains the pre-requisites of an effective QMS
- categorises the processes involved.

## Introduction

The military and nuclear industries have been implementing quality systems for many years and, in the 1970s, similar systems were implemented in manufacturing organisations. Quality system standards are essential tools for implementing a quality management programme.

Pharmacies are responsible for delivering numerous products and services, enhancing patient safety and ensuring that pharmacy practices are both efficient and effective. In addition, a focus on continual improvement is required to identify and manage all risks in the practice setting. A quality management system (QMS) assures the effective management of quality in pharmacy practice, adds value for the pharmacy and its patients and enables pharmacists to meet the ever increasing demands for better services.

Four major components are involved in the delivery of products and services in

pharmacies: regulatory requirements, code of ethics, internal procedures and standard operating procedures (SOPs). While these components are essential for effective and efficient pharmacy practices, they do not ensure quality improvement. A well designed quality management system (QMS) enhances customer satisfaction and ensures quality improvement in all pharmacy activities. It can easily incorporate existing policies and procedures.

This paper forms a basis for reviewing a QMS and developing a structured and consistent approach for conducting pharmacy activities to reduce variability and improve healthcare outcomes.

## Benefits of implementing a QMS

Organisations that have implemented an efficient and effective QMS have realised several benefits.<sup>1</sup> The top five benefits are improvements in:

- organisational effectiveness. A QMS enables the organisation to establish goals for its critical operations and provides a means for measuring the performance in each area.
- customer satisfaction. A QMS encourages customer feedback from multiple sources and the information is used to improve the delivery of products and services.
- compliance. Pharmacies have to comply with regulatory requirements as well as internal and external standards. These can be integrated into the functional QMS and compliance can then be monitored through management reviews, audits and corrective and preventive actions.

- organisational culture. A QMS facilitates the development of a quality culture and creates an environment and a sense of belonging where the staff can take pride in their work.
- Documentation. A QMS facilitates the management of documentation so that relevant documents are made available to those who need them.

Other benefits include effective risk management, continuous improvement of processes through regular audits, enhanced staff morale through improved management efficiencies, reduction of waste and better utilisation of resources.

## Quality assurance programmes, codes of practice and standards

There are no international standards designed specifically to meet the needs of pharmacy practice. Various countries have developed their own programmes, codes of practice and standards. Some of these are:

- General Pharmaceutical Council (GPhC) standards for registered pharmacies. These regulations are applicable to registered pharmacies in the UK and 'are designed to strengthen the regulation of pharmacies and improve the quality of pharmacy practice'.<sup>2</sup>
- Code of medicines, ethics and practice. Issued by the Royal Pharmaceutical Society (RPS) of Great Britain, this code of practice is a guidance document to 'help pharmacists practice confidently and professionally'.<sup>3</sup>



- Quality, Innovation, Productivity and Prevention (QIPP) Programme: This programme has been developed by the Department of Health in England to promote quality improvements in health service care and achieve efficiency savings.<sup>4</sup>
- Chartered Quality Institute (CQI) Small Business Standard. This has been developed by quality professionals with CQI support to provide an effective approach to the management of quality.<sup>5</sup>
- European Foundation for Quality Management (EFQM) Excellence Model.<sup>6</sup> This provides the foundation to achieve sustainable success in any organisation.
- Professional practice standards. Issued by the Pharmaceutical Society of Australia. Version 4 of the professional practice standards is aimed at achieving and measuring high quality, reliable healthcare services and products in Australia.<sup>7</sup>
- Good Pharmacy Practice standards.<sup>8</sup> These standards have been developed jointly by the International

Pharmaceutical Federation (FIP) and the World Health Organisation (WHO) and are designed to contribute to health improvement and help patients with health problems to make the best use of the medicines.

## Quality initiatives in health services in the UK

During the last few years numerous quality initiatives have been introduced in the health service in the UK. Three programmes have made a major impact on healthcare of patients. They are briefly described here.

### QIPP programme

The QIPP programme designed by the Department of Health in England is a large scale programme involving all NHS staff, clinicians, patients and voluntary sector to transform and improve the quality of care NHS delivers. This programme was estimated to save £20 billion by 2014-15 which the NHS will invest in frontline care.<sup>9</sup> The aims of the QIPP programme are to:

- improve quality
- encourage innovation
- deliver preventive programmes
- enhance productivity.

The programme is implemented through commissioning and pathways, provider efficiency and system enablers. However, according to the Department of Health, Primary Care commissioning bodies have achieved savings of only £11.8 billion over the first two years of the programme.<sup>10</sup>

### Pharmaceutical quality assurance service

In 2008, NHS Pharmaceutical Quality Assurance Committee published a strategy to assure the quality of medicines supplied to patients while minimising the risk. The committee developed a framework of pharmaceutical quality assurance services which applied to purchasing, packaging and preparation of medicines in hospitals. These services included the development of quality assurance (QA) standards and guides, QA and quality control (QC), supply and manufacture of medicines in hospitals,

investigating, testing and monitoring activities, R&D services, staff training and advisory services.<sup>11</sup>

### Homecare Service

The RPS of Great Britain published a set of professional standards for homecare services in England in 2013.<sup>12</sup> The standards are divided into three domains: patient experience, implementation and development of safe and effective homecare services, and governance of homecare services (Table 1).

In a QMS, these ten standards cover the quality system elements as:

- vision and mission
- planning
- provision of resources
- purchasing
- communication
- quality control
- human resources
- risk management
- reviews.

In their own right they are excellent quality initiatives. However, the full potential of any quality assurance programme can only be realised when they are built into a well-managed QMS. The following describes the development of a QMS and how existing programmes

can be incorporated.

## Prerequisites of a QMS

The sustainability of a QMS depends on the organisation's environment in which it has been created. Successful businesses deliver what the customer wants, are reliable and are able to adapt to an ever-changing business environment while making a profit for the organisation. Four prerequisites facilitate the organisation to identify customers' needs and gain staff commitment: mission statement, strategic plan, management commitment and quality culture.<sup>13</sup>

### Mission statement

The mission statement defines the purpose for the existence of the organisation, its values and the customers it wishes to serve. Its creation should involve the people in the organisation and must inspire commitment, innovation and courage. The statement includes (a) the change aimed at, (b) a business statement, and (c) a value statement e.g. to lead [change aimed at] the UK homecare service [business statement] through specialist and professional services delivered within a culture of care for the community and integrity [value statement].

### Strategic planning

The focus of strategic planning is to develop strategies to manage environmental opportunities and threats effectively in relation to the organisation's strengths and weaknesses. It is a process of identifying the organisation's external and internal environments, creating a vision and a mission, establishing goals, developing strategies to meet the goals and allocating resources.

### Management commitment

Top management must demonstrate commitment to the project in order to motivate the staff and genuinely believe in the value of the project, share a positive approach to the project and commit the necessary resources.

### Creating a quality culture

Culture can be defined as norms, values, attitudes and beliefs shared by the members of the organisation.<sup>14</sup> Senior managers must create an environment where the staff can develop a sense of ownership and urgency, encourage innovation, take risks and pride in their work.

## Classification of processes

Pharmacies play an important role in the community they serve. The delivery of products and services to the customers is governed by the processes employed in the pharmacy. Processes define the way activities in the pharmacy are conducted. Business processes are interrelated structured activities which produce a specific service or a product for a particular group of customers.<sup>15</sup>

The Juran Institute<sup>16</sup> classifies processes into three categories:

### Core Processes

These are operational processes that add value and have a direct impact on the customer. For example, dispensing, medicines use reviews, blood pressure monitoring services etc.

### Support processes

Activities such as information technology, human resources etc. are support

Domain	Standards
1. Patient experience	1. Patient engagement 2. Episode of care 3. Integrated care
2. Implementation and delivery of safe effective homecare services	4. Effective use of homecare and medicines 5. Homecare medicines expertise 6. Safe use of homecare medicines 7. Supply and use of homecare medicines
3. Governance of homecare services	8. Leadership 9. Governance and financial management 10. Workforce

Table 1: Standards for homecare services

processes that provide resources for conducting the core processes.

**Management processes**

These are processes that govern the operation of the system. In the context of a quality management system they can be considered as assurance processes

that monitor not only the financial performance but also the effectiveness and efficiency of pharmacy services.

The stages involved in implementing a QMS are shown in Figure 1.

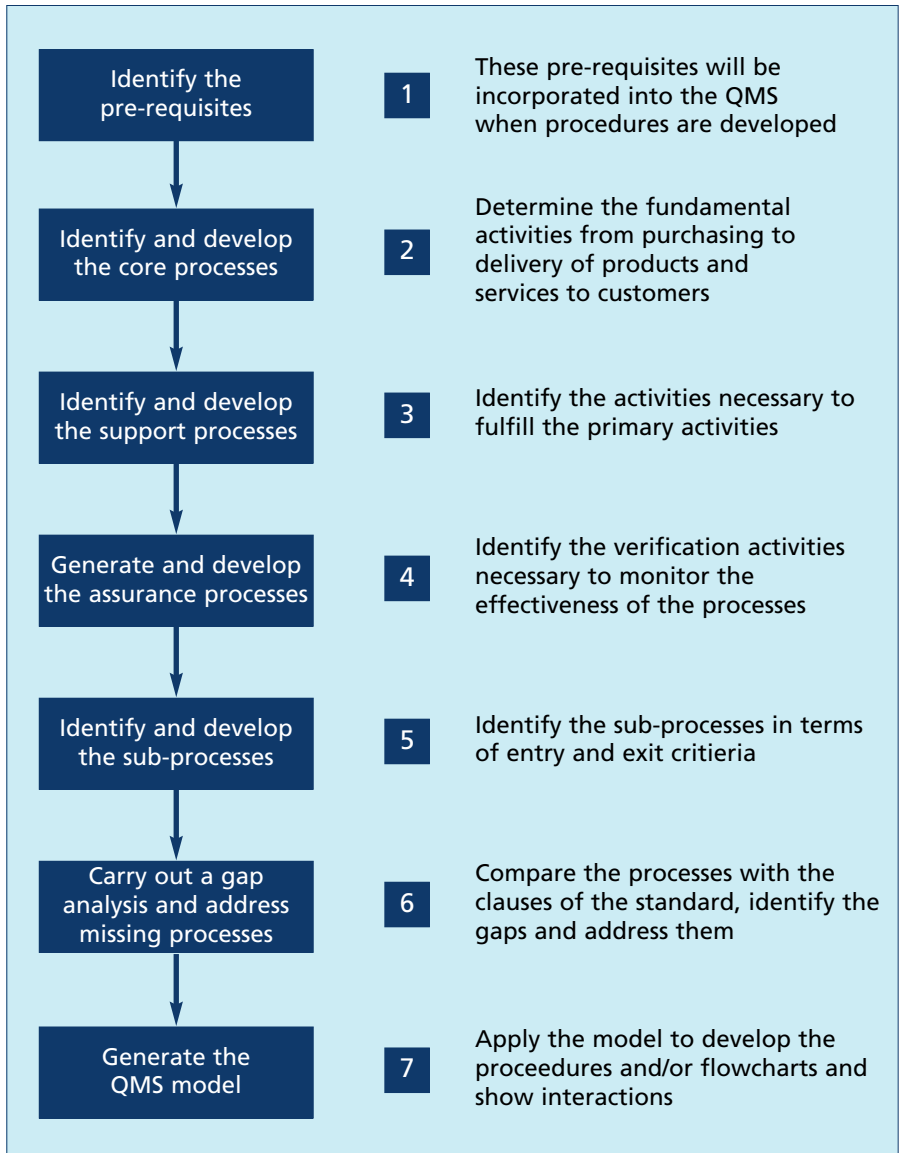


Figure 1: Process for designing a QMS

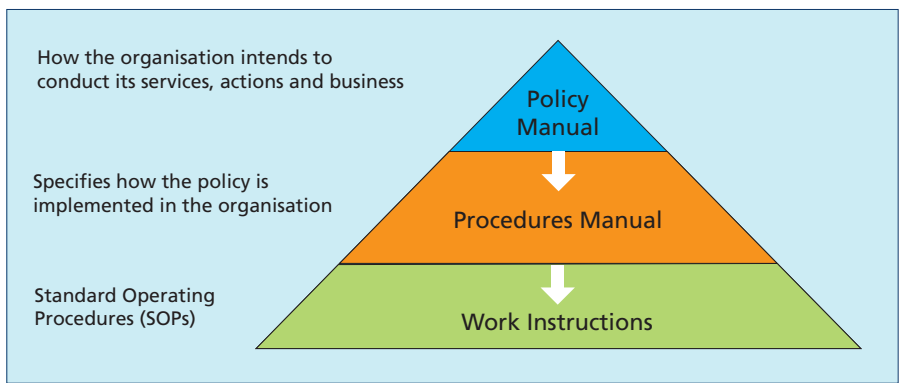


Figure 2: Hierarchy of QMS documentation

**Documentation hierarchy**

A QMS consists of a policy manual, procedures manual and work instructions, also known as standard operating procedures (SOPs). This is shown in Figure 2.

**Policies** are clear, simple statements of how the organisation intends to conduct its services, actions or business. They provide a set of guiding principles to help with decision making.

**Procedures** describe how each policy is implemented in the organisation. Each procedure outlines at least:

- (a) Purpose: The intention of the document
- (b) Scope: Defines the applicability of the procedure
- (c) Responsibility: Defines the responsibilities of people involved with the procedure
- (d) Associated documents: All reference documents related to the procedure
- (e) Resources: Materials necessary to carry out the procedure
- (f) Measures and controls: A means of measuring the effectiveness of the procedure
- (g) System description: Step by step description how the procedures are carried out.

Some organisations incorporate the policy statement in the procedure. However, it is useful to maintain a separate policy manual which can be produced at the request of a third party who intends to do business with the organisation. Policies and related procedures vary between pharmacies because they are designed to reflect the core values, approaches and commitments of a specific organisation and its culture.

**Work instructions or SOPs** are generally represented as a flowchart which might reflect a single activity or incorporate a number of activities. A flowchart for receiving prescriptions could stand on its own or be incorporated within the dispensing process. The latter option is more useful because the details



can be described during a one-to-one training session. The assessment can then be maintained in training records. Flowcharts use various shapes that represent different activities in a process. The shapes are connected by arrows or lines which show the sequence of steps. These are known as flowchart symbols.<sup>17</sup>

## Keeping it 'alive'

QMS is a dynamic entity. A QMS gathering dust in a shelf is of no use to anybody. It has to change with changing internal and external environmental conditions. New processes and procedures have to be incorporated when new pharmacy activities are undertaken. Regular internal audits and reviews will reveal deficiencies that should be promptly addressed. Thus, when the QMS has been effectively established, the management can then decide to test the effectiveness of the QMS by comparing it against an established standard.

## Small Business Standard of the Chartered Quality Institute

The small business standard (SBS) of the Chartered Quality Institute (CQI)<sup>5</sup> is an

ideal standard which includes the essential elements for developing a QMS and also serves as a platform to progress to an international standard such as the ISO 9000.<sup>18</sup>

Quality management standards are voluntary standards, but are useful tools to measure the effectiveness of a QMS. The elements of the SBS of the CQI are:

- management responsibility
- business reviews
- customer care
- staff
- work environment and processes
- suppliers
- documentation
- preventing and correcting products or service problems
- records.<sup>5,13</sup>

## Gap analysis against the SBS

A QMS offers tools that enable organisations, whether private or public, large or small to organise, manage and structure their activities to achieve internal and external benefits.

When the QMS has been fully

implemented, pharmacies can assess its effectiveness by conducting a gap analysis. This is essentially a tool to determine the procedures that need to be improved and added to complete the full management system. Gaps, if any, show the processes to be developed to comply with the SBS. When missing procedures are developed, pharmacies should consider the requirements of the standard as well as the needs of the patients and other stakeholders.

## Requirements for an effective QMS

Standards, procedures and work instructions alone do not make an effective QMS. The drivers of a properly designed QMS are the mission statement, quality objectives and strategic planning.

Senior managers must demonstrate commitment and leadership continuously and motivate the staff so that they can take pride in their work. Only then can the staff can take ownership of the QMS.

## Declaration of interests

- None

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