

Booklet – Quality Management System

Some history of quality

The Oxford dictionary defines *quality* as the degree of excellence of something¹.

Historically, from 1979 to 1987, the first concept of quality was the *quality control* which aims to *detect* with the British Standard (BS) 5756.

In 1987, *ISO (International Organization for Standardization) 9000* was first published and the second concept associated was the *quality assurance* which aims to *prevent* with ISO 9001/2/3. *ISO 9000:1994* emphasized *quality assurance* via preventive actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures.

ISO 9001:2000 replaced all three former standards of 1994 issue, *ISO 9001*, *ISO 9002* and *ISO 9003*. The 2000 version sought to make a radical change in thinking by actually placing front and centre the concept of *process management*.

In 2005, ISO 9001 is supplemented by another standard of the family: *ISO 9000:2005 "Quality management systems. Fundamentals and vocabulary"*.

How to define the Quality management system (QMS)?

A QMS can be defined as: “A set of co-ordinated activities to direct and control an organisation in order to continually improve the effectiveness and efficiency of its performance.”²

QMS Model

The QMS model could be represented as in Figure 1.



Figure 1. QMS Model

Customers define requirements as inputs, and monitoring of customer satisfaction is necessary to evaluate and validate whether customer requirements have been met.

The major clauses of the process are the resource management; the management responsibility; the product realization; and the measurement, analysis and improvement. **Resource management** include education and training regulation, personnel certification, equipment management. **Management responsibility** include especially quality policy, business planning and management review. **Product realization** includes for example customer requirement management, process control, identification and traceability. **Measurement, analysis and improvement** include customer satisfaction management, internal audit or quality improvement team.

Top 10 of QMS' benefices

There has to be some good reasons for implementing a QMS. Let review the top reasons for implementing a QMS.

QMS^{3, 4, 5}:

- Review management levels
- Improve your consistency
- Make better decisions
- Keep better control of records and documents

- Take better control of internal controls
- Improve the morale of your employees
- Increased level of efficiency
- Increased level of profits
- Improve relations between suppliers and vendors
- Improve customer satisfaction

Key of success and examples in hospital pharmacy ...

In order to implement a QMS with success it's important for all pharmacy employees to be educated and share the same view. Marti Gil et al⁶, who describe the incidents detected by the staff of a pharmacy service during the implementation of a QMS based on the ISO 9001:2008 standard, conclude that it is important to educate health staff in detecting weaknesses or failures in the system in order to perform the "Deming Continuous Improvement Cycle". Bechet et al⁷, which aim was to establish how the use of customer feedback could be enhanced within a Swiss regional hospital pharmacy, brought into focus the importance that employee knowledge and involvement are paramount to the success of a customer-focused QMS.

Some authors demonstrate the benefits of the implementation of a QMS system. For example, Recuero Calve et al, which aim was to analyse continuous quality improvement in the oncology pharmacy unit of a pharmacy service certified with a QMS based on ISO 9001:2008 standard, show that QMS is an important tool which help to improve healthcare quality, pharmacotherapeutics and patient safety⁸. Vilaboa Pedrosa C et al, who describe the process of implementing a QMS in the implementation of surgical antimicrobial prophylaxis in a tertiary general hospital, conclude that the implementation of QMS promotes proper application of surgical antimicrobial prophylaxis⁹. Finally, Cheikh et al¹⁰ who establish a QMS that includes the traceability of medical devices have been taken corrective measures in 21% of cases (definitive change of medical device), preventive in 8% of cases (compliance test before use) and palliative in 71% of cases (exchange of defective device).

It's up to you!

¹ Quality definition. Oxford dictionary. On line.
<http://www.oxforddictionaries.com/definition/english/quality>

² Department of Trade and industry. Quality management systems. On line http://www.businessballs.com/dtiresources/quality_management_systems_QMS.pdf

³ Mark1 Business Systems Limited. Top 10 Benefits of a Quality Management System. On line. <http://www.mark1systems.com/blog/quality/top-10-benefits-of-a-quality-management-system/>

⁴ Kevin F. Bright hub project management. What are the benefits of a Quality Management System? On line <http://www.brighthubpm.com/methods-strategies/104270-what-are-the-benefits-of-a-quality-management-system/>

⁵ Belt B. Quality Management System. Top 5 Reasons to Implement a Quality Management System. On line <http://qualitymanagementsystem.com/top-5-reasons-to-implement-a-quality-management-system/>

⁶ Martí Gil C, Martínez-Valdivieso L, Marcos-Pérez G, Flor García A, Moreno-Rodríguez D, Barreda Hernández D. Continuous improvement process: involvement of the staff in a pharmacy service. *Eur J Hosp Pharm* 2015;22:A205-A206 doi:10.1136/ejhpharm-2015-000639.504

⁷ Béchet C, Bonnabry P, Pichon R. Improvement of customer focus in a Swiss regional hospital pharmacy: a mixed method study. *Eur J Hosp Pharm* 2015;22:267-273 doi:10.1136/ejhpharm-2014-000571

⁸ Recuero Galve L, Martí Gil C, Martínez Valdivieso L, Sánchez Gundín J, Flor García A, Barreda Hernández D. Quality management system: Analysis and improvement in an oncology pharmacy unit. *Eur J Hosp Pharm* 2016;23:A164 doi:10.1136/ejhpharm-2016-000875.369

⁹ Vilaboa Pedrosa c, Mateos Salvador M, Gutierrez Urbon JM, Seco Vilariño C, Martín Herranz M.I. Quality management of antimicrobial prophylaxis for surgery. *Eur J Hosp Pharm* 2012;19:101-102 doi:10.1136/ejhpharm-2012-000074.44

¹⁰ Cheikh A, El Wartiti A, Enneffah W, Badsì N, Ajaja M, Al Baroudi S, Belmekki M, Bennana A, El Hassani A, Cherrah Y. The place of materiovigilance as tool of traceability in the quality management system (QMS) in hospital pharmacy. *Eur J Hosp Pharm* 2015;22:A150 doi:10.1136/ejhpharm-2015-000639.362