TECHNICAL TOOLKIT

QUALITY MANAGEMENT SYSTEMS IN NON-REGULATED AREAS

In many industries, leaders have traditionally viewed a quality management system (QMS) as an additional burden and cost on a business – 'quality' owned the system. This view is still widespread from where standards are necessary to where they are not. Often the mantra 'it is only R&D therefore quality doesn't apply' being the norm and acceptable practice. However, due to significant errors within scientific and non-scientific organisations in recent times which have reached national and international headlines, quality has become high profile. This has led to more calls for establishing quality systems where previously there was no appetite for one.

YOU HAVE BEEN ASKED TO IMPLEMENT A QMS

First, the strategy must be defined – at a high level the scope of the QMS and boundaries, what resources are available, ownership of the QMS and timescales for implantation must be determined. A clear objective should also be set. The process for designing and building the QMS must be clear and involvement and buy-in to the system from all users must be secured (Figure 1).

A QMS can be described as 'a system of standards and practices established within a company or industry to ensure consistent quality of products or services'. A great QMS should be tailored to the specific needs of an organisation and add value. It must be determined what stakeholder, user and customer requirements are. By knowing this, a QMS can be designed and built to meet the specific needs of the organisation (Figure 2).

With no specific regulatory or ISO requirement for a QMS within the organisation's industry, a review of published quality system standards from various sources should be undertaken, utilising what is applicable. The most widely known and used QMS is ISO9001 but, with no limitations, parts of other standards or regulations may give appropriate direction in designing your QMS. For laboratories, The UK Good Laboratory Practice Regulations and ISO 17025 could also be referred to. Guidance documents are also a useful source of information.

FIGURE 1. LIFE CYCLE OF A QMS, BASED ON QUALITY IN RESEARCH GUIDELINES FOR WORKING IN NON-REGULATED RESEARCH (RQA, SEPTEMBER 2014)

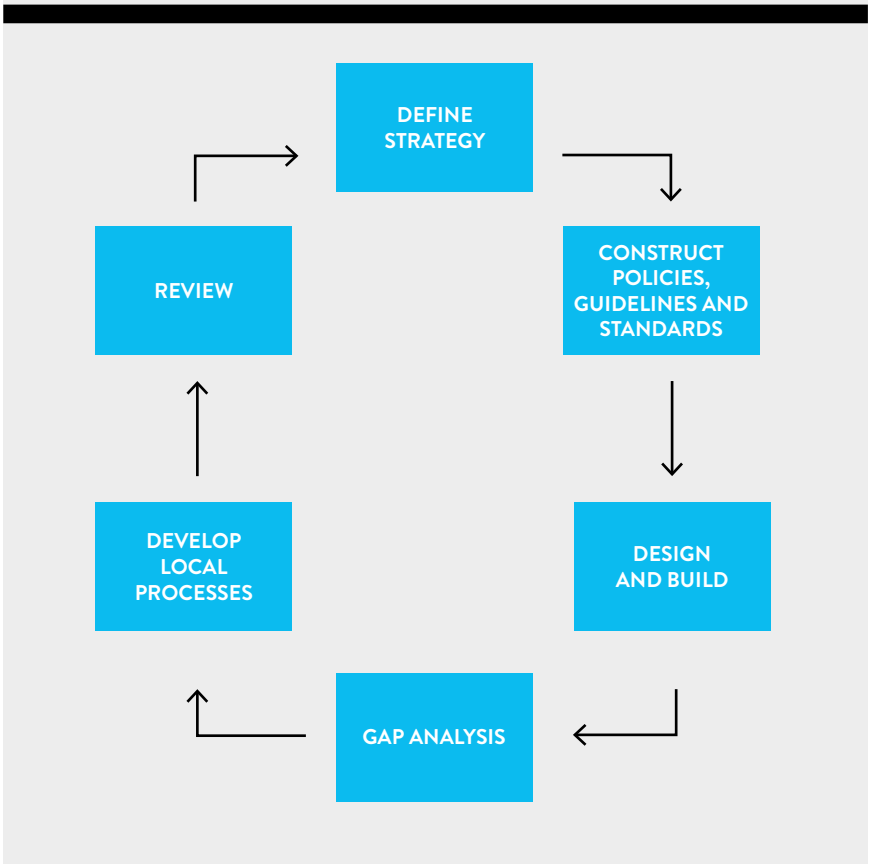


FIGURE 2. REQUIREMENTS OF A QMS AS DETERMINED BY INTERESTED PARTIES

WHAT SHOULD A QMS CONTAIN?

All quality system regulations and standards contain the same fundamental components:

- Clear ownership and responsibilities
  - Of the QMS
  - Of related processes
- Documented standard processes (the controls) – these must be controlled and available to all personnel
- Independent oversight
- Records.

In addition, for laboratories the following should also be included:

- Facilities
- Equipment including computerised systems
- Materials and reagents
- Robust assays
- Planning, performing and reporting of experiments.

As the QMS will be bespoke to the organisation, a document or a set of documents describing the QMS specifications should be available and include an outline of the above items. This can be used to reference back during the creation and during independent review of the QMS. This document or set of documents should not remain 'set in stone' and should be updated as the QMS matures or expectations change.

DESIGN

The design of the QMS should come from determining the organisation's core processes and be linked to the QMS specifications (Figure 3).

Once you know what your QMS requirements, specifications and the core processes are, a gap analysis can be performed; this analysis will also identify possible areas for improvement.

GAP ANALYSIS

For each item identified in the QMS specification, analyse your current situation, considering the following questions:

- Who has the knowledge you need?
- Who will you need to engage with?
- Is this knowledge in individuals' heads or is it documented?
- What is the best way to access this information:
  - Brainstorming
  - 1-2-1 Interviews
  - Observations
  - Other?

Once the gaps have been determined, the actions to bridge the gaps can be planned.

The gap analysis may also identify broader issues, such as varying processes with lack of control, insufficient or poor data recording practices and lack of ownership of processes. Other specific issues may also be uncovered (e.g. deficiencies with equipment maintenance and cleaning).

A tool which can be used during the gap analysis and to determine the actions required to bridge the gaps is process mapping. Process mapping can be simple input to output flow diagrams to complex multifaceted diagrams but all consist of four steps (Figure 4).

From this exercise, users should design and agree upon a standard process which can then be documented.

In recent years, failings in the overall completeness, accuracy and consistency of data over its entire life cycle (referred to as 'data integrity' issues) have hit the headlines. Data integrity should be a key focus of the QMS. Improvements in data recording can be made by agreeing a standard which is suitable and applicable for the organisation. The purpose of recording data should be emphasised, for example, to be able to reconstruct the analysis and, if necessary, for another individual to repeat the process. As a minimum, the ALCOA principles should be applied:

- Attributable – what does the data relate to? Who recorded the data and when was it recorded?
- Legible – is it readable?
- Contemporaneous – has it been recorded directly at the time of the observation?
- Original – is it a direct recording, not a transcription?
- Accurate – is the observation documented exactly as observed? ››

FIGURE 3. HIGH LEVEL PROCESS MAP OF A TYPICAL LABORATORY ORGANISATION

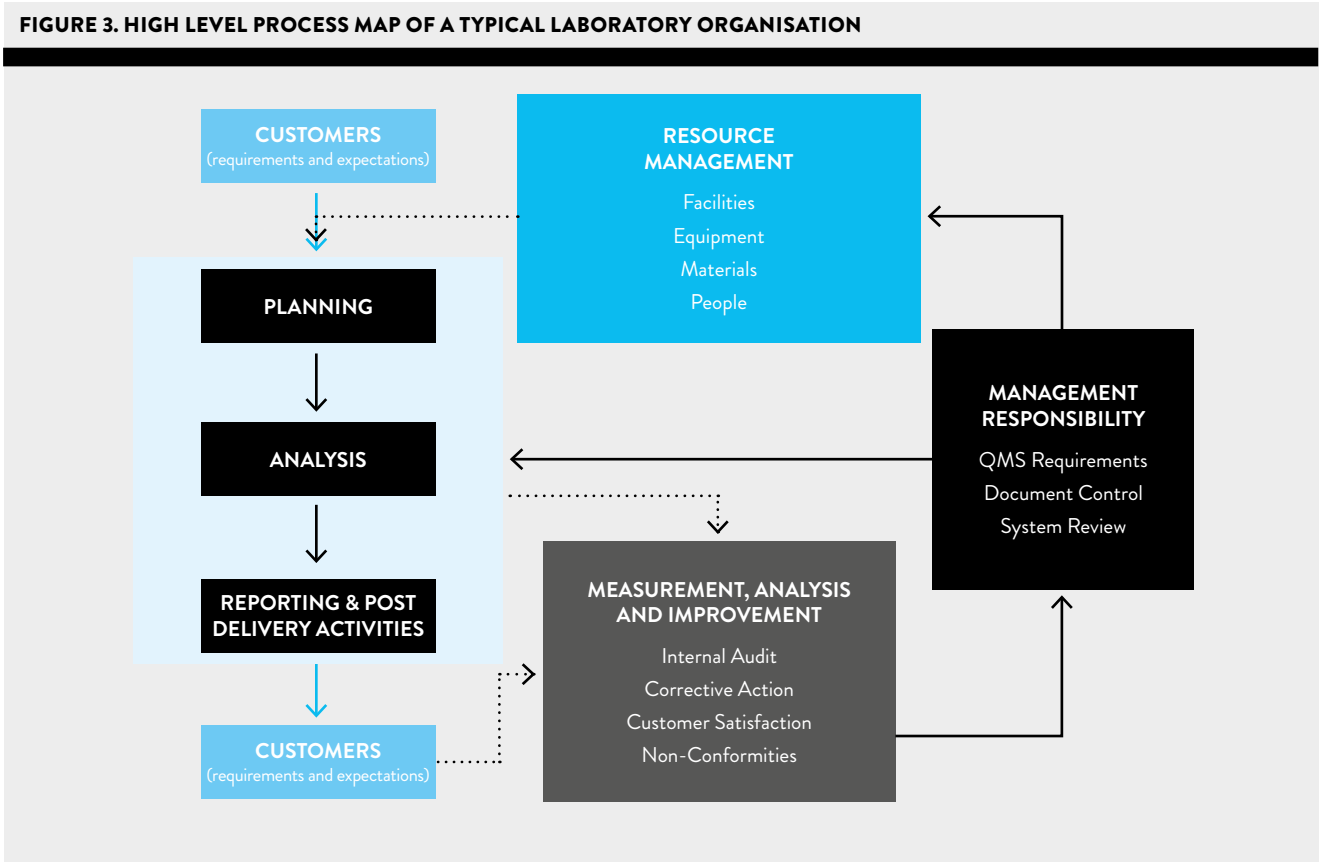
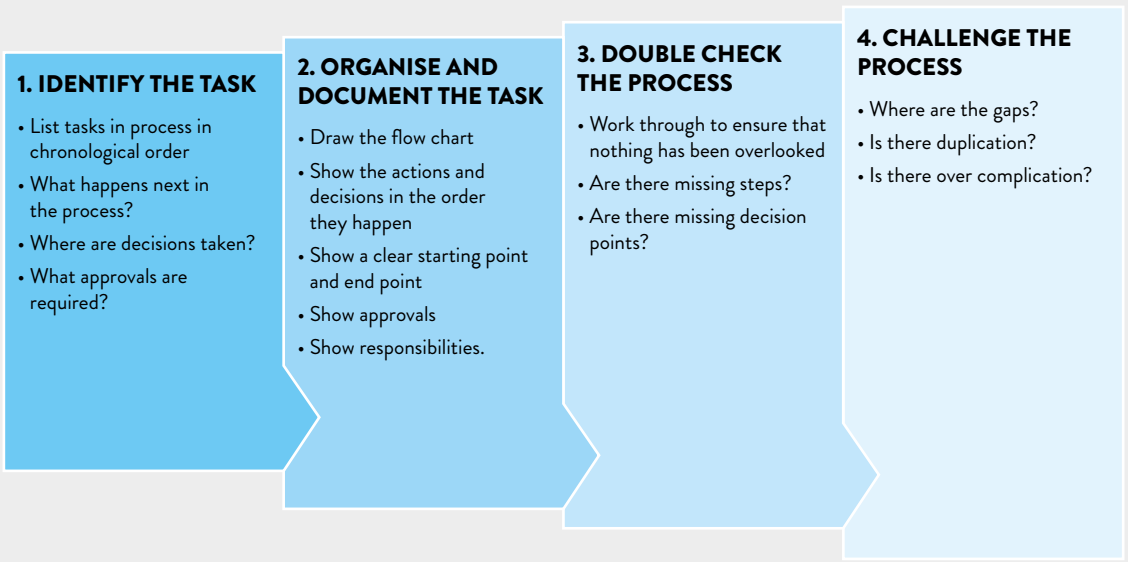


FIGURE 4. FOUR STEPS TO PROCESS MAPPING



Additionally, any changes to data must be performed in a controlled manner – why has data been changed, who made the change and when? For standard data recording the use of forms rather than free text lab books will assist the correct data recording practices. The MHRA and FDA have both published draft guidance on their expectations relating to data integrity.

Deployment of the QMS into the working environment should be planned and controlled. How this is done will be dependent on the organisation but you should be mindful that a lot of change in a short period of time will cause discomfort to individuals which will also need to be taken into consideration.

MEASURE OF SUCCESS

Every QMS requires an independent oversight, referred to as audit in the regulatory environment. At the system level, this will be a review of how users are complying with instructions, normally performed by the quality function. This review should be collaborative – asking questions like 'how easy do you find following X instruction, have you identified any problems with instructions, are they too detailed or not detailed enough?'.
A report of such reviews should be written, including areas for improvements as well as any positives. Any areas of non-compliance to be addressed should be agreed upon and an individual assigned to own the actions to be taken. The frequency and areas of review should be determined but must over time cover all the QMS.

Initially, frequent reviews of the QMS should be performed. Later, as the system matures, the reviews can become less frequent and assessed on the level of risk.

In addition, there should be ongoing peer review of the underlying science and the generated data. The scientific peer reviews should include an overall appraisal of the experimental design, the data collected, the results and associated conclusions.
A review of the data is referred to as quality control and includes a determination that the results are valid and re-constructible from records. The level of the checks will depend upon the robustness of the processes and identified levels of risk. For example, if tables are manually generated, a 100% check of the values may be necessary. However, if the tables are generated directly from software, is a 100% check required?

IN CONCLUSION

The implementation of a QMS should not be underestimated as the rewards can be great. It should be a collaborative project between users and quality; users are familiar with the organisation and quality understand quality systems. Quality professionals have many skills required to ensure that a bespoke QMS meets the stakeholder, customer and user requirements, to run projects and to manage change.

Any quality system must be suitable for the organisation and should be simple, efficient and flexible. The system should not be static and should evolve over time with the organisation.

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USEFUL INFORMATION

- Quality in Research – Guidelines for working in non-regulated research (RQA, September 2014)
- MHRA GxP Data Integrity Definition and Guidance for Industry, Draft July 2016
- FDA Guidance for Industry, Data Integrity and Compliance With CGMP, Draft April 2016
- Quality Systems Workbook (RQA, 2013)
- UK Good Laboratory Practice Regulations 1999, No 3106
- ISO17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories
- www.mindtools.com