

Balancing the Quality System –Part 2 of 3



Agenda

- What do we mean by a balanced QMS ?
- The importance of being customer centric
- The customers of the QMS.
- Approaches to becoming more customer centric – Part 2

Steps to putting the **customers** of the QMS **central**.

- Transforming the house is no different to transforming the quality system, and in general you will be having to deal with a QMS that you have inherited, rather than having to build something from scratch.
- Similarly, to **transforming** a quality system this project has several customers: it needs to look good for potential buyers - you can't cut corners.



1: Gaining control

In the same way if you had a house that was derelict, you'd start with addressing issues that were no brainers, ones that needed to be sorted immediately. Windows that were broken that needed replacing. Busted door locks that need to be fixed, etc...

- Ensuring basic cGMP
- Address special cause events
- Regain statistical control
- Address chaos – more on this on the module on Complexity.

2: Completing an inventory

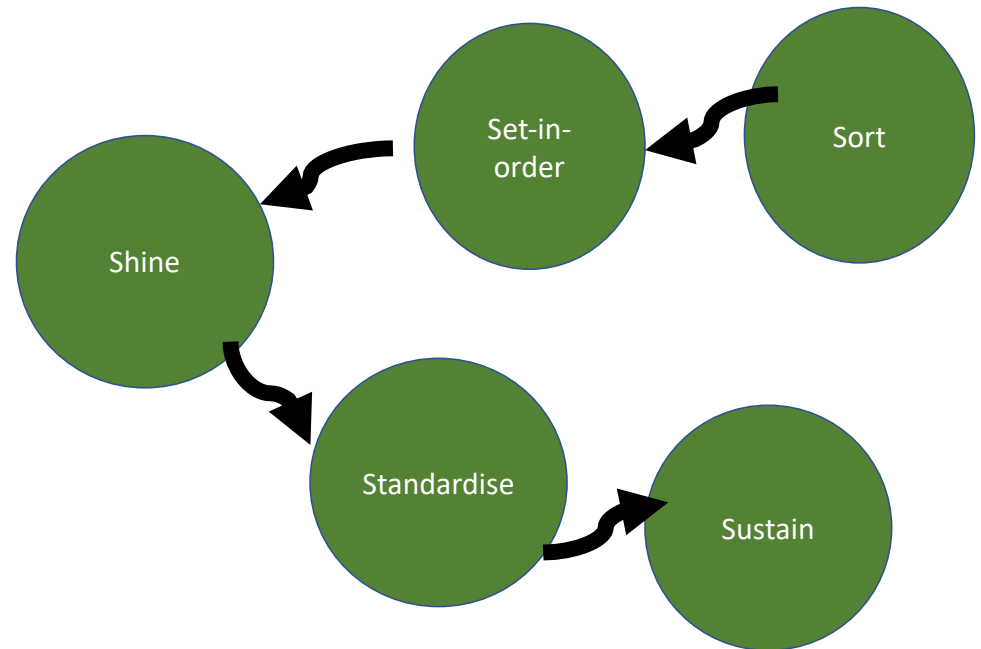
You'll need to complete an inventory of what you have. What is the heating system like, does it function ? Where are the bedrooms ? What is the storage available ? Similarly for a QMS..

- Reviews of procedures
- Interviews
- Surveys

More of this in the modules on People, Process and Technology and building a transformation map.

3: Spring cleaning

Use 5S methodology to spring clean the QMS



Applying 5S to the QMS

Sort

Basically, the process starts with working out what you need. If you don't use something throw it away or store it until you require it.



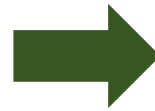
Clearing a derelict house can be a lot easier and quicker than clearing the dead wood from the QMS. The waste is more obvious in a house. Whilst with the quality system the waste is sometimes hidden.

- ✓ **Can procedures, documents and forms be obsoleted.** Do you really need them ? Are there forms of uncontrolled documents in the workplace, such as reminders and a cheat-sheets ? The requirement for controlled documentation expected of the Quality function is no different to that expected from functions that manufacture the product.
- ✓ Whilst electronic document management systems documents may not take up physical space, they cross-reference other procedures and will take resources and effort to maintain and keep up to date. Additionally, they are a compliance risk.

Applying 5S to the QMS

Set in Order

This step involves making sure you have things close to where they are needed. Will the dining room be relatively close to the kitchen? Is the pantry within easy reach of the kitchen?

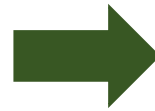


- ✓ **Are procedures and instructions for executing the QMS readily available at point of use?** Any documents that are a challenge to get hold of will be a challenge to comply with.
- ✓ Do those within Quality have ready access to the data they need to make the appropriate decisions?

Applying 5S to the QMS

Shine

The next step is cleaning. Are areas where quality activities reside cluttered, dirty, and disorganised ? If so, they do not present the area in the best light during an inspection.



✓ **Is the work area clean and presentable ?**

Are the Post-it™ notes covering production and other quality records ?

Applying 5S to the QMS

Standardise

This stage involves ways of ensuring that you know when things aren't correct, and the workplace is drifting away from where you want to be.



- ✓ Consider using visuals ie: graphics and flowcharts within procedures to explain the stages of the process. Add checklists to error proof that the key stages have been carried out in the necessary order.

Applying 5S to the QMS

Sustain

The final step is focussed on ensuring that the gains made during the previous stages are maintained.



- ✓ Regular audit that the systems have been maintained.
- ✓ Periodic review of documents to ensure that both they are consistent with what is executed, and the content is up to date and consistent with both internal documents, and any new external standards and regulations. It is very easy for procedures to drift over time from what is needed.
- ✓ How often are procedures reviewed and is this reviewed more than a cursory review of the content for adequacy ?

Steps to putting the **customers** of the QMS **central**..

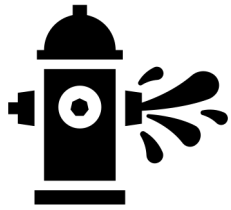
4: Removing waste

Use lean approaches to ruthlessly remove waste from the QMS that is getting in the way of delivering value to its customers.



A close-up photograph of a person's hand dropping a green plastic bottle into a recycling bin. The bin is made of grey plastic with yellow and blue slots. The background is a blurred green field.

Remove waste from your
Quality System and make it
flow.



Defects

Defects within our derelict house would include broken fixtures and fittings.

Defects within the QMS include:-

- Validation deviations.
- Processes that are not followed leading to non-conformances.
- Incorrect Supplier specifications.
- Inaccurate technical reports.
- Corrupted Quality Data.
- Misaligned Quality Objectives and Key Performance Indicators.



- ✓ Revision of specifications for appropriateness
- ✓ Standard Work
- ✓ Error proofing
- ✓ Six Sigma approaches to reduce variability
- ✓ Clear Procedures
- ✓ Data verification
- ✓ Improved Management Review
- ✓ Rigorous application of the CAPA system.



Inventory

A house that has more furniture than required is wasteful as it takes up space that could be required for other items and requires cleaning and up-keep.

Types of inventory related to the quality system include:-

- Excessive number of documents that are required to be periodically reviewed.
- Non relevant information being collected.
- Quality Data that is collected but never reviewed.
- Quality records that are no longer needed.



- ✓ Reduce the number of controlled documents.
- ✓ Remove all non-relevant information from procedures, prune back.
- ✓ Question whether all specifications are needed and are critical to quality or function.
- ✓ Remove requirement to capture non-relevant data in forms.
- ✓ Eliminate the capture of data that does not needed to be captured.



Waiting

- Waiting for approval of documents.
- Waiting for approval of batch-records for product release.
- Waiting for point resource to become available.
- Waiting for test results.
- Waiting for management approval.
- Waiting for critical meetings to take place.



- ✓ Eliminate signoff of documents as a sequential activity requiring documents to move between functions, incurring delay. Bring functions / individual together to approve as a focussed activity.
- ✓ Move the Quality approval to form part of a joint Quality / Operational cell.
- ✓ Cross train extensively to eliminate point resource. Ensure approvals are always able to be delegated with documented accountability.
- ✓ Reduce the number of approvals on documents ! Are all needed ?
- ✓ Drive accountability for document approval down to the lowest management level possible. Do not allow lower management to "hide" behind higher level approvals.
- ✓ Eliminate redundant meetings.
- ✓ Use technology to facilitate meetings that are needed.



Over-production

Waste due to over -manufacture. Over-production includes:-

- Excessive documentation that goes beyond requirements.
- Multiple copies of documents.
- Excessive data that is not required.



- ✓ Ensure that documents and their contents do not go beyond what is required.
- ✓ Utilise electronic work-flows to remove multiple redundant paper copies of documents.
- ✓ Collect only data that is necessary.



Motion

Waste from excessive movement of people or equipment.

- Searching for documentation.
- Moving data from one software application to another.
- Trying to find the correct the individual in another function to approve a report.
- Walking to the printer / scanner etc.



- ✓ Electronic systems that allow documentation to be available at point of need.
- ✓ Electronic systems that allow approvals within a work-flow from any location.
- ✓ Ergonomic work-cells with appropriate resources at close proximity.
- ✓ Workspaces designed around the individual.



Over-processing

Waste from performing activities which go beyond what the customer requires.

- Collecting data that is not needed.
- Duplication of data entry.
- Specifications that are not necessary.
- Specifications that are narrower than required.
- Redundant or duplicate release testing.



- ✓ Review specifications to determine whether these are needed or too narrow.
- ✓ Is all the data collected really needed ?
- ✓ Are all parameters being covered during verification / validation required ?
- ✓ Can the incoming inspection activities be moved to the supplier ?
- ✓ Can a test be removed ?



Transport

Waste from excessive transportation of materials or products.

- Moving the physical batch record around with the product.
- Moving reports between departments for signatures.
- Moving data between individuals.
- Moving data between systems.



- ✓ Move the QMS as close to Production unit as possible.
- ✓ Replace physical batch records with electronic batch records
- ✓ Have central databases that can be access remotely.
- ✓ Connect databases together.



Talent

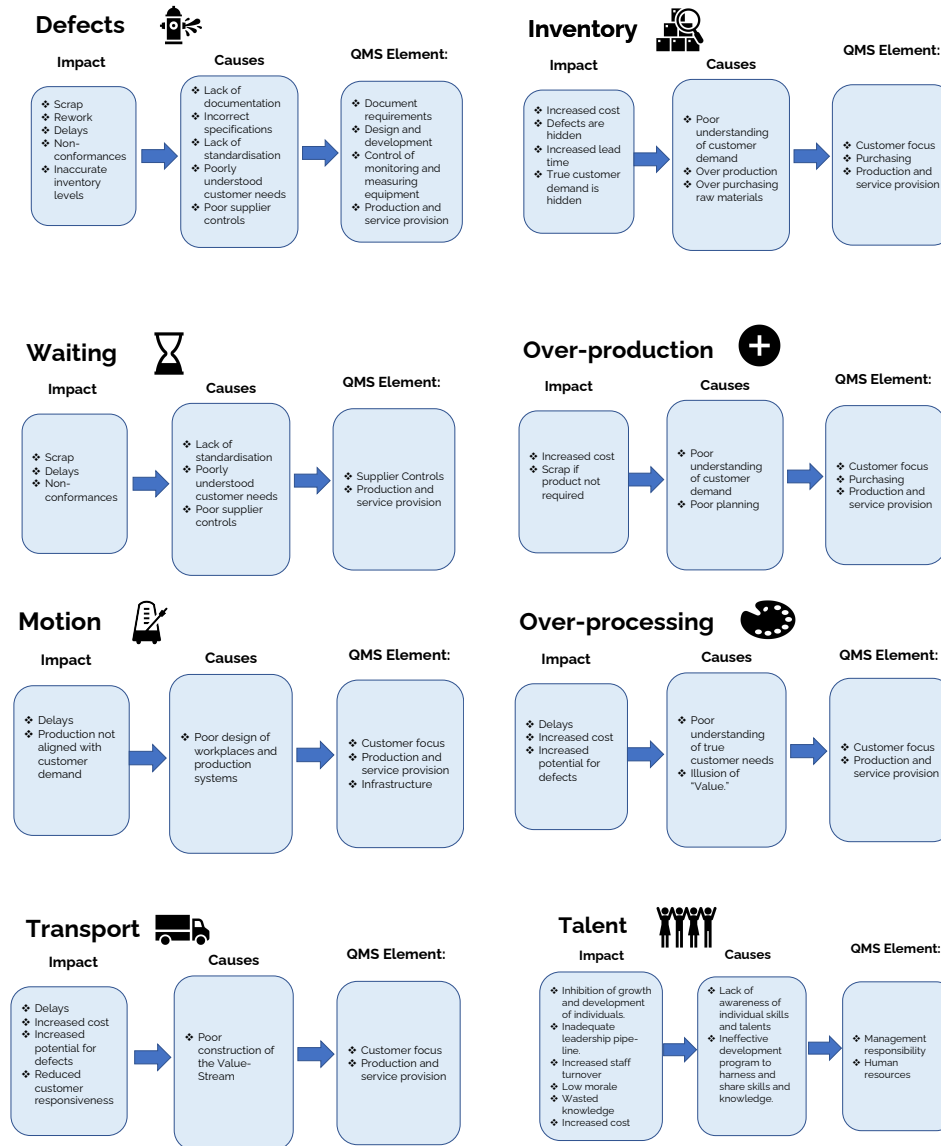
Waste from under-utilizing talent, skills, and experience.

- Poor operational flexibility
- Inadequate future-proofing



- ✓ Develop a thorough Training and Development program.
- ✓ Cross train.
- ✓ Recognise and celebrate high achievement.
- ✓ Carry out a skills audit and understand your inventory of talent.
- ✓ Use the creative power of employees.
- ✓ Listen.
- ✓ Build diversity of views, skills and opinions.

The 8 Wastes applied to the Quality System



This waste is **preventing** you satisfying your customers.

It is **preventing** your Quality System from being effective.

Work **tirelessly** to remove !

Drawbacks in lean thinking

- Manufacturing approaches have not always delivered their **full** potential in healthcare organisations. *
- Organisations are complex, changing and evolving systems and **not** machines.
- Your Quality System is a complex adaptive system.
- You will need to apply **newer** thinking around how Quality Systems and organisation actually behave to **improve**.

* Kaplan GS, Patterson SH, Ching JM, *et al* Why Lean doesn't work for everyone *BMJ Quality & Safety* 2014;**23**:970-973

EFFICIENCY



Speed



Quality



Costs