



Managing Change

Part 4 of 4

Agenda



Managing the Change
Process – Practical help

Where you are on the
maturity spectrum

Prioritisation

Two of the truisms in life are:

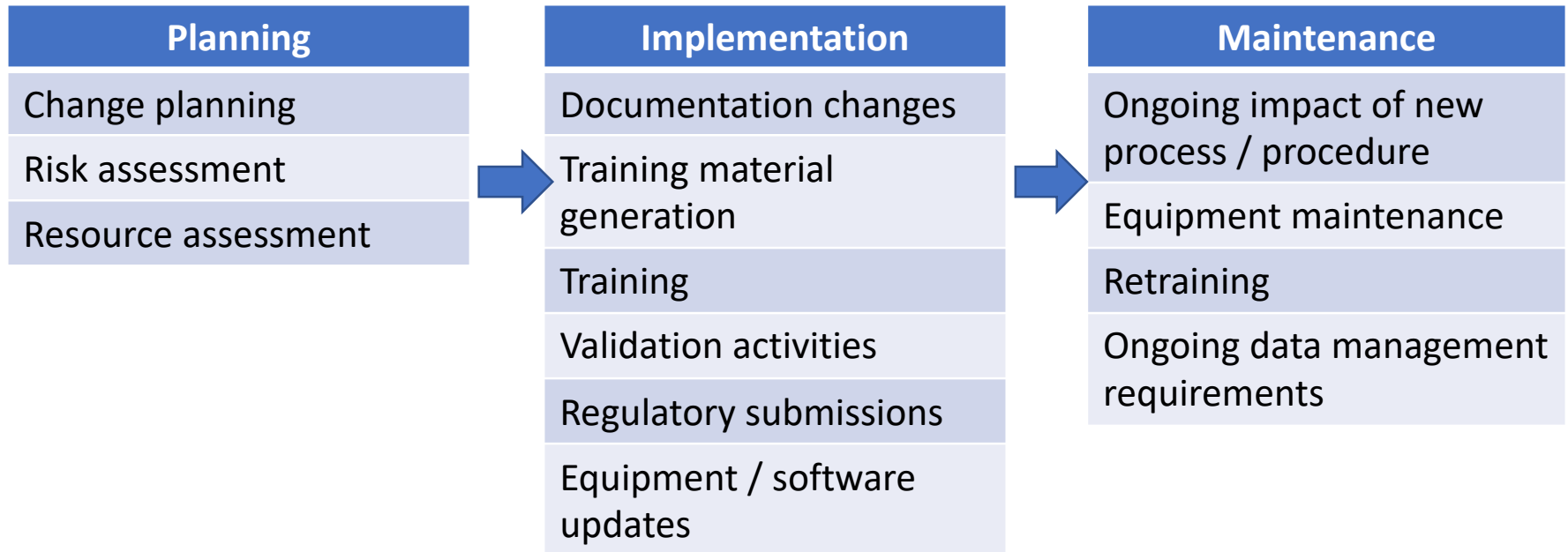
1: We seldom can do all the things we would like to.

We rarely have all the resources, time, and money to address all the activities that we would want.

One of the biggest mistakes in organisations, especially from leaders, is that because they want something to happen it can, will and must happen. Dream on.

2: No change comes free. All change costs.

Activities that require effort to make a change



Prioritisation

High



Low



High

Examples Benefit v Effort



Dimension	Classification	Examples
Benefit <ul style="list-style-type: none">• Compliance• Business Health (Cost / efficiency)• Customer Experience	Low	<ul style="list-style-type: none">• Minor improvement in regulatory compliance.• Minor cost savings or efficiency improvement.• Minor improvement in customer satisfaction.
	High	<ul style="list-style-type: none">• Significant or mandatory change needed for regulatory compliance.• Significant cost savings or efficiency gains.• Significant improvement in customer satisfaction / reduction in complaints.
Effort <ul style="list-style-type: none">• Resources (people/equipment/costs)• Time	Low	<ul style="list-style-type: none">• Can be implemented within sponsoring function alone.
	High	<ul style="list-style-type: none">• Requires cross-functional or specialist resource - equipment / validation required or regulatory submission.

The use of this Benefit v Effort approach has several benefits:

- It allows direct comparison between activities in an objective manner, such that the 'squeaky wheel' does not always get the oil.
- It allows activities that have clear 'no brainer' benefits compared to the effort to go ahead immediately.
- It focuses you to really assess whether activities have benefits expected.
- It allows a degree of prioritisation of items, allowing the activity to be placed in a queue to be delivered when resource become available.

Integrating change with Risk Management



As we will see in the next module Change Management and Risk Management are linked.

Tools to use during Change Management include

- 1: **The Risk Register**
- 2: **The Pre-mortem exercise.**

Murphy's Law

" If something can go wrong, it will "

Why Risk Management ?

- Understand project risk and management tolerance.
- Share ownership of risk with team and management.
- Ensure mitigation plans and negotiate resources as needed.

It is far better to anticipate events changing – they will – and put mitigations in place, than just reacting to them.



1: Risk Register

KD at Risk	DPO Impacted	Probability of Occurrence (1-10)	Severity (1-10)	RPN	Mitigation What, When, Who	Status	Probability of Occurrence (1-10)	Severity (1-10)	RPN

Example of a Risk Register Template to identify Risks, assess impact and detail mitigations needed.



2: Pre-mortem Exercise

- Ask yourself or team members to imagine they are at the end of the change activity and it has been a disaster.
- **Brain-storm the reasons you feel it all went so wrong ?**
- This it is a useful exercise as it sensitises the team to recognising things that may go wrong and dampens unbridled optimism at the start of the project that may blind-fold you to viewing risk adequately.



Change effectivity

We assess CAPA effectivity.
We should be as stringent at
assessing **Change
Effectivity**.

- Did the change generate the potential benefits expected ?
- Did it require the resources and time expected ?
- How do we need to **improve** the change process to do better next time ?



Planned v Emergent Change

- Organizations and People do not behave like machines however much we want them to.
- You need to start with a plan...
-but accept that it will change.

Planned Change

Diagnosis
Vertical governance
Project start and endpoint
Linear plan
Control uncertainty
Hierarchical leadership
Learning through quantitative data

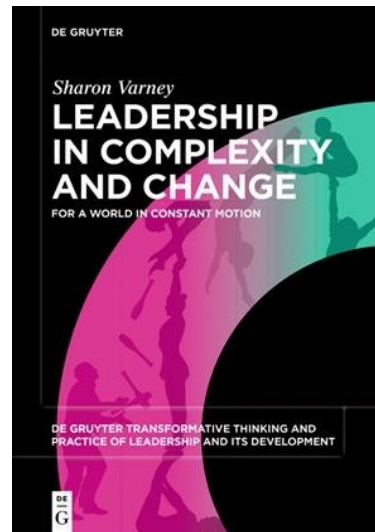
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Emergent Change

Dialogue
Horizontal governance
No beginning or end
Non-linear plan
Embrace uncertainty
Distributed leadership
Learning through narration

Further material..

This aspect of the complexity of change will be covered more in a later session...



**A Balanced
Quality
System**



**Managing
Change**



**Balancing
Risks**



**A Quality
Mindset**



People



Process



Technology



**Making the
QS work
for you**





Datod's Quality
Organization Maturity
Model





Your company struggles with managing change. Change management often focuses on how documents are controlled, maintained and updated. Change is highly reactive in nature and not proactively managed. There is no prioritization of changes or the changes underway. Change within the Quality System is led by the Quality Organisation, with limited input from other stakeholders. There is limited use of root cause investigation techniques to identify improvements. When change is implemented the effectiveness of the change is seldom evaluated.

Senior management has little visibility of the number of changes are happening in the business or struggling with managing the volume of change underway.

Your company can improve its change management capabilities by implementing a prioritization process for changes, improve the visibility of changes and increase communication and collaboration with other stakeholders. Additionally, your company needs to use appropriate root cause analysis to identify potential improvements and measure the effectiveness of implemented changes.

By taking these steps, your company can better plan and implement solutions to the problems your Quality organization needs to address.



- Change is driven by a limited number of sources.
- Change is highly **reactive** and inwardly led by the Quality Organization.
- There is limited use of methodology to get to identify causes of problems and remove waste and inefficiencies from the Quality System.
- There is still no clear or coherent road-map managing the end-to-end change process.

Next Steps:

- ✓ Widen the number of drivers for change based on improving compliance, costs and meeting end customer expectations.
- ✓ Start managing change rather than controlling how documents are updated.
- ✓ Start formalizing the way Quality Data is translated into Quality Objectives through a collaborative Quality Planning process.



Your Quality organisation is still struggling to manage change. Your change management process may be still focusing on how documents are updated and controlled, rather than how changes are actively managed. You are aware of the issues that need addressing and understand the need to build a process to effectively manage and prioritize change. In addition you are aware of the need to broaden the inputs to the change process.

You will need to leverage the Quality Planning process to translate Quality Data into Quality Objectives linked to customer needs.

Senior management is beginning to get visibility of the changes underway and the need to manage the change pipeline more effectively. Change is still led by the Quality organisation but you are now aware of the need to involve other functions. You are aware of the need for more methodical approaches to fixing problems and improving the Quality System for its customers.

Change is still highly reactive in nature but you understand the need to be more proactive. As you move forward, it will be important to continue to involve other functions in change management, develop more methodical approaches to problem solving, and proactively manage the change pipeline.



- The change process is still not formally or effectively managed.
- There is some use of methodology to identify causes of problems and remove waste and inefficiencies from the Quality System.
- Whilst there is no clear and coherent road-map managing the end-to-end change process, the Quality organization is aware of the need for such a road-map.



Next steps:

- Update Quality System Management review (QSMR) policies and procedures to drive holistic evaluation of the Quality System.
- Create appropriate procedures and training in effective root cause investigation.
- Apply improvement methodology such as lean or Six Sigma to increase the efficiency and effectiveness of the Quality System with its customers' perspective core to your thinking.
- Create, review and update a Quality Transformational Map.
- Create a Quality Data and Quality Planning procedure linked to QSMR and implement.
- Continue assessing key processes in the Quality System against the eight waste types of lean. Identify short, medium, and long-term projects as part of a formal change program.
- Implement an appropriate management forum to ensure that the CAPA, change, continuous improvement and New Product Development pipeline is balanced, prioritised, and resourced as needed.



Your organization is beginning to effectively manage the end-to-end change process. You are beginning to have a true change management process rather than one that focuses on change control.

Senior management has visibility of the changes underway and is beginning to manage the change pipeline more effectively. The change pipeline is more balanced with respect to regulatory, customer and cost expectations.

Whilst change is still led by the Quality organization there is an expectation that change is a collaborative process. You are using more methodical approaches to fixing problems and improving the Quality System for its customers. Change is becoming more proactive in nature.

Your next steps should be to build on these successes and further develop your collaborative approach to managing change. This will require you to engage all stakeholders in the change process, from initiation through to implementation and closure. It will also necessitate the development of robust communication plans and clear processes for monitoring and managing changes. In addition you will need to be able to better prioritize changes. Seek ways you can continually improve the change process as a closed-loop system.

By taking these steps, you will be able to even more effectively manage the end-to-end change process, ensuring that all stakeholders are aware of and committed to the changes taking place.



- Change is driven by a wide range of sources.
- Appropriate improvement tools are understood and applied.
- There is a formal process for managing change from short to long term aided by a Quality Transformation Map.

Next steps:

- Continually reassess the Quality Transformation Map for suitability and course correct as needed.
- Look at ways to effectively prioritize change and stratify how it is managed based on balancing risk and benefit.
- Ensure you have a closed-loop process to measure the effectiveness of change and continually improve the change management process.



Managing change is a critical function within any organization, and the Quality organization is highly effective at managing the end-to-end change process. Your process effectively manages change as opposed to controlling its implementation. It is strongly connected to the other Quality System subsystems such as risk management, CAPA and training.

Senior management has clear visibility of the changes underway and is able to prioritise changes in an agile and effective manner.

The change process is continually improving based on an ongoing assessment of its effectivity. You often reassess your transformational roadmap to ensure it is appropriate and relevant. The change pipeline is balanced with respect to regulatory, customer and cost expectations.

Change is viewed as collaborative process with joint ownership of the Quality System. Change is always led by the most appropriate individual or function.

There is effective use of methodical approaches to fixing problems and improving the Quality System for its customers. These tools are used pragmatically and there is awareness of their shortcomings. Change is highly proactive and positively managed for your end customers.



- Change is actively and effectively managed.
- Appropriate improvement tools are understood and applied, where needed.
- There is an effective formal process for managing change from short to long term aided by a Quality Transformational Map.

Next steps:

- ✓ Continue your relentless pursuit of making the Quality System more effective, efficient and delivering true value for all of its customers

Summary

- A quality system that fails to change is one that will fail to meet its changing customer needs.
- Ask what is holding you quality system back from meeting current and future customer needs ?
- Change management is far more than document control.
- Make sure you are addressing the correct causes with the right fixes.
- Prioritise benefit against effort before progressing. Beware of 'feeding the beast'.
- Build and articulate a map of where you want to get to and how you will get there.
- Involve the organisation.