



Building a Transformation Map (T-Map)

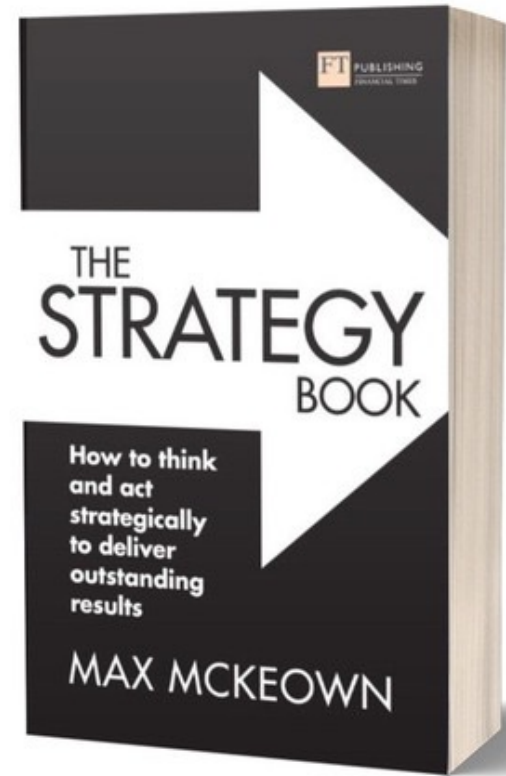


Strategy

- Strategy is all about shaping events to influence the future.

" Skilled strategists accept the world is complex and figure out what to do to shape events. "

- Reacting is as important as planning.
- Strategy is all about making decisions.





Change

- It is all about winning **hearts-and-minds** in making a change for the better.
- Most strategy involves a degree of change.
- All resistance to change is linked to a perceived threat to power or position.



Questions

In many respects planning, executing, and maintaining a quality transformation is an exercise in answering the following:

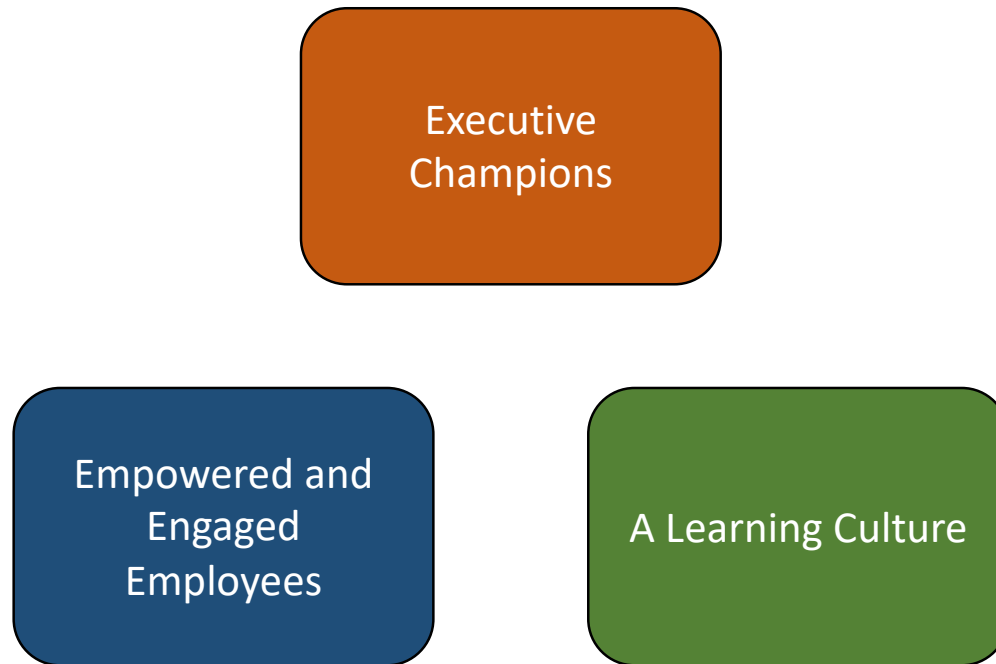
- **Why?**
- **What and When?**
- **and How?**



Why ?

- The why?
- In essence you need to address head-on the concept and often quoted "**Culture of Quality**".
- Individuals - and yourself- need to understand why quality is important and what they can do about it.

Elements of a Quality of Culture





Executive Champions

- Leadership being seen to embrace quality needs to be visible and felt by the entire workforce. It should be aligned and core to the purpose of the organization.

Practical examples demonstrating this include:

- The Quality Policy should be on display. It should be simple enough for employees to remember the key messages. It should also make it clear that its obligations apply equally to all employees.
- In executive meetings, quality should one of the first topics and not relegated to the end of the meeting as an afterthought. If employees see that quality is discussed front-and-center at the executive level, they are more likely to position it similarly themselves.
- In company town halls, the topic of quality should one of the first discussed and the CEO must be seen taking the lead in discussing its importance to the business.



Empowered and engaged employees

If leadership is genuinely bought into the concept of a culture of quality, then employees need to be able to voice concerns around its aspects. No ifs. No buts.

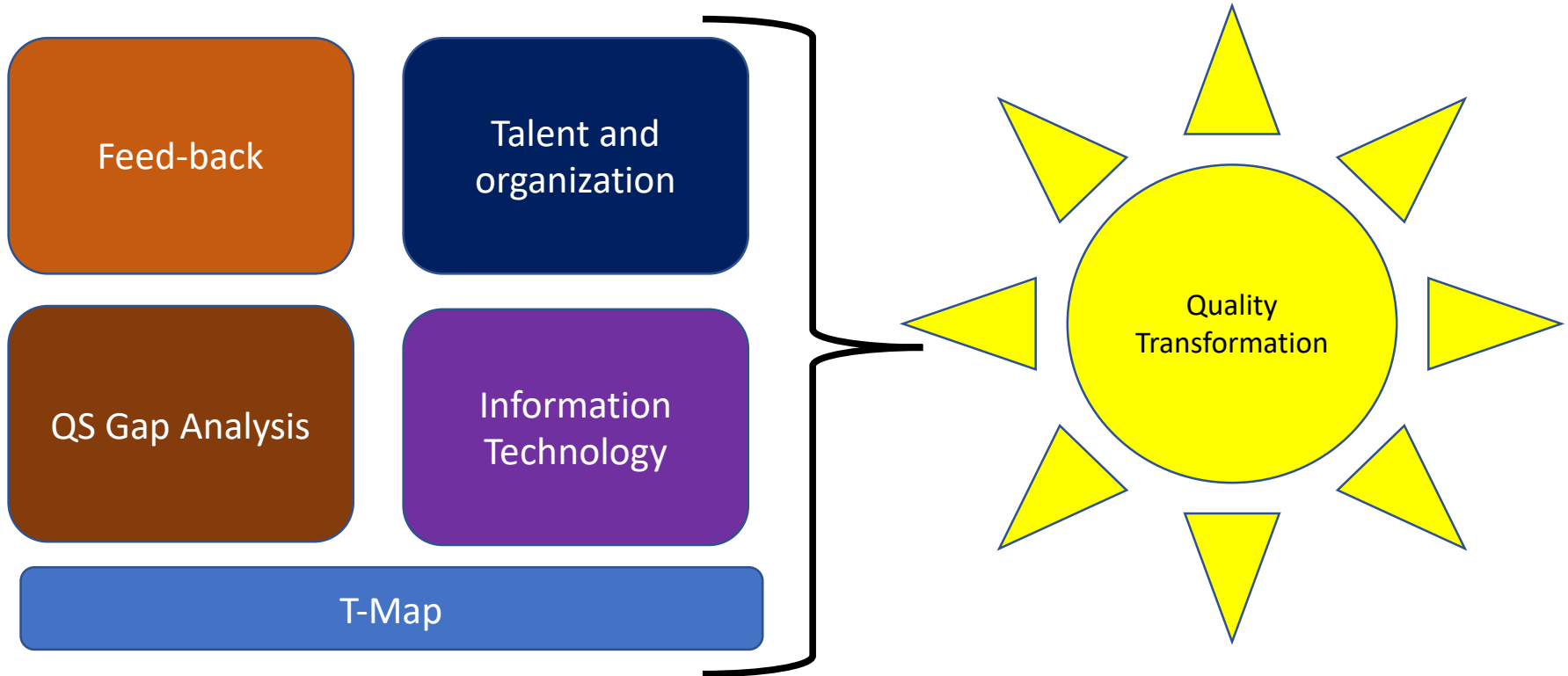
There also needs to be evidence that concerns are being actively heard and responded to. Many organizations proclaim a 'no-blame' culture. This is far easier to say, than make happen, but larger organizations than yours have made it happen.

A learning culture

- Having a vocal executive champion and empowered and engaged employees will have little impact unless there is a culture where improvement is expected. There needs to be an expectation that the organization learns and grows.



The what and when? – planning a quality transformation.



Feedback

You are going to need to get feedback

- We recommend that you interview at least 10 percent of the total workforce or at least 50 people ensuring that you connect with all the major functions within the business, even those you would rarely work with.
- An effective way to structure the interview is around the following questions:
 - **What's working?**
 - **What's not working?**
 - **What's missing / holding you back?**

Important

- Despite what you hear – check, check and check facts before coming to any firm conclusions.
- This is a critical decision point in the process; this is the first 'go/no-go' decision point for your transformation. You may decide after initial analysis that you can achieve your objectives via other means.
- Be cognisant that in your position as a business leader often individuals will tell you things that they think you want to hear. Do not be scared to keep asking: why is that?

Talent and organizational review

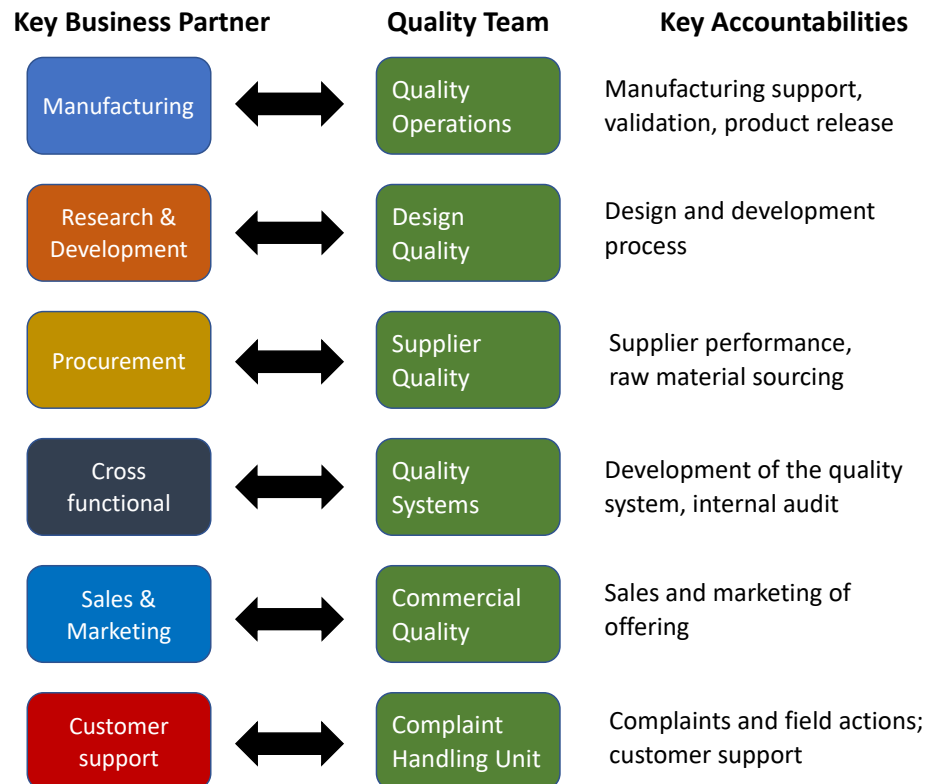
From the feedback exercise you will get a sense of whether your Quality organization is supporting the business. However, a more sensitive issue is whether, or not, your current staff are delivering. In this case the questions become:

- **Who's contributing?**
- **Who's not contributing (and why)?**
- **Who's missing?**

Great care is obviously needed in soliciting this type of feedback.

Aligning Quality with the needs of the business

- The aim of this step is to assess overall capability and its ability to service the customer and organization.



Colocation of Quality with stakeholder groups.

- Co-locate Quality with the groups it supports.
- In the model proposed, Quality is integrated with its business partners throughout the extended supply-chain and associated business units. For many organizations this really is a paradigm change in the role of the Quality function.
- In moving a Quality team to sit physically with their business partner, direct contact, discussion and ultimately a mutual coaching environment is created. This builds teamwork and ultimately leads to shared objectives and metrics.



Organisational design

- Make sure you have your organisational design set and in place before starting the T-Map.
- Changing your organisation mid-transformation will disrupt the implementation.
- Make changes quickly and comprehensively.
- Accept there will be a degree of short-term pain for a longer-term gain.

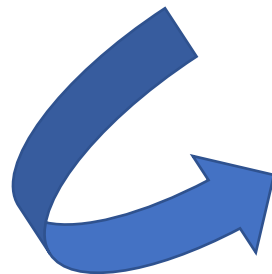
Quality system gap analysis

One vital - and obvious - point to make is that despite all the content in this book around improving the efficiency, usability and positioning the Quality System to meet multiple customer groups it still must be fully compliant.

This next step in the transformation involves a comprehensive and thorough gap assessment to understand the level of compliance with all the regulations and standards that apply to you.

Scoring system for scoring QMS elements for compliance.

Gap	Summary	Score
Critical	Would expect a Critical audit observation during regulatory inspection / Warning letter from FDA	10
Major	Would expect a Major audit observation during regulatory inspection – 483 from FDA	5
Minor	Would expect a Minor audit observation during regulatory inspection – Warning letter	3
No Gap	Compliant with regulations and standards	1



Ensure the Executive and the organisation understands the risks of non-compliance and why it is a vital part of the transformation.

QMS Element	ISO13485:2016	IVDR	External Audit	Internal Audit	Score
Management responsibility	1	3	1	3	9
Design Control	3	5	1	3	45

Tools - Information Technology

- The role of information technology is now central to the management of quality in most businesses.
- A new IT tool will not be the transformation in itself. If the culture of quality doesn't change then the outcome will be the same, just with a different IT solution.
- If modifying a current application or deploying a new IT solution start detailing the ideal process you want, with the end-users who will have to live with the consequences. Do not allow a quality transformation to be confused with a technology deployment exercise.

The how? – goals, training and recognition



Goals and objectives

Training and support

Reward and
recognition

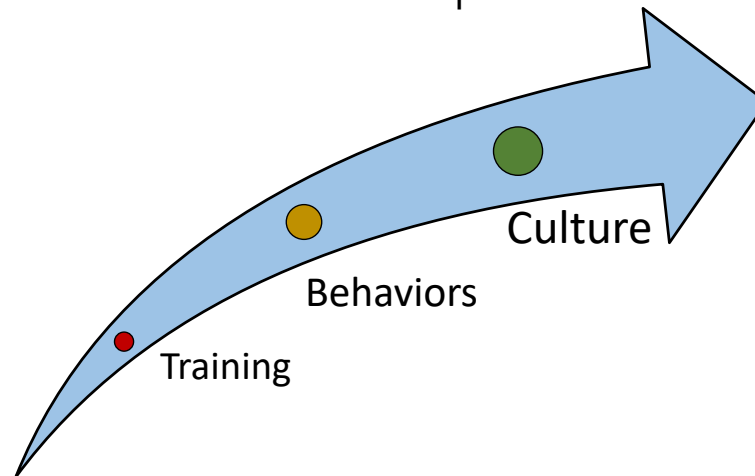
Goals and objectives

You are going to have to work with the business and to find appropriate goals, both at the senior leadership level and down through the organization whose completion will help move your transformation in the needed direction.

Your role as a leader is not to develop, implement or even identify solutions. Your job is to create appropriate goals and give the organization the appropriate tools and training to solve these problems themselves.

Training and support

- Training takes many forms. The way you behave as a leader and the things that you tolerate, and those you will not tolerate are also a form of training for your organization.
- Training defines a consistent set of behaviors across a population.
- Once you have a set of consistent behaviors you have the foundation of a culture. Training, therefore, is fundamental to creating the culture you want to establish. In practice, this means a significant, dedicated, and focused effort, sustained over a period of years to ensure that a culture is established and remains in place.





Rewards and recognition

- Giving individuals appropriate goals, training and then hoping a transformational change will occur may work as a one a one-time activity, but it will not be sustainable.
- You as a leader need to recognize and reward achievements and continually encourage your organization on its journey, a journey that will have several successes and failures along the way.

Building your transformation map

- A transformation map or T-Map is a deceptively simple tool that can describe the strategic journey of an organization from current to desired future state over a medium-term time frame - typically 3-5 years.
- It is usually a one-page visual description of the steps necessary to execute a strategic transformation.
- More than anything it is a communication and engagement tool to show how multiple change elements are united in realizing a better future state for the organization.



What you will need...

A skilled facilitator; a cross functional team – ideally no less than 10 and no more than 20 people and a large venue with plenty of wall space.

It may be preferable to hold multiple sessions and aggregate these exercises. Ideally run the sessions with staff not involved in the initial feedback exercise, to get input from a broader selection of staff.



Introductions

- Explain purpose
- No limitations



Define
Current State

- What works ?
- What doesn't work ?
- What is missing ?



Affinitize

- Group into themes



Define Future
State

- What does ideal look like ?



Define T-Map

- How do we make the journey ?



Maintenance

- How do we ensure we reach our destination ?

Introductions

- This should last no more than 30 mins and should cover the purpose of the session. The general ground-rules for any brain-storming activity apply.



Step 2: define the current state (30-60 min)

This session covers the current “as-is” state. You normally contain the scope to focus the session e.g.: what is it like to use the Quality Management System? The key questions to ask are:

- What works?
- What doesn't work?
- What is missing?


Step 3: affinitize (30-45 mins)

- This step comprises of collecting the comments into groups, which usually begin to form 5-10 key categories.
- Ask the team to comment on the key categories – were there any surprises or key insights/learning points?
- What were some of the themes within the categories?
- Note these, as they will be used in the construction of the T-Map .



Step 4: define future state (30-60 minutes)

- For each of the key categories, ask the team to define what 'ideal' would look like. Again, use sticky-notes to capture thoughts and ideas.
- It is recommended that you organize the wall so that current and future state notes are relative to each other, with space in between for the final step.
- Ask the team to comment on the future state comments – were there any surprises or key insights/learning points? What were some of the common themes?

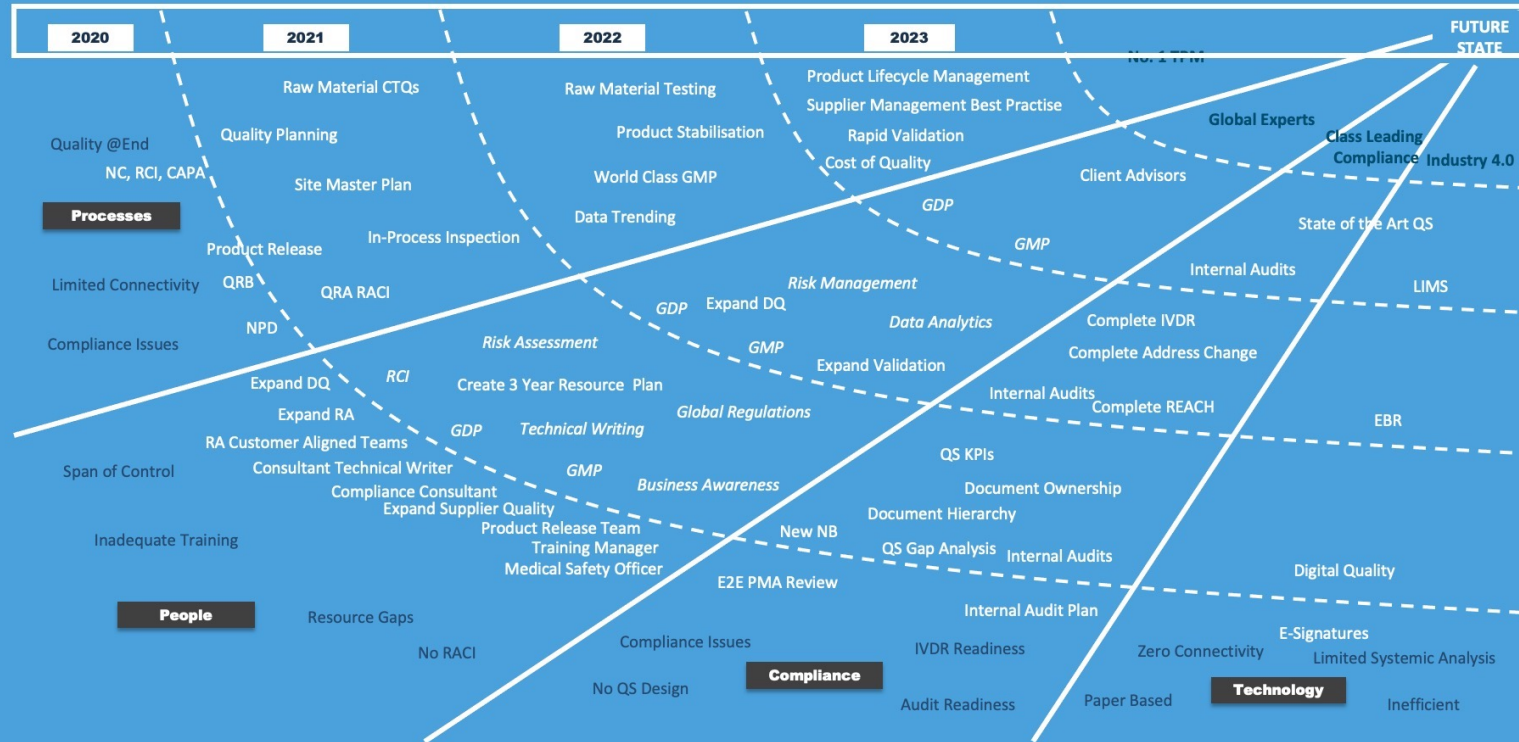


Step 5: defining the transformation map (60-90 mins)

This final step is the one that requires the undivided attention of a skilled facilitator. The key question to ask here is: how can you make the journey from current state to future state? Other questions include:

- What capabilities, systems, processes need to be changed or put in place to achieve the future state?
- Is there a sequence of actions or projects that need to be completed or can a parallel track approach be used?
- What level of investment will you need?
- Can your transformation be realistically delivered within the horizon of the timeframe?

Quality Transformational Map Aug 2020-23



✓ Complete
🟢 On Track
🟡 Delayed with recovery plan
🔴 Delayed with business impact
✂ Planning phase

Step 6: maintenance of the transformation map

- The T-Map is - more than anything else - a communication tool. It should be reviewed regularly with the entire organization to show how the strategy is progressing. You should be clear in highlighting completed steps and how the next steps are either in planning phase or already in execution.
- However, it needs to be a flexible tool. Even with a relatively short strategic horizon of 3-5 years, situations and environment can change and the T-Map should not be religiously adhered to.



Key learnings

- Use the T-Map as a communication tool: don't underestimate the importance to show the progress and remind the organization where you started and where you are heading.
- The cross functional team will naturally incorporate Systems and Complexity based thinking and, as a result, the T Map will create a cohesive, multi-faceted program of change.
- Most organizations have three main types of people with views on change: The Evangelist, the Team Player and the Doubting Thomas. When selecting people to be involved, make sure you include representatives from all three groups. The Doubting Thomas can often be a) source of truth, b) reality checks and c) often turns into an Evangelist when they see their views are being heeded.
- Some T-Map changes (e.g., changing your CAPA process) will be projects in their own right; in these cases, we recommend you implement individual project plans and track progress closely. Others (e.g., increasing headcount in a particular team) will require management action.