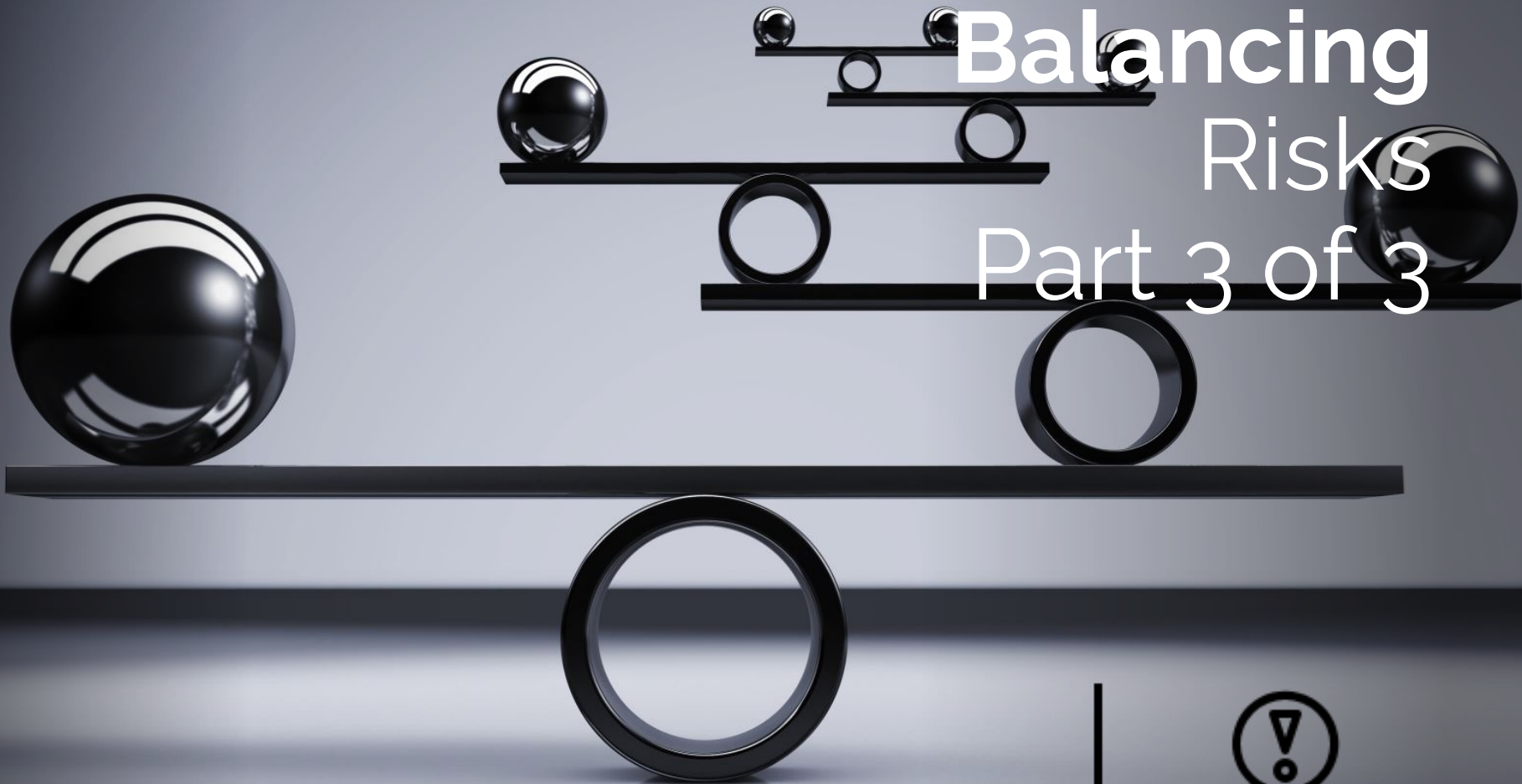


Balancing Risks Part 3 of 3



Agenda



Practical aspects of
assessing risks

Balancing risks on the
maturity scale.

Practical tips

Learn from your past

- One of the common features of virtually all disasters is that the system was 'blinking red' well before the event.
- From the Deepwater Horizon catastrophe in 2010, where an oil-platform blowout caused the greatest environmental catastrophe in history to the Shuttle Columbia disaster in 2003, was that near miss events proceeded the eventual failure.
- In all cases, the signs were there in the system. Previous near miss incidents occurred which would have prevented loss of life if they had been listened to.



Your worst enemy may be
yourself..

Being intelligent and working hard will not protect you.



Practical tips



Signals in the Quality System

- Near miss events
- Customer feed-back / complaints
- Audit observations

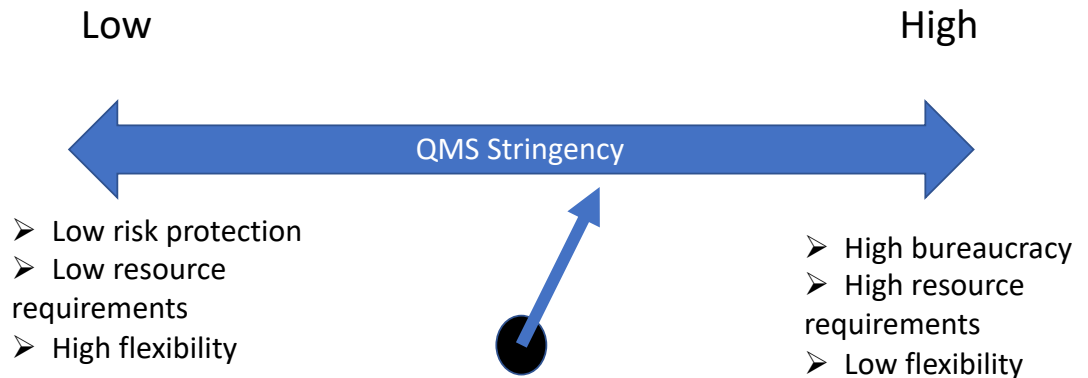
Organisations that set high expectation of individuals to raise their hands and react to near miss events are more protected, but only when leadership sends a message of expectations that is consistent and constantly reinforced.

Practical tips

Proportionality

- If you operate a quality system of extreme stringency then you will create a system that is overly bureaucratic, resource hungry and slow to react. Neither will it always ensure that you are in full compliance, or the customer protected.

- At the other extreme, if you operate a system that is too light-touch and hands-off, eventually you will pay the price as issues are not fixed.



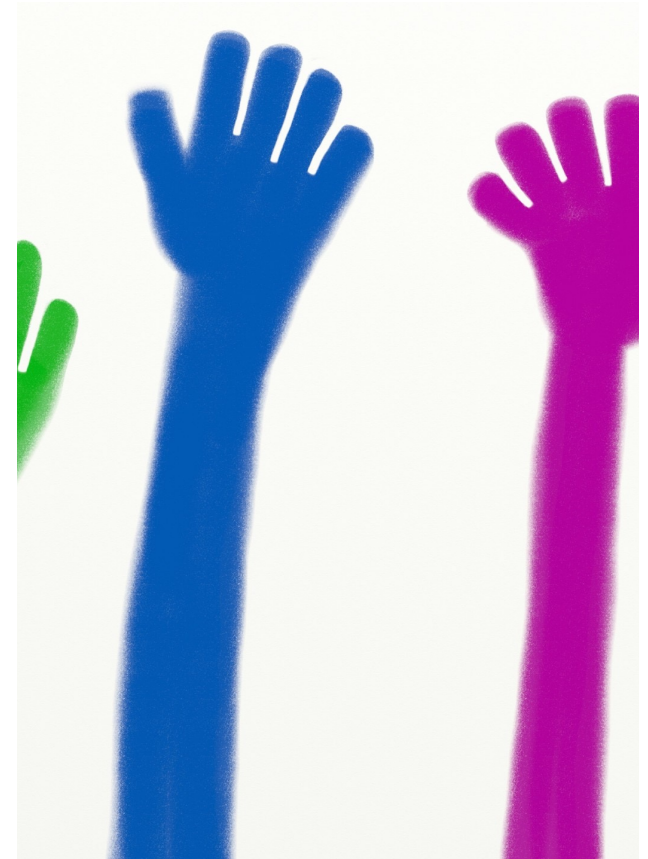
Practical tips

It's a grey area and sometimes you'll get it wrong

Near miss events

- Customer feed-back / complaints
- Audit observations

Organisations that set high expectation of individuals to raise their hands and react to near miss events are more protected, but only when leadership sends a message of expectations that is consistent and constantly reinforced.



Practical tips

Drive risk management approaches down through the organisation.

- Risk management should not be confined just to areas such as New Product Development. It should be part of the whole product cycle.
- Risk management should be embedded throughout the QMS
- Effective risk management is the very essence of quality management demonstrated through acts each and everyday put the customers' of the QMS at the centre of decision making.



Practical tips

Break-down information barriers

- A large degree of protection against abuse of information is gained through critical thinking and reflection.
- You as a leader need to make sure your organisation has the right information, in the right hands, and people are using it to make the right decisions.

Practical tips

Drive a learning environment

- Organisations that set high expectations of individuals to raise their hands and react to near miss events are more protected.
- Leadership needs to send a message of expectations that is consistent and constantly reinforced.



Practical tips

Move decision making down to where the information is.

➤ *'Don't move information to authority, move authority to the information.'*

Chicago. Marquet, L. David. 2015. *Turn the Ship Around!* London, England: Portfolio Penguin.

➤ Ask, " Am I the most appropriate person to be making this decision ? "

➤ Do not micro-manage.



Practical tips

Seek diverse opinions

- Encourage diverse view-points.
- Be aware of my-side bias.
- Diversity is not about just about ethic, gender and sexual equality.

Practical tips

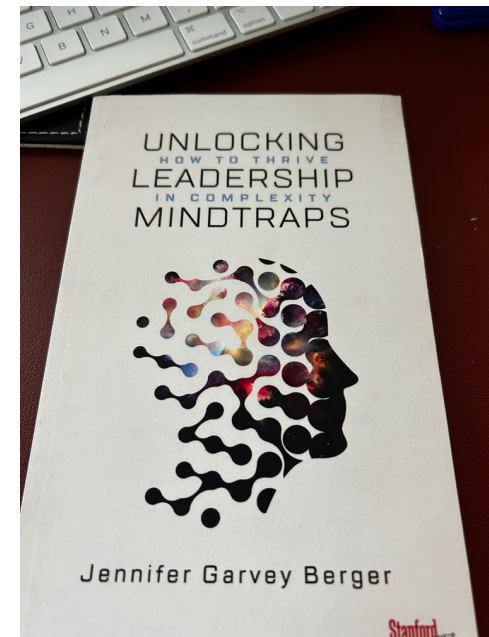
Drive risk management into day-to-day actions.

- Effectively balancing risks with opportunities is the **core attribute** of an effective Quality professional.
- This needs to be demonstrated on a daily basis through the decisions and actions you take and also don't take.



Beware of leadership mind-traps

Mind-trap	Protection
Your desire for a simple story, blinds you to the real one.	Write three different stories.
Just because it feels right, doesn't mean it is right.	How could I be wrong ? Listen to learn, not fix.
Looking for agreement robs you of good ideas.	Encourage conflicting opinions.
Trying to take control strips you of influence.	Stand-back, observe. Experiment.
Shackled by your ego to who you are, you can't reach for who you will be next.	Ask what do I want to be next ?



**A Balanced
Quality
System**



**Managing
Change**



**Balancing
Risks**



**A Quality
Mindset**



People



Process



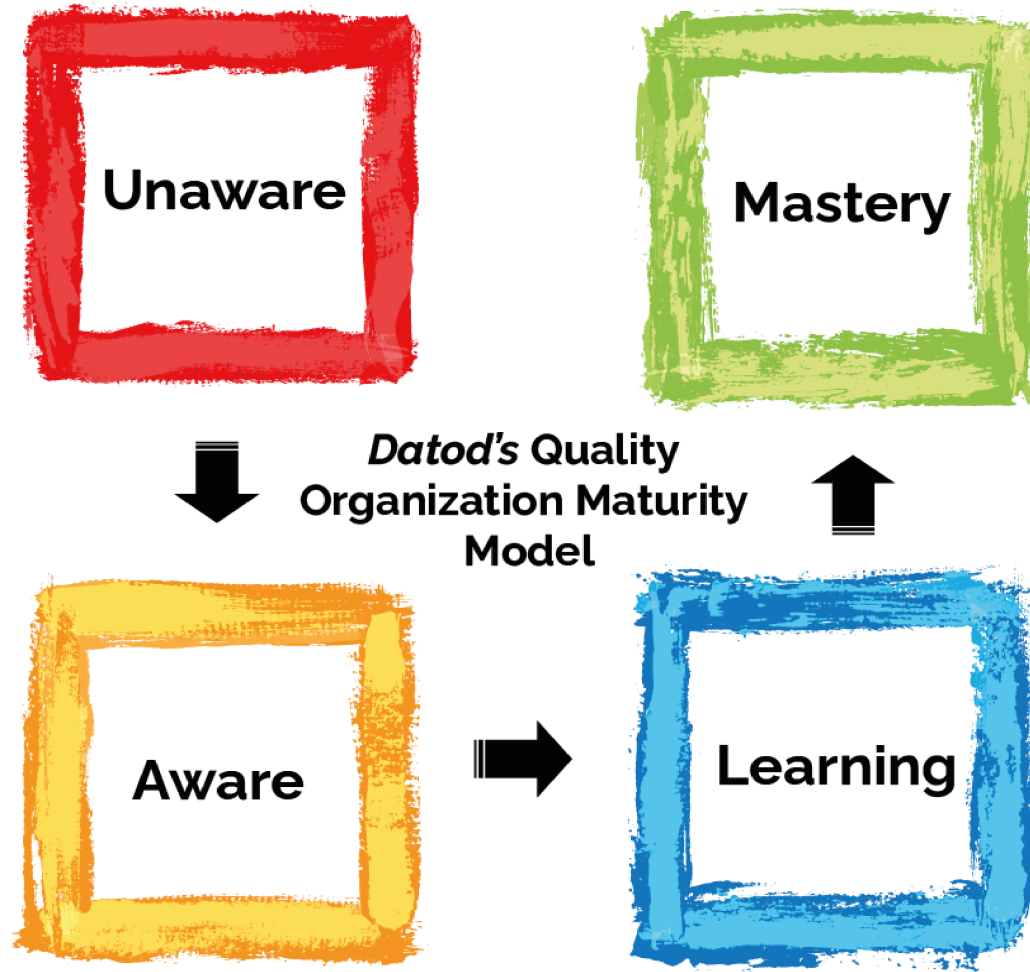
Technology



**Making the
QS work
for you**



Let's look at **Balancing Risks** through the 4 maturity levels.





Your ability to balance risks with opportunities is poor. The use of risk management is largely restricted to areas such as new product development where the regulations mandate such an approach.

There are no documents outside of this area that give guidance on how to effectively manage risk more broadly. Risk management is generally approached from a compliance perspective. The implications of not making a change are generally not considered. When risk is assessed a limited number of perspectives are considered.

Generally, your Quality organization approaches risk from a reactive rather than a proactive perspective. Taking balanced risks is generally not encouraged and you have generally a risk averse culture. As a result, the organisation may be unnecessarily conservative in its decision-making, which leads to missed opportunities.

There is a lack of understanding of how to take balanced risks, which can lead to taking unnecessarily risky decisions or no decision at all. In order to effectively manage risk, your organization needs to develop a more comprehensive approach to risk management with additional perspectives to make better decisions.



- Use of risk management is only restricted to areas mandated from a regulatory perspective.
- There is no evidence of broader risk management approaches and their use.
- Evidence of a risk averse culture within the business.
- Lack of understanding of the appropriate risk management tools and when to apply them.
- Limited formal documentation to help assess risk.

Next steps:

- ✓ Consider application of risk management other than areas it is mandated. Integrate more into all of the decisions you make.
- ✓ Encourage the business to take a more pragmatic approach to managing risk.
- ✓ Create and roll out documentation training around risk management tools and approaches.
- ✓ Seek wider inputs when assessing risk.



Your ability to balancing risks is still basic. The use of risk management is still largely restricted to areas such as new product development and change management. There are no documents outside of this area that give guidance on how risk management can be more broadly applied.

Risk management is generally approached from a compliance or customer needs perspective. The risks of not making a change are generally not considered. There is awareness that the the Quality organization needs to seek additional inputs to effectively assess risk, but this does not always happen.

Generally, the organization approaches risk from a reactive rather than proactive perspective. Taking balanced risks is generally still not encouraged. As a result, the organization may be unnecessarily conservative in its decision-making, which can lead to missed opportunities.

There is also a lack of understanding of how to take balanced risks, which can lead to taking unnecessarily risky decisions. In order to effectively manage risk, the organization needs to develop a more comprehensive approach , one that takes into account all potential risks, both positive and negative. Only then can the organization make informed decisions that maximise opportunity while minimising downside risk.



Aware



Learning

- There is awareness of the need to more broadly manage risk, but little evidence this translates into behaviours and actions.
- Awareness of the potential to use a range of risk management tools but not their application.
- Limited documentation still available to give guidance on assessing risk.
- Leadership articulates the need for a risk based approach but the business struggles how to put this into practice.
- Awareness of the need for diversity of opinion, but challenges in making this happen practically.

Next steps:

- ✓ Expand on the documentation and guidance available when assessing risk.
- ✓ Look at apply risk management from a more proactive rather than reactive perspective.
- ✓ Demonstrate with real examples a pragmatic risk based approach.
- ✓ Continue to seek diverse opinions when assessing risk.



Your ability to balance risks is becoming more effective. It is taking a proactive as well as reactive perspective. Risk management tools are also being used outside the normal remit of risk management.

There is good awareness and use of a range of risk management tools. Though knowledge of which tool is best to use, is at times inconsistent.

Importantly you are considering compliance, customer and cost perspectives during any assessment of risk. You are also aware of the potential harm of not taking action.

Balancing different perspectives is still a challenge. You are more conscious of seeking alternative viewpoints. In addition, you know when to wait to ensure the correct decision is made.

Leadership sees taking balanced risks an opportunity to grow the business and serve the customer and is actively attempting to change behaviours around how risk is controlled, managed and exploited.



- There is both and use of risk management approaches outside of traditional areas.
- A range of documents are available on how to apply risk management effectively.
- Evidence of a broader range of risk management tools in use.
- Clear signals from leadership for the need for a more risk based culture supported by examples of what this means practically.

Next steps:

- ✓ Continue training in risk management approaches and when certain tools are more applicable than others.
- ✓ Leadership to continue to share the power of risk management and to lead by example.
- ✓ Continue to fight against siloed and blinkered approaches when assessing risk. Know when to collect more data, wait to understand issues more clearly and when to act.



Balancing risks is an important part of business growth. Your organization is highly effective at balancing risks with opportunities. Leaders see taking risks as an opportunity to grow the business, serve the customer better, and lead by example.

Employees are encouraged to seek out alternative viewpoints. Decisions are based on a clear understanding of probability and incorrect decisions are learnt from. Balanced risks are taken but not in a reckless manner.

You have a range of documentation in place to guide risk management decisions, and take into consideration the compliance, customer, and cost perspectives when assessing risk. Ultimately, the needs of the customer outweigh compliance and cost implications. However, the company always seeks win-win outcomes for all customer groups.

Risk management is applied reactively and proactively throughout the organization, and is evident in all aspects of the Quality System. employees have a deep understanding of how customer needs drive business decisions. This allows them to make sound judgments that benefit the customer and the company.



- A rich understanding of risk management approaches which are applied regularly in practical and pragmatic ways.
- Extensive documentation and support around risk management approaches.
- Clear evidence of leadership leading by example with practical examples of the power of effective risk management.

Next steps:

- ✓ Consider acting as a resource for risk management capability for other areas of the business outside of the Quality System directly.

Summary

- Effective risk management is your only protection against making stupid and bad decisions that will harm your business.
- Understand the inherent risks within the risk management process ie: bias and overconfidence.
- Embrace diversity of opinion. Temper with critical thinking and reflection.
- Document, document, document.
- Revise, revise, revise.