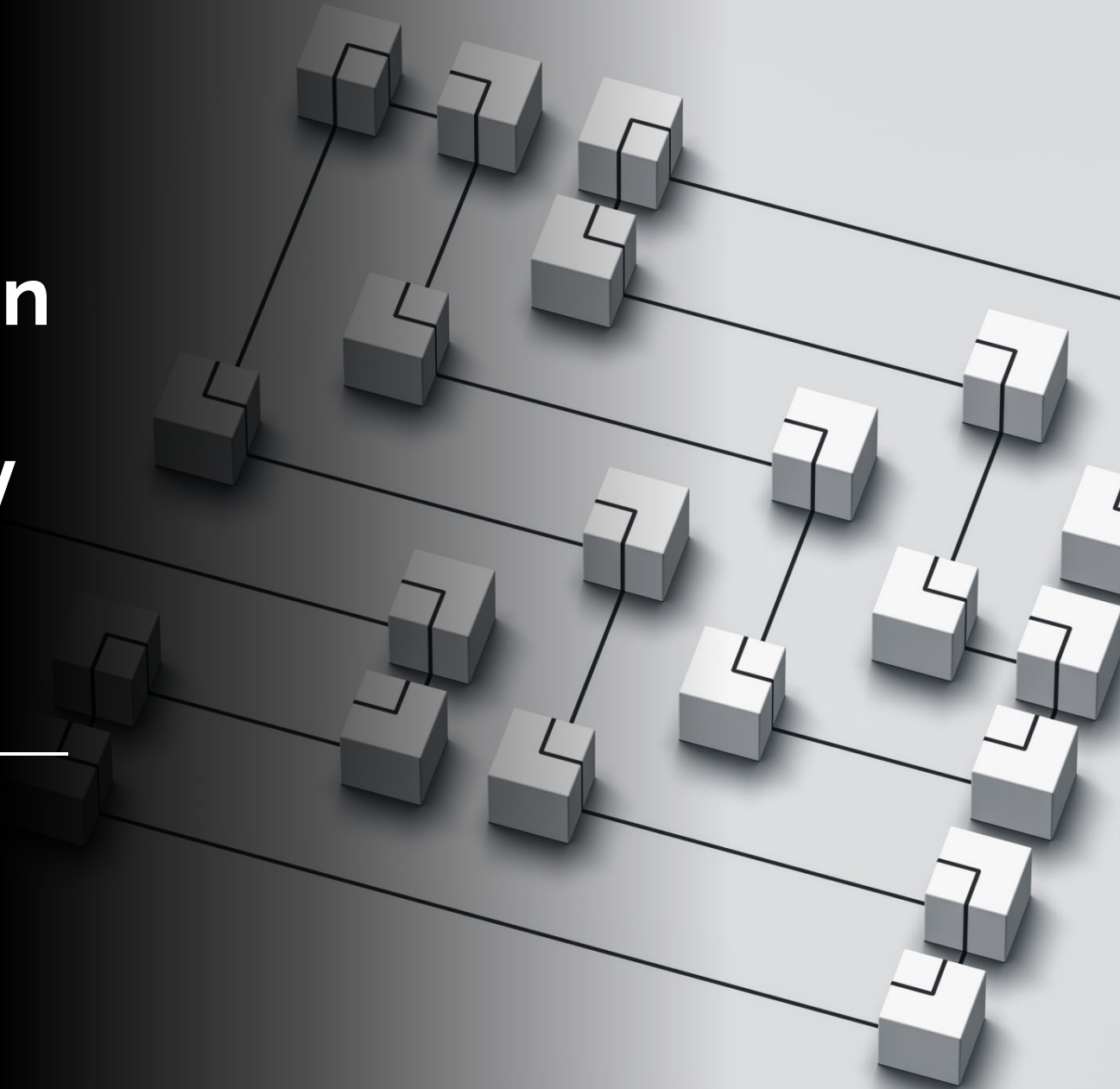




Organization - Technology

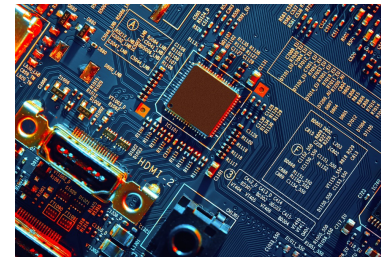
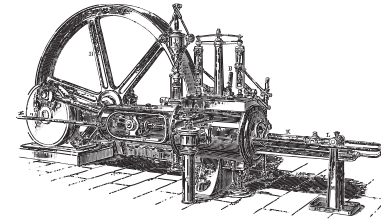




Technology

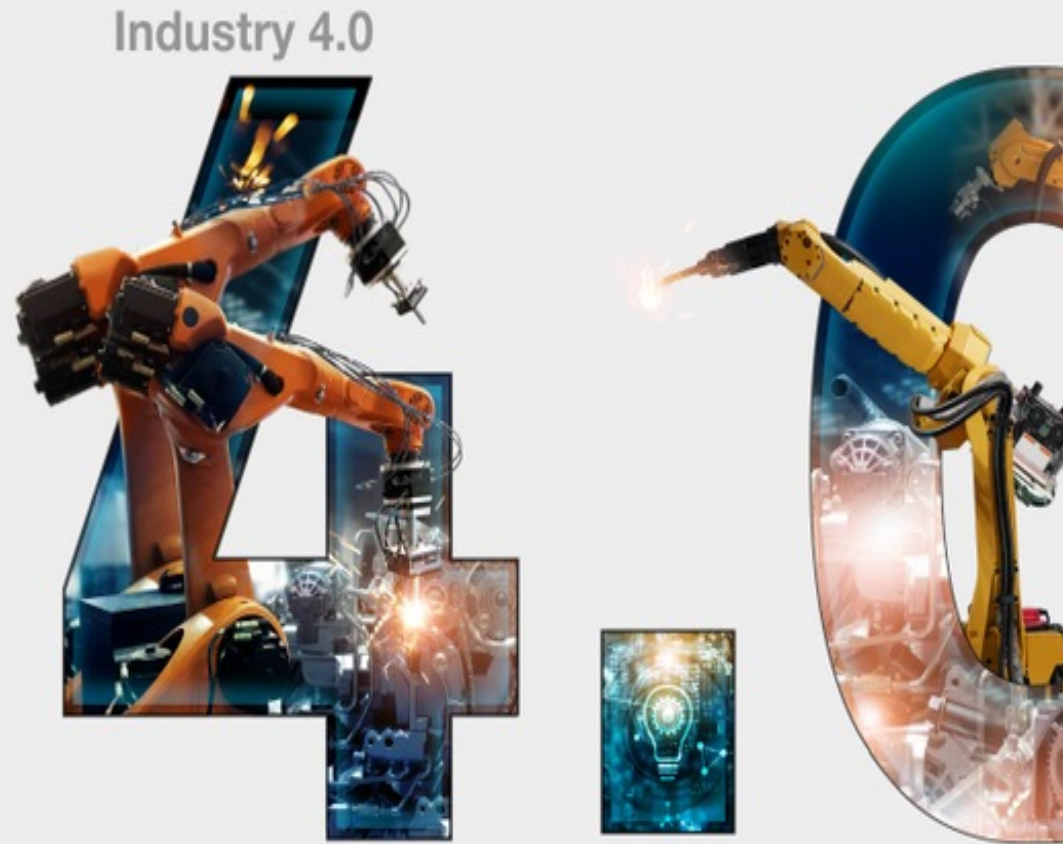
Industry 4.0 ?

- 1st Industrial Revolution
- 2nd Industrial Revolution
- 3rd Industrial Revolution
- 4th Industrial Revolution ?



Industry 4.0

- Identified as a concept by the German government in 2013.
- Use of Big data, real-time analysis, artificial intelligence (AI).
- Generally supported by vendors and consultants with often biased perspectives.
- Hype or truth ?



Industry 4.0

The counter arguments that we are not living in the 4th Industrial age include

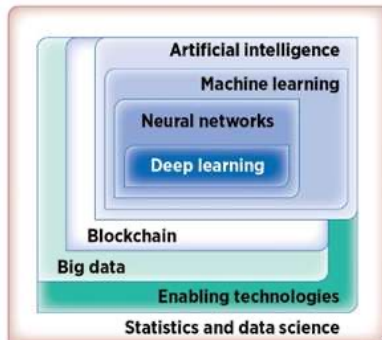
1: Previous ages were spawned by a single technology that created whole new - often unexpected - business models.

2: Only with hindsight is the context and impact of change truly apparent.



Quality 4.0

- Artificial intelligence and deeper statistical analysis
- Real time analysis
- Concept supported by ASQ



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QUALITY 4.0

Quality Glossary Definition: Quality 4.0

Also called: Industry 4.0, digital transformation

Technological advances of the past decade have resulted in a new industrial revolution often referred to as the fourth industrial revolution or "Industry 4.0." It's a revolution driven by the exponential growth of data, the workplace, the workforce, and the markets organizations serve.

"Quality 4.0" is a term that references the future of quality and [organizational excellence](#) within the context of Industry 4.0. Quality professionals can play a vital role in leading their organizations through this transformation.

- [The evolution of Quality 4.0](#)
- [Establishing and implementing Quality 4.0 principles](#)
- [Quality 4.0 tools](#)
- [Quality 4.0 value propositions](#)
- [ASQ and BCG Quality 4.0 study](#)
- [Quality 4.0 resources](#)

THE EVOLUTION OF QUALITY 4.0

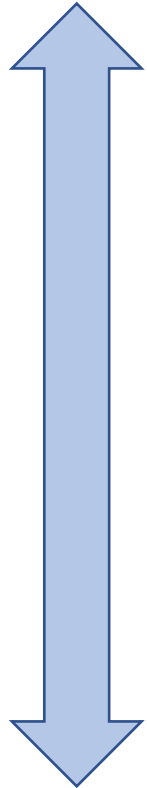
During the first industrial revolution (late 1700s and early 1800s), innovations in steam and water power made it possible for production facilities to scale up and expand potential production levels.

By the late 1800s, the discovery of electricity and development of infrastructure enabled engineers to build machinery for mass production. Iron ore production increased, enabling machines to be built more efficiently.

The widespread availability of reliable power created a resurgence in competition. Toward the end of World War II—around the time when ASQ (then ASQC) was formed—digital computation and automation began to transform manufacturing.

The impact of technology on jobs

Human



Mental:- Innovation, idea creation, judgements based on emotion, feeling

Intermediate:- Analysis, decision making v specifications, activities that at extreme of human capability (surgery)

Physical:- packing, shipping, production

Technology

Data availability:- Internet

AI:- automation of standard scripts:- contracts, reports, analysis, procedures, diagnosis.

Automation:- robotics, mechanisation

Highly-skilled

Semi-skilled

Non-skilled



Impact of AI on the Quality professional

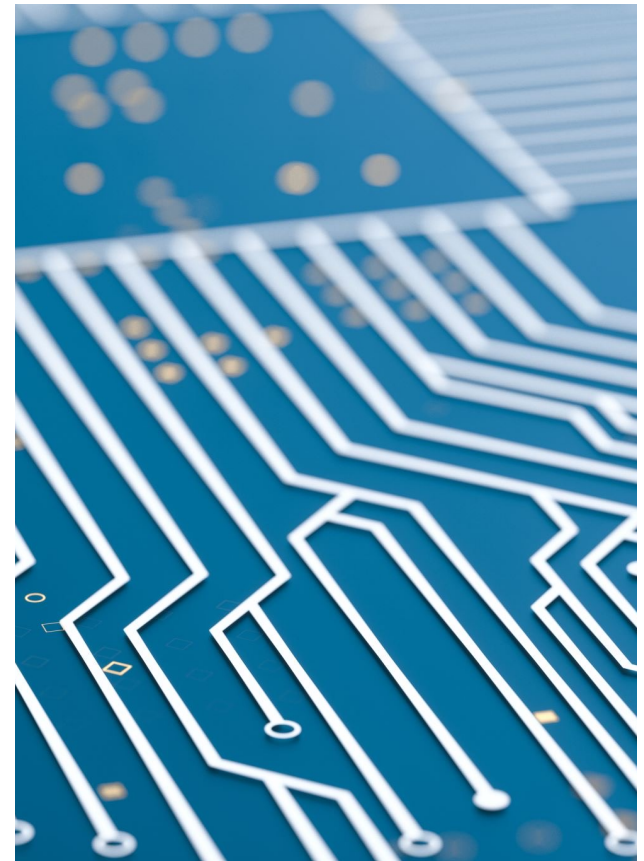
Human

QSM Area	AI replaces	AI augments	AI resistant
Customer feedback	Basic data analysis	Complaint trending in real-time, patterns in data, analysis of qualitative data	Field action strategy:- timings, communications, management of stakeholders
Quality System Management Review	Data presentation / graphing	Capacity mapping, risk profiling, communication of data	Resource allocations, strategic decisions on risk v benefit
Internal audit	Report generation, audit planning	Compliance of procedure v regulations or standard	Compliance of procedure v reality
Design Controls	Physical files for DHF	Gaps in documentation, regulatory submissions, improving process v historical data	New markets, product development, regulatory approval strategies.

Impact of Quality 4.0

Whilst the impact of information technology and artificial intelligence has huge potential to impact the quality system, the primary questions you as a leader probably have when faced with the deluge of information heralding this brand-new age is.

- 1: Will application of approaches defined in Quality 4.0 really benefit the customers of the quality management system ?
- 2: Will the benefits from applying these approaches be outweighed by the resources I have available ?

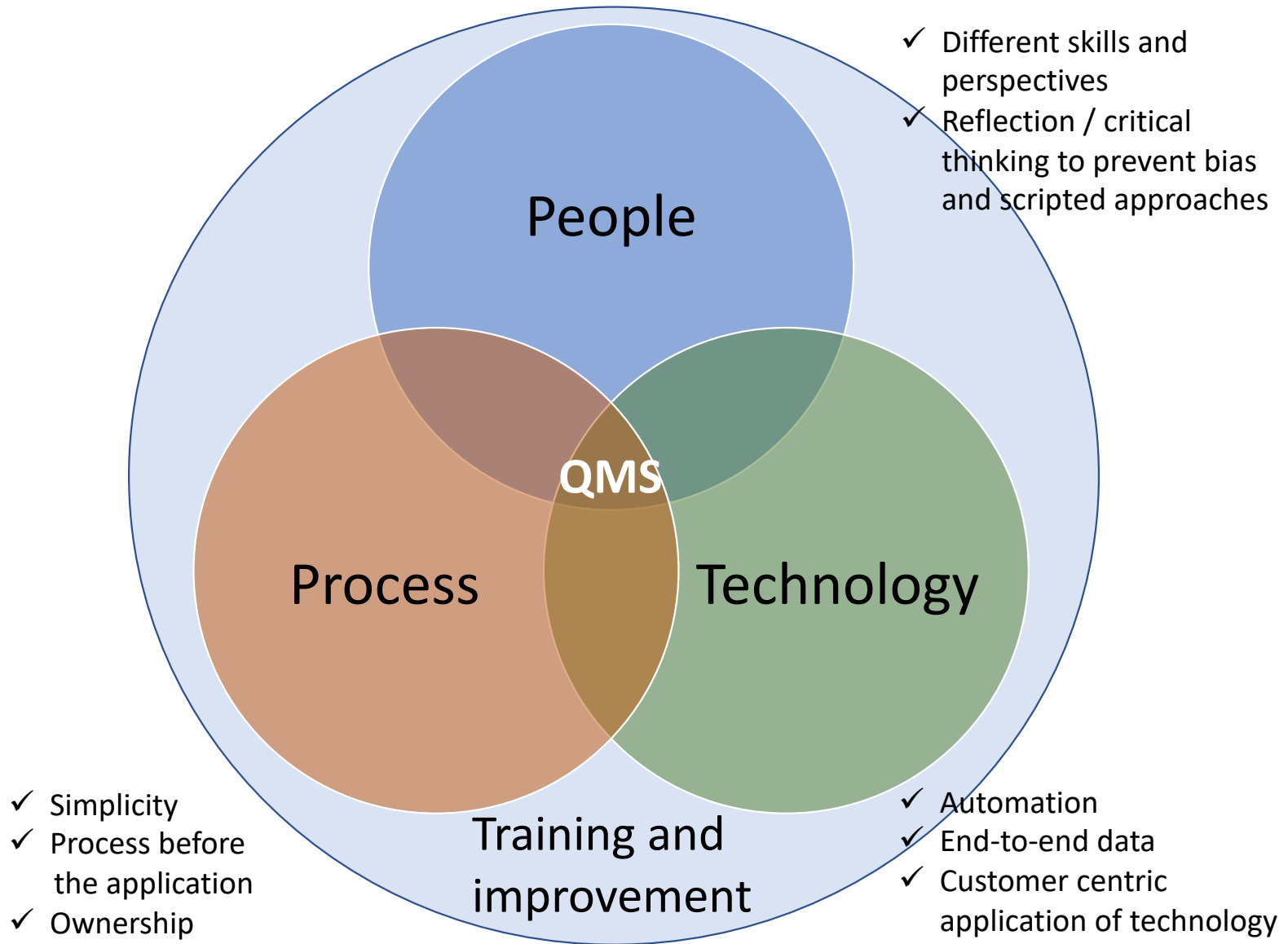




- Apply technology only when it improves your ability to meet your customers' expectations.

Technology

- Technology is only a tool to help deliver value.
- Use eQMS to error-proof, hard-wire approaches, gain efficiencies and allow comparison of data across sites.



**A Balanced
Quality
System**



**Managing
Change**



**Balancing
Risks**



**A Quality
Mindset**



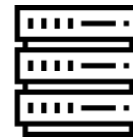
People



Process



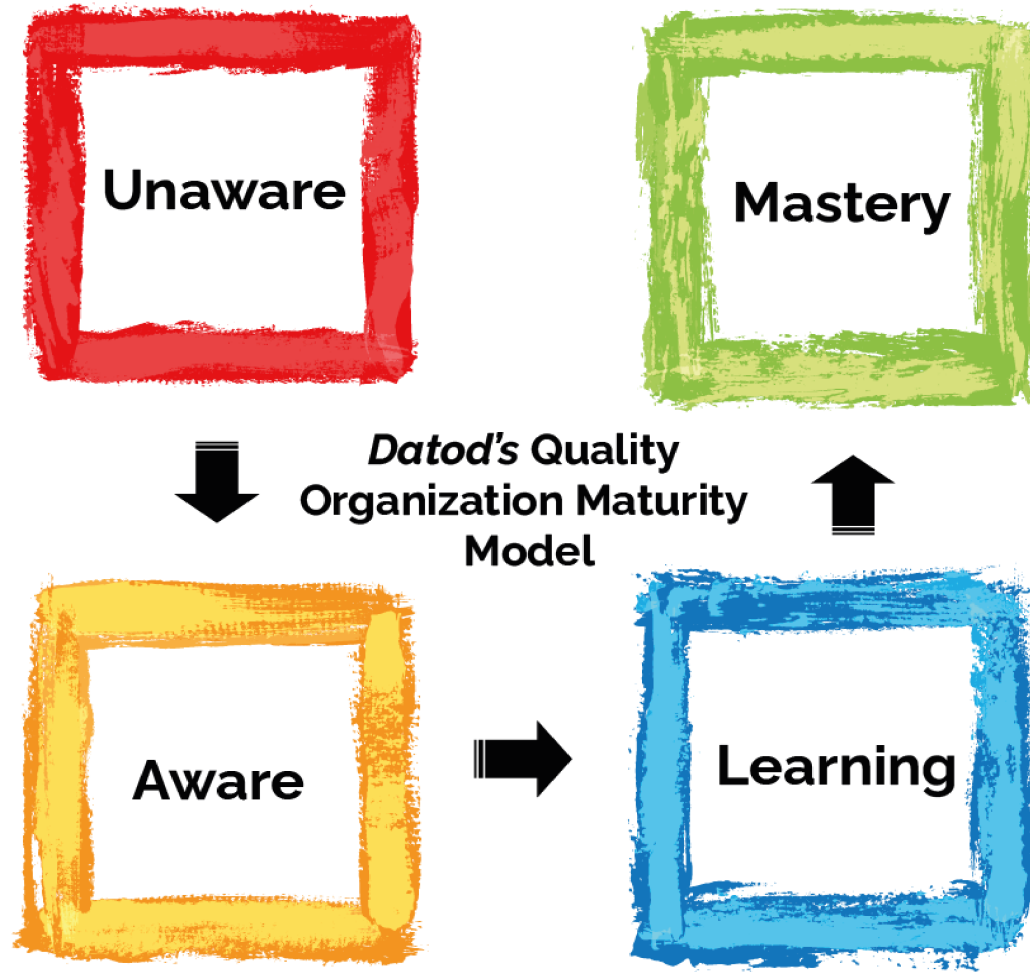
Technology



**Making the
QS work
for you**



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





Your ability to harness technology is poor. Your systems are predominantly paper-based. Though there are electronic systems for the management of documents. Instructions describing the procedures are mainly on paper.

Data is siloed in a range of electronic applications, paper records and spreadsheets. There is extensive transcription of data and the potential for human error. Electronic applications do not meet end-user needs. There is limited capability within the organisation to effectively analyse and exploit data and make appropriate decisions.

There is a lack of awareness and understanding around how technology can be used to improve business processes and create efficiencies. Departments and individuals are not driving demand for technology solutions. There is an over-reliance on legacy systems which inhibits the exploitation of new technologies that could improve productivity and quality of delivery.

There may be a lack of technical skills and knowledge within the organisation which results in a reluctance to adopt new technologies.

In order to realise efficiencies, it is essential that an organization's employees have the necessary skills to use new technologies effectively. Processes must be designed with technology in mind from the outset in order to maximise its potential. A clear understanding of how technology can be utilised must be communicated throughout your organization in order to gain buy-in. Only then can your organization hope to make effective use of technology and realise the efficiencies it promises.



- Whilst documents are held in an electronic document management system the majority of processes are paper-based.
- Data is siloed and often unavailable or potentially corrupt.
- Electronic systems that are available do not meet end-user needs.
- Information Technology generally drives process design irrespective of final customer requirements.

Next steps:

- Complete an inventory of paper-based v electronic systems.
- Start gaining Voice of the Customer for moving processes from paper to electronic applications.
- Begin to invest in capability to exploit the data you have in your organization to better fulfil your customers' needs.



Your ability to leverage the power of technology is still poor. Your systems are predominantly paper-based though there are electronic systems for the management of documents. A number of business systems outside the Quality organisation are electronic. You are aware of the need to better leverage technology to become more effective and efficient and feel you are being left behind. Instructions describing the procedures are mainly paper-based, though some have transactional steps governed by electronic systems. When technology is applied it tends to be an IT driven initiative.

Data is siloed in a range of electronic applications, paper records and spreadsheets. You are aware of the need to better connect data-bases together. There is extensive transcription of data and the potential for human error. Other functions are investing in error-proofing through technology. Electronic applications are not integrated increasing inefficiencies and affecting productivity.

A centralised repository for information does not exist making it difficult to track work progress and measure performance against targets and objectives.

There is an opportunity to improve your performance by better leveraging technology throughout your Quality System. You are at a point where if you do not make investments in technology you will be left behind.



- There is awareness of the need to build a road-map around how best to apply technology to better serve the Quality System's customers.
- Systems are made electronic based on business risk , end user benefit and resources.
- The deficiencies in data-analysis are known.



Next steps:



- Build an actionable road-map to leverage the power of technology.
- Continually articulate that improvements through technology are coming. a path forward.
- Build capability to mine data to better serve customer needs.



Learning

Your ability to leverage technology is becoming effective. There is clear evidence of technology driving better data-driven decision making, which is benefiting the customer. Many processes are paper-based, but there is a clear transformative plan to leverage technology and modernize legacy approaches. Leadership consistently messages the change that technology is bringing to the organization.

There is clear evidence of moving towards a fully integrated eQMS solution, resulting in huge efficiencies and enhancing the ability of individuals to execute their jobs.

Electronic systems have input from end-users during their design and are centered around their needs. IT provide solution delivery, rather than setting user requirements.

Process flow is hard-wired to reduce errors and achieve process consistency. Data is becoming less siloed and more connected.

The capability to analyze and exploit data is more evident. Data is more readily available, allowing decisions to be made quickly and effectively.

The Quality organization is beginning to use technology in effective ways that improve outcomes for customers.



- There is a clear road map of applying technology to meet customer needs and to error-proof and future-proof processes.
- Decisions are driven by customer needs and technology implemented to meet these requirements and expectations.
- The Quality organisation is aware of the plan for remediation and improvement activities underway.
- Leadership continually articulate that improvements through technology are coming.

Next steps:

- Continue investing in and executing your technology road-map.
- Explore ways that technology can better allow the Quality System to fulfil customer needs.
- Continue investing in ways to understand data and turn it into action to benefit your customers.



Your ability to leverage technology is highly effective. There is clear evidence that technology is being used to great effect to ensure that Quality System meets its customers' needs. All electronic systems are centered around meeting end-user needs and the final customers' expectations.

You have more or less moved to an effective eQMS system resulting in huge efficiencies, with resultant compliance and operational gains. Process flows are hard-wired to eliminate errors, deliver process consistency and ensure compliance.

All individuals in the Quality organization are comfortable and confident with the use of technological solutions. New and novel approaches to how technology can deliver for the customer are regularly explored.

Data is connected and moves seamlessly through the Quality System and analyzed in real-time and agile data-driven decision making - benefiting your customers - is clearly evident.

The effective use of technology creates a positive up-beat environment where work is rewarding rather than a struggle to achieve results.

It is evident that technology has been mastered to enhance the ability of the Quality System to deliver value to your customers.



- Data resides electronically in a single eco-system or connected data-bases covering the end-to-end manufacturing or service process.
- Data is both quantitative and qualitative and available at the point of need with no requirement to manipulate further.
- Technology supports effective and swift decision making based on transparent and verified data.
- Technology enhances the ability of the business to meet customer needs and ensure control, compliance and regulatory audit.

Next steps;

- Continue exploring creative ways to leverage technology to allow the Quality System to better deliver for its customers.

Summary

- Harness the power of technology when appropriate.

