Congenius

Congenius Whitepaper

How to maintain an effective QMS

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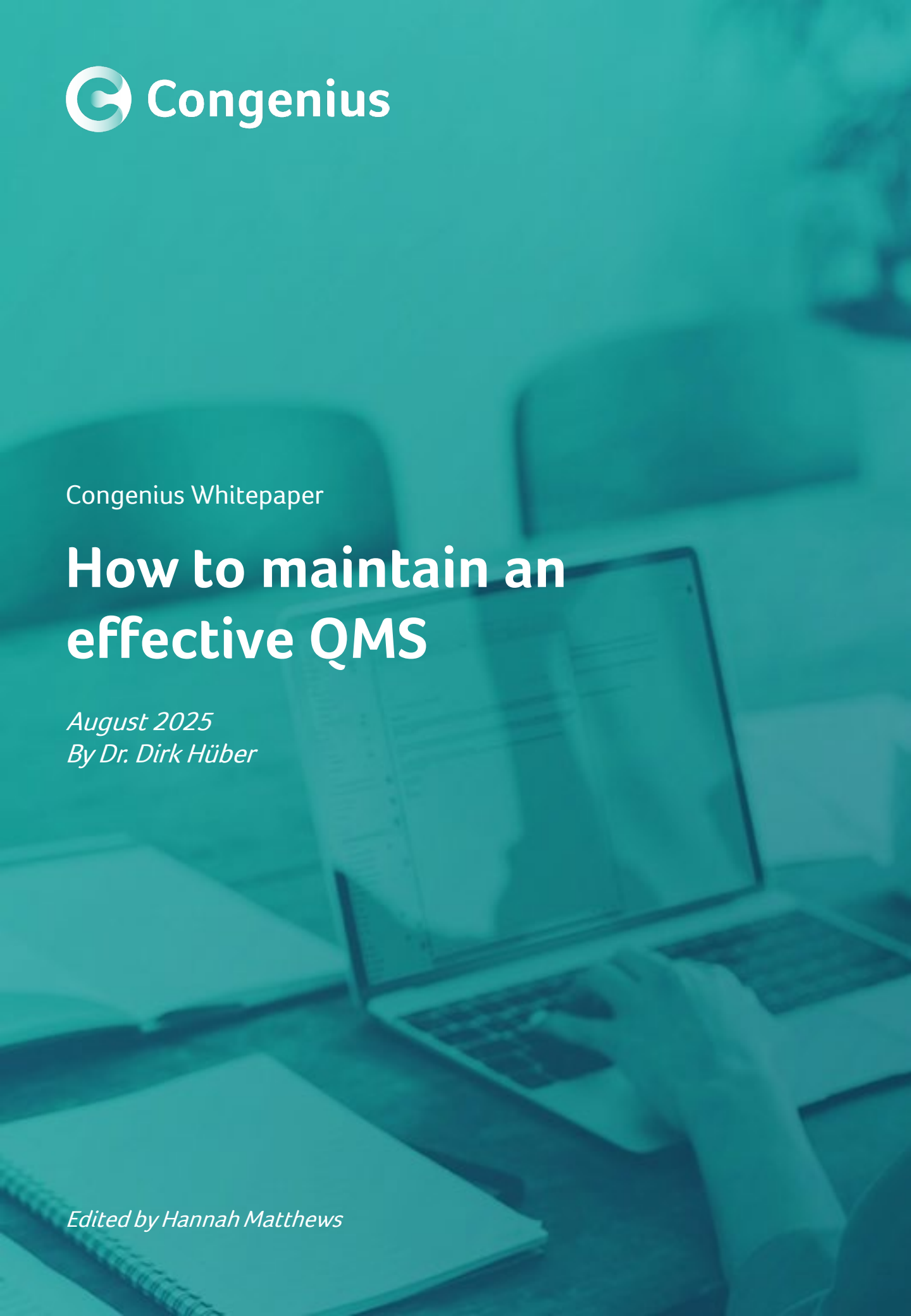


Edited by Hannah Matthews

Introduction

Maintaining an efficient and effective Quality Management System (QMS) over time is a substantial challenge. But what makes it so difficult?

The main reason is that the environment in which a QMS exists is anything but static. The organisation that the QMS serves inevitably changes due to employee fluctuation, business growth, modifications to products and their related technologies, updates to tools and infrastructure, and ongoing evolution of the global regulatory landscape. All of these aspects require the QMS to adapt accordingly - thus, a QMS, by nature, cannot be static.

The challenge for organisations, therefore, is to adapt their QMS to stay efficient and effective during the constant change of its environment.

In this whitepaper, our Head of Quality Dr. Dirk Hüber explores this challenge - unpacking the various difficulties regarding QMS maintenance and discussing strategies to avoid potential pitfalls.

Read on to discover:

What makes an efficient and effective QMS?

What makes an efficient and effective QMS?

The efficiency and effectiveness of a QMS is driven by its users who (easily and routinely) apply its processes.

Therefore, a QMS must address the needs of the users, meaning that the SOPs, instructions, and the forms and templates that constitute the QMS, must always strive to make the life of the users as easy as possible. For the authors writing these documents, this means:

Considering your audience

Is your audience general, or are they specialists? In the latter case for example, one may presume familiarity with certain topics and place less emphasis on these.

Guiding the user

To perform a task, ideally a user should need to use only one document as opposed to several documents in parallel. E.g., to fill a form or template, all information necessary should be in the form or template as guidance (e.g., blue text in Word), without needing to consult the SOP or instruction to which the form or template belongs.

Only providing information necessary to follow the process or the instruction

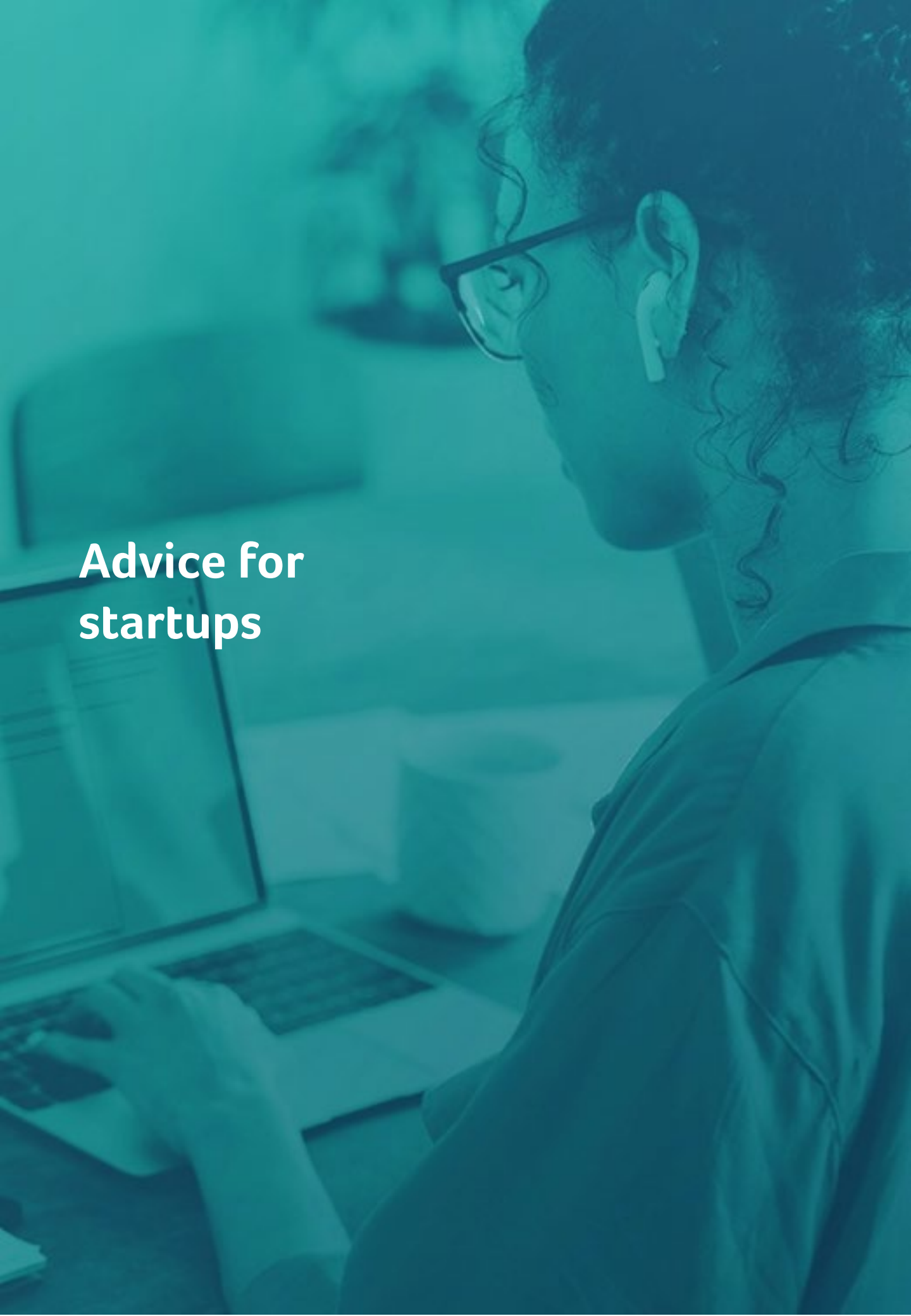
Keep it as simple as possible, and as detailed as necessary.

Providing flexibility to address new or unforeseen situations

Thereby considering the maturity and experience of the users.

Of course, in our regulated world there are also formal aspects that must be followed. However, formality is never an end in itself. If you introduce formal rules, always first seek to understand the value of such, and then implement so that maximum value can be achieved with minimum effort.

The one guiding principle to make a process efficient and effective is to answer the needs of the user, i.e., what does the user need to live the process in an efficient and effective way? As such, the user of the process is the best information source when properly designing your processes.



Advice for startups

Advice for startups

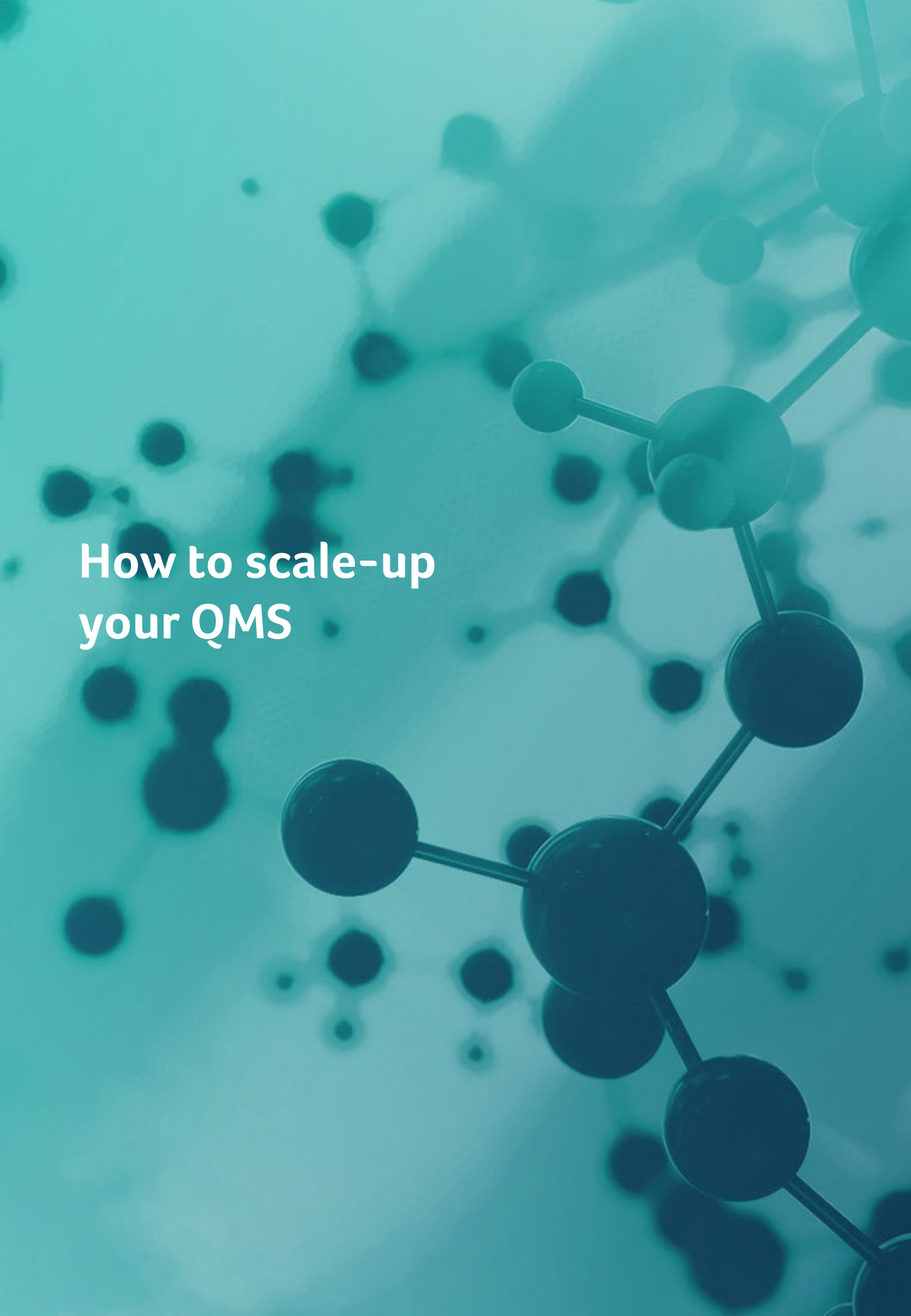
For a small company or a startup, efficiency means a limited number of simple, straightforward processes, which only include the essentials and often little detail.

This is justified because in a small organisation it is easy to communicate between all functions (which are often represented by a single employee); thus, many details may be left to informal communication.

Nevertheless, even in a simple QMS with only a small number of SOPs, structure is still important. Structure helps to understand the interfaces between the processes and helps to maintain an overview should the QMS need to be extended.

The easiest way to define a structure for the QMS is to follow the structure of ISO 13485, as this standard for medical device QMSs is globally recognised. Other applicable standards (e.g., ISO 14971) or requirements for the QMS in regulations (e.g., in MDR, MDSAP, or other country specific requirements) can then be integrated into this structure seamlessly.

To build and maintain a simple QMS and ensure its efficiency and effectiveness, a good understanding of the requirements and processes in a medical device QMS is essential. To live the QMS, the organisation needs a certain amount of such understanding as well - thus, education and training on these topics is important to fill any knowledge gaps, and it's worth having at least one person on the team with a decent understanding of the specific requirements and processes in a QMS for medical devices.



How to scale-up your QMS

How to scale-up your QMS | Business growth

The growth of a company and its business may happen within various areas:

- Increase in product volume
- Growth / diversification of organisation
- New markets
- New sites (in other countries)

Increase in product volume

An increase in product volume means an increase in the same work, to be performed by an increased staff. This usually requires a higher formalization of the processes affected, so that the growing staff, sometimes less experienced than the original staff, may perform their tasks in the same way and with the same quality as before.

The challenge is to find the right balance between the required formalization and sufficient flexibility. Implementing bureaucratic rules will not ensure compliance and quality - it'll actually create new problems. Instead, a plan is needed for consistent training and support of new staff while they are adapting to their new jobs, to help them understand what is expected from them, and why, as well as a strategy for ensuring quality while the new staff is still adapting and learning (e.g., via additional temporary controls).

This aspect becomes especially important with fast growth or in areas with high fluctuation.

How to scale-up your QMS | Business growth

Growth / diversification of organisation

As your business increases, and with it the staff performing all the tasks that support the business, sooner or later a specialisation of tasks is the consequence. Whereas in smaller companies few employees perform a multitude of tasks, in larger companies more employees perform specialised tasks. The organisation's personnel shifts from generalists to specialists.

A consequence for the QMS is that more specific processes are developed that describe in more detail the tasks the specialists perform, often with the intention of having more control over the growing number of employees. Often, this leads to functional instructions instead of interlinked processes, and the interfaces between functions and their tasks break up. In the long term, this can cause inefficiency and frustration.

To avoid this from happening it is important that strict oversight over the QMS is implemented by a competent person with very good process and holistic system understanding, who will challenge overly detailed instructions within the QMS. Formalism should only be implemented where it creates value, not to regulate and control employees in their tasks.

How to scale-up your QMS | Business growth

New markets

New markets can potentially lead to additional requirements both for the products themselves and also for some processes. Often it will be possible to fulfil additional process requirements with existing processes by just adding a little explanation or adaptation in terminology, without substantially changing the tasks nor the evidence for the process.

However, the dossier submitted to the competent authorities for registration in a new market might require the creation of new documentation or adaptation of existing documentation. If so, such documentation should always be created from existing information, only presented in a different form. The best way is to set up a modular approach for your technical documentation for the different markets (for more information on creating technical documentation, see our whitepaper here).

For a well-designed QMS, entering a new market should not require any major change to its processes as such, but at most some adaptation to terminology and just some new forms or templates.

How to scale-up your QMS | Business growth

New sites

Implementing a new site, usually to increase manufacturing capacity, poses several challenges – but for the purpose of this whitepaper, we'll focus on those related to the QMS.

Even though the processes should be the same at all sites (regardless of whether they are under the same QMS certificate or if they have their QMSs certified separately), the local environment often requires some variations for local implementation. Such variations are not only caused by the need to translate process documents into the local language, but also by differences in culture, organisation, or equipment and tools. Therefore, the implementation of local instructions for global SOPs might become necessary.

Another challenge is the global governing of the QMS processes. To achieve alignment between different sites, regular exchange between global functions is necessary. This includes collecting feedback from the local sites on the global QMS processes and involving local stakeholders in maintaining them. Only in this way can a mindset of one global company, working together, be achieved.

Of course, these challenges become significantly more demanding in cases where an existing site or company is acquired and merged. In these scenarios, it's not only two QMSs with their processes that meet and must be aligned, but also two different cultures and mindsets.

How to scale-up your QMS | Product evolution

The extension of the product portfolio can take place at different levels:

New variant of an existing product / platform

New product, using the same basic technologies in manufacturing and the product itself

New product employing new technology

New variant of an existing product / platform

For a new variant of an existing product, be it derived directly from an already existing product, or from a platform, the QMS processes must be able to maintain variants in an efficient way. This includes, but is not limited to, configuration management, maintaining the technical documentation (especially for shared documents), addressing complaints, nonconformities, and CAPA across all affected variants, and implementing changes across variants.

The more variants there are, the more complex these tasks become. Thus, one should develop approaches early on for how to deal with these topics in the most efficient and cost-effective way (e.g., core platform validation). If, due to the number of variants developed, these processes have already become inefficient in satisfying your organisation’s needs in a timely manner, any improvements will become rather costly.

New product, using the same basic technologies in manufacturing and the product itself

The development of a new product based on the technology already employed for existing products, does usually not require any adaptation of the QMS.

How to scale-up your QMS | Product evolution

New product employing new technology

If a new technology becomes employed, you must first check which process standards apply to the new technology. The requirements of such process standards should then be implemented in the respective processes of the QMS.

The more a new technology deviates from already employed technologies, the more likely the regulatory process requirements as well as industry practice may deviate from already established QMS processes.

For clarity and ease of use, in such cases we recommend developing technology dependent (sub-) processes. Where different technologies become employed within one product, an overarching process might be required that describes how the different technology dependent sub-processes interact and align. This is the case, e.g., for the development process of electromechanical devices, which contain mechanical parts, electronics, and firmware, thus employing three different technologies requiring three different development approaches.

To achieve such an expansion of the QMS for new technologies in an efficient and seamless way, one should anticipate this in the structure of the QMS and build the QMS in a modular way wherever technology-dependent aspects may come into play within the QMS processes.

The importance of process thinking

The importance of process thinking

To effectively master all the topics mentioned so far, there is one indispensable ingredient: process thinking. Process thinking means the ability to:

Oversee the whole network of processes.

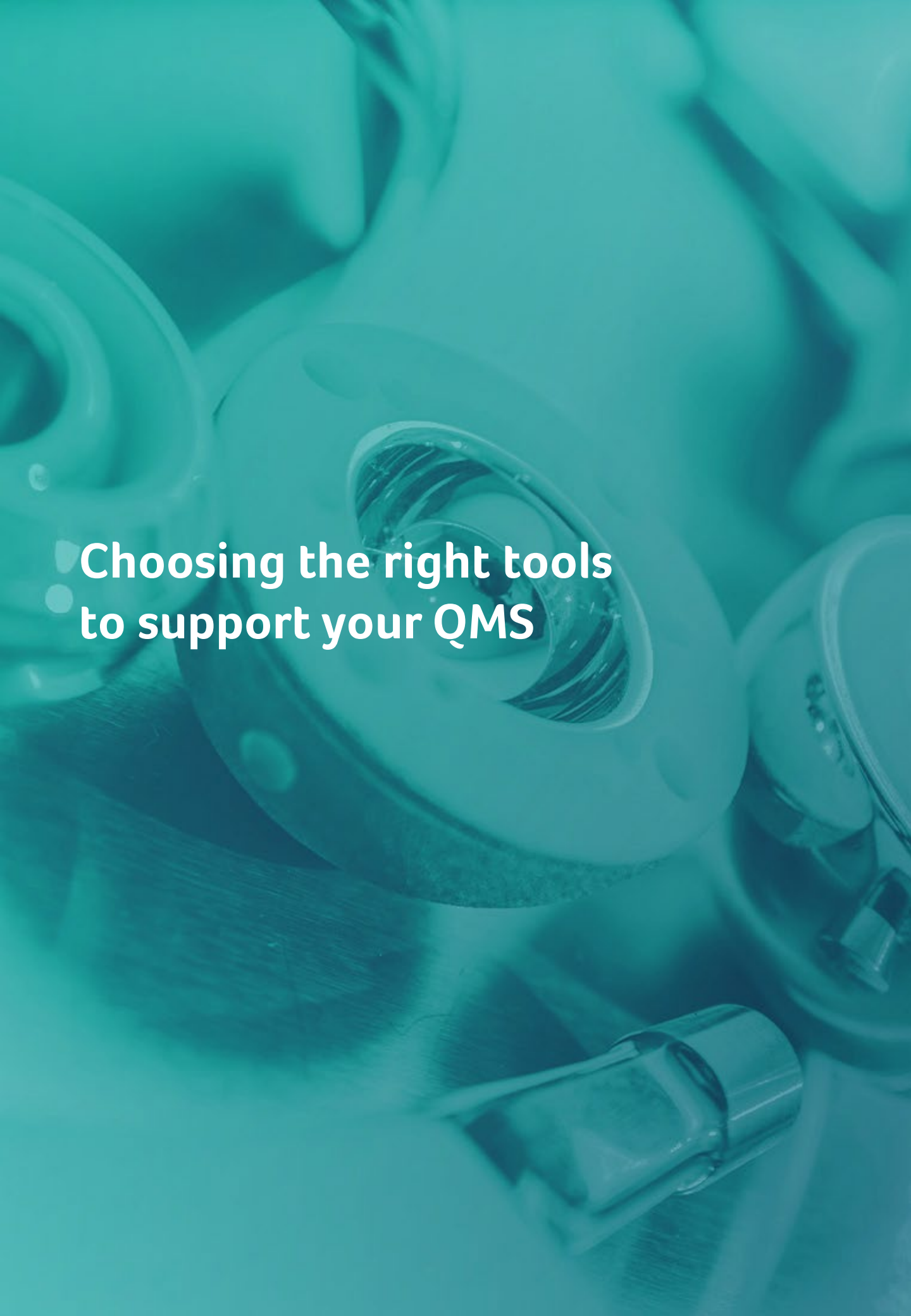
Understand its node points and the respective interfaces for each process to understand its essentials and how it contributes to the success of the organisation.

Know what it takes to implement a process and its interfaces effectively and efficiently, i.e., understand the user needs and how users think, act, and react.

Process thinking is demanding and therefore, unsurprisingly, rather rare. However, it is fundamental for achieving process excellence. Thus, the function responsible for maintaining the QMS (often “Quality Systems” or “Quality Management”) should have a member capable of process thinking, to support process owners and to oversee the holistic QMS.

Besides that, the compliance experts should read the Annexes of the standards which explain the ideas and intentions behind a standard. This helps to proactively get a start in understanding the process aspects of a standard that regulates the QMS. It is not so important to know the regulations and standards in all their detail, but rather to understand what they intend to achieve.

As experience shows, a formalistic approach to the QMS always leads to a formalistic QMS - which is ineffective and inefficient, even though it might be (but is often not) formally compliant. We will revisit compliance towards the end of this whitepaper.



Choosing the right tools to support your QMS

Choosing the right tools to support your QMS

This chapter explores the tools that support the QMS and its processes and discusses aspects to consider in their selection and application.

Business process tools

Business process tools are boon and bane at the same time. Boon because they can help with designing the processes in a QMS and understanding how these processes interact - as well as exhibiting this information to users in an interactive graphical way. Bane because business process tools often lead to complex, overloaded process representations that overstrain the normal user (including many process owners) and therefore make a QMS less transparent instead of more so.

This contradictory situation can be resolved by revisiting the initial user need that the business process tool was intended to address; providing users an easy overview of each process within the QMS and its interfaces to other processes.

To achieve this, the graphical representation of a process must focus on the essentials – not every detail - of a process. Practice shows that this goal may be achieved by limiting the graphical representation of a process onto a single A4 page if printed, with (if any) only a few connectors between process steps that cross each other.

If this is achieved, the graphical representation of a process can be grasped by a normal user. Practice also shows that such a reduction to the essentials is always possible, even for the most complex processes. However, it does require experience and deep process understanding.

Therefore, designing a process with a business process tool should be done in a workshop with the process owner and the key stakeholders and be moderated by an experienced senior person with strong ability in process thinking. For a complex process, several workshops with a total of 6-8 hours might be required; for simple processes, a single workshop of 2-3 hours is sufficient. In any case, the process owner and the key stakeholders will have acquired a much better understanding of their process after such workshops have been held.

Choosing the right tools to support your QMS

Electronic process tools

In this context, “electronic process tools” refers to digital tools which support certain processes within the QMS, like Document Management Systems, eQMS tools, or tools and toolchains used in product development.

Nowadays it is almost unfeasible to operate the processes within an organisation, including those that implement certain processes of the QMS, and to maintain the output documentation, without the help of electronic tools. This goes far beyond tools for classical quality management processes like document management, change management, or NC & CAPA management; engineering is now unthinkable without electronic tools, and the same goes for manufacturing, material management, or logistics. All these and additional processes are essential parts of the QMS.

However, while on the one hand, managing and operating many processes without such electronic tools would be outright impossible, all too often the tools become a burden to users. Interestingly, this is more often the case the more a process is driven by the quality department – whereas, for example, tools in the toolchain for software development are usually perceived by the software engineers as reasonably user friendly, tools for change management are often not perceived that way.

The reasons for this are varied, but they may always be traced to the same root causes:

- Users are insufficiently involved in selecting and setting up such tools
- Thus, formal compliance and technical IT aspects dominate the decision for a tool

However, especially for processes that are often applied by non-experts, an electronic tool should give clear user guidance, both in help texts and in its structure.

To identify a user-friendly tool that fits into the existing IT landscape, can be validated and maintained with reasonable effort, and still has the flexibility to become adapted to the needs of the organisation without being cost and effort prohibitive, is a challenge – but a challenge that must be overcome to obtain electronic processes that are both effective and efficient – the latter in application as well as financially.

Choosing the right tools to support your QMS

Embracing Artificial Intelligence in electronic tools

Modern electronic tools often contain functionality based upon artificial intelligence (AI) and / or machine learning (ML). Such functionality can be very helpful e.g., for routine tasks or data analysis.

The following aspects should be considered when employing AI or ML functionality:

Is the system open, or closed to your organisation only? In open systems, all data provided e.g., in prompts, are publicly known.

Is the model on which the algorithm is based appropriate for what it is intended to simulate and / or analyse? And is the model validated to be representative for the aspects of the real world it is supposed to represent?

Do the data on which the model is trained fully represent the aspects of the real world which the model shall simulate and / or analyse? This question applies especially to data that only rarely occur in the real world and therefore might even not be known to exist.

Are the training data validated to be correct? Training data for AI and ML models are usually tagged by humans to enable the model to identify the elements it is supposed to learn. This can result in tagging mistakes, as well as bias in the training data, including, but not limited to cultural bias. All AI or ML systems (including so-called generative systems) are essentially machines that extract human knowledge. As human knowledge is inevitably biased, bias in AI and ML system results is unavoidable. AI and ML based software is only a data-based system – therefore, the quality and correctness of the training data determines the quality and correctness of the output of an AI and ML system.

Is output provided by the AI or ML system verified or its plausibility checked by a human?

Are decisions taken by humans based on the verified output of the AI or ML system? If decisions are taken by the AI or ML system, what is the risk connected with those decisions?

Those aspects mentioned above that are not under the control of the organisation using an AI or ML system, but under the control of the vendor, should be clarified during the assessment of the AI or ML system and its vendor.

Adapting to regulatory requirements

Adapting to regulatory requirements

The ever-changing regulatory environment has a significant influence on the QMS and how it should be maintained. Here are some tips for how to adapt accordingly:

Re-think rather than "patch"

As regulatory requirements evolve, it is challenging to incorporate new or changed requirements into QMS processes such that they remain efficient and effective. Instead of applying piecemeal solutions to the affected processes, a better approach is often to re-think the processes and determine which parts of a process require a re-design. The goal is to find the right balance between keeping proven practices as far as possible and defining new ways of working, so that the resulting process is smooth and efficient.

Prepare to update your existing product records

Another aspect within this context is the updating of existing product records to meet new or changed regulatory requirements. There is no simple answer for how to perform this in the best manner. Rather, each case needs to be analysed individually. A basis for such an analysis is to understand the intention of the new or changed requirements and the value they might add to your products and their documentation. From this, an efficient strategy might be found to update the affected product records – but this isn't always possible, so be prepared for the potential workload.

Implement a regulatory vigilance process

To support both aspects above, a regulatory vigilance process is required. This includes monitoring the applicable regulations and standards with regards to planned and implemented changes, reporting of these to stakeholders (formally, usually in management review), evaluation of planned and implemented changes by the process owners, and if required based on this evaluation, planning, implementation, and monitoring of implementation of any changes to QMS processes and product records which may be necessary.

Why company culture and mindset are essential

Why company culture and mindset are essential

To reiterate, an efficient and effective QMS is made by its users – the employees of your organisation. Therefore, an important ingredient necessary for maintaining a QMS effectively is the culture and mindset within your organisation with respect to compliance and quality.

If the mindset and culture is focused on formal compliance and control, the QMS will become inefficient and usually also ineffective. Such a situation is often a reaction of the quality employees to marginalisation by top management. When this happens, quality staff tend to retreat to formal compliance and control. Resulting, Quality is then perceived as a hindrance by other functions, which prompts a self-reinforcing cycle of marginalisation.

If, however, Quality is perceived by the organisation as a support in daily business, with other functions taking responsibility for their own work, quality and compliance can be achieved with much less formal control – leading to a more mature organisation, creating real value for the business. This can be accomplished by hiring key personnel with the right attitude, but a fundamental driver is the attitude of top management and what they exemplify with their daily behaviour.

The optimum mindset is one that strives for effectiveness and efficiency throughout the whole organisation. If this is achieved, compliance, to a large extent, is a given - provided the intentions of regulatory and normative requirements are well understood.

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Should you have a QMS challenge, our Quality team can help.

Simply get in touch to start the conversation.

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