Congenius

Congenius Whitepaper

Quality Culture & Quality Transformation in the medical device industry

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1. Introduction

Introduction

> “Nothing is as steady as change.”

A successful business must constantly adapt to a changing environment. Markets, economic and political frameworks, technology – they permanently undergo change. Business leaders and managers know this and act accordingly by initiating change in strategy, organisation, or within product portfolios.

But there is an entity that often enough flies below the radar, and whilst overlooked, is equally important for the success of a medical device company. That entity, is **Quality Culture**.

The Quality Culture within a company is often not conducive to fostering success, frequently focused on formal compliance, but falling short of supporting the other needs of the organisation.

In this whitepaper, our Head of **Quality** Dr Dirk Hüber identifies and describes the common visible symptoms for such a situation, discusses some of the typical causes that lead to a sub-optimal Quality Culture, and outlines a proven approach for how to sustainably achieve **Quality Transformation** in an organisation.

The approach for such a transformation must be well-balanced between **evolution** to engage stakeholders (i.e., organisational development), and **revolution** to create disruption (i.e., change management), in order to accelerate the transformation so that it may be achieved within a reasonable timeframe. Such a combined approach is also called process transformation. We use the term **Quality Transformation**, because the cardinal point of our approach is Quality, and the associated culture within an organisation.

Pre-reading note

This whitepaper builds on the concepts introduced in our 2022 article on **How to achieve successful quality improvement**.

2. Why is Quality Transformation needed?

Why is Quality Transformation needed?

As consultants, we have exposure to organisations that develop diverse product portfolios, and vary in size, setup, and maturity level. We work with many different people, within varying company cultures. Yet, within this kaleidoscope we recognise a pattern: in a well-led and well-managed company:

- The **vision is clear and understood**, both internally and externally;
- The **strategy is adapted to the organisation's current needs**; and
- The **products are successful** and fulfil the customer expectations

These factors are constantly monitored and adjusted if needed. But whilst everything can seem to be perfectly in order, in most companies we know, it is not. Typical symptoms that demonstrate there's something amiss include:

- Projects often **missing timeline and budget**, especially for new types of products
- **Too many tasks / projects** running in parallel without allocated segregation
- Efforts for quality and compliance having the **wrong focus**, with less effectiveness and efficiency
- **Tensions** between Quality and other functions
- **Too many observations** in audits from regulatory authorities and customers
- Too many **complaints**, **nonconformities**, and **CAPA**, some of them reoccurring
- Too many **deficiencies in submissions**

Of course, there may be other symptoms, but in most companies, one sees at least some of those symptoms outlined above, or similar. The consequences of such symptoms may be quite severe: less efficiency, increased costs, employee fatigue, later market access with loss of money, increased efforts and costs for addressing compliance issues, and, although not always obvious, quite often a decrease in product quality over time.

Similarly, as these symptoms form a typical pattern in many companies, the causes behind such symptoms show a typical pattern as well. In order to take effective action, one must identify the root causes before taking corrective measures. Thus, let us now explore the typical causes that may lead to such symptoms.

3. Potential causes for a sub-optimal Quality Culture

Potential causes

In the following pages we discuss causes (or rather cause chains) that we often see in practice.

The causes mentioned do not form a complete list, however, they are, according to our experience, causes that most likely contribute to such symptoms that indicate something is not as it should be.

Still, it is worth noting that in reality there is usually not a single cause, but a mixture of various causes. In fact, the causes often reinforce each other, potentially leading to a self-reinforcing downward spiral.

So let us explore a few typical causes in different areas and dive a little into the cause chains in order to understand what is behind the symptoms we have described in the previous section.

In the next pages we unpack the following potential cause chains:

- **Wrong self-conception by Quality**
- **Poor decision-making**
- **A QMS grown over time**
- **Very detailed processes**

Potential causes | Wrong self-conception by Quality

The Quality organisation in a medical device company has two roles to play: Quality has a control task but should also serve as a support function.

Often, the control role far exceeds the support aspect: quality personnel take on the role of quality police and thus become part of the problem.

Instead, Quality should be part of the solution - supporting the organisation to overcome challenges and solve issues. In doing this, the Quality function becomes increasingly respected and trusted, and other functions will be encouraged to proactively approach Quality in case of issues. Consequently, much less control is needed, and the support role of Quality becomes more dominant. Accordingly, the Quality function will be able to increase the quality awareness and mindset within the whole organisation.

So how does one facilitate the shift of a company's Quality function from a controlling entity to a supportive one?

The representation of Quality in top management is crucial.

If Quality itself is not represented in top management, e.g., by a CQO, but rather by another function, e.g., a COO, the perceived importance of Quality may fall into question. This can negatively affect respect for the Quality function from other departments and can also be detrimental to the self-respect of Quality employees, who may resort to defensive and "controlling" behaviour. To facilitate mutual respect and support, and to avoid a "them against us" situation, it is crucial to ensure specific representation of the Quality function in top management. A lack of representation may make it difficult to attract experienced senior Quality personnel, which leads us to our next point:

Employing Quality professionals with relevant industry skillsets will facilitate respect.

To be respected by other functions, Quality employees must understand to some extent the subjects they are to oversee from a quality perspective. For example, a quality engineer should be able to have eye-level discussions with a product or process engineer – meaning that the quality engineer should be at least as qualified as the product or process engineer, and able to tackle a range of technical topics and regulatory challenges in addition. Ensuring your Quality team is formed of qualified and experienced individuals will help encourage mutual respect across your organisation's departments, and in turn, facilitate a supportive Quality culture, improved employee retention, and ultimately, greater business success.

The Importance of Leadership

The decisions taken by management play a fundamental role in ensuring a supportive Quality culture.

Potential causes | Poor decision-making

Another common cause for the symptoms we have previously described is poor decision-making.

Poor decision-making by Quality can result in decisions that are not pragmatic, but rather black and white, and always request the maximum to be done.

Poor decision-making by other functions can involve over-delegation of decisions and solution-finding to Quality, and a subsequent lack of shared accountability for decisions taken.

Such behaviour is usually caused by a poor culture of failure – one which passes blame instead of collaboratively and constructively discussing what went wrong and what may be learned from it. This behaviour can also lead to a lack of accountability within the whole organisation.

The Importance of Leadership

A suitable culture of failure must be induced and exemplified by business leaders – a culture which encourages entrepreneurialism, courage for pragmatism, collaboration, and accountability.

Potential causes | A QMS grown over time

If a non-conformance arises, be it during operation or as an audit finding, the path of least resistance is often to address the non-conformance by amending the respective QMS process with additional instructions that are directed to prevent or at least to capture the special situation that led to the non-conformance.

Over time, many of such special instructions are collected in the QMS processes, which become increasingly complex and consequently more and more inefficient. Worse still, is that QMS processes may become so complex and inconsistent, that it becomes impossible to adhere to them, or adherence becomes too costly.

Therefore, processes are no longer followed, or cannot be followed anymore, thus creating new non-conformances. These new non-conformances are then addressed by adding new additional instructions into the QMS. This self-reinforcing downward spiral obstructs a lean and operational management system that serves the company effectively.

Such a situation can be caused by a range of reasons, but those we have already explained are usually strong contributors. In particular, the perceived need to protect oneself from blame can induce the urge to try to cover each and every event within the QMS. Such an undertaking is of course doomed to fail, as new unforeseen events often lead to new non-conformities.

Another contributing factor is lack of oversight and steering of the QMS. To guide and mentor process owners (distributing responsibility for the QMS) and thereby keeping a strict and systematic QMS structure in an expanding business that requires the adding of new processes to the QMS or the splitting of existing processes, is a very demanding task that requires a high level of process understanding, mentoring ability, authority, and ability for indirect leadership. Accordingly, some of these abilities are often missing in the function that maintains the QMS.

Potential causes | Very detailed processes

The processes of the QMS may also become very detailed if a company is active in the same areas over a long time and a huge wealth of experience is accumulated. Such experience may then be recorded in the QMS processes, leading to very mature and detailed processes.

The advantage is that less experienced employees are able to follow the processes and not much can go wrong.

The disadvantage is that there is no necessity to obtain a deeper understanding and comprehension of the process and its subject. Employees may become complacent and in turn find it difficult to adjust to new situations. Therefore, the risk that one does not follow the processes in all detail as required leading to an increased number of non-conformities and audit findings is high.

In such a case, the right level of detail is out of balance. This again might be caused by an urge to capture every possible event, and consequently by an insufficient understanding of how much should be described in a process and how much freedom should be given. Indeed, sometimes one meets the false perception that in a regulated industry like ours every detail shall be prescribed and no room for own decision-making shall be given, which ironically ignores the regulatory requirement for risk-based decision-making.

4. Identifying the need for change, and implementing the transformation

Identifying the need for Quality Transformation

Improvement is only possible if there is awareness that improvement is necessary.

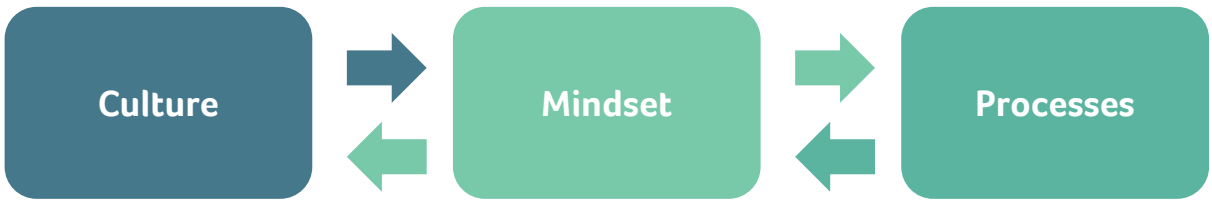
Whilst awareness within middle management is often present due to its proximity to operations, this is not so often the case within top management, whose role is naturally more strategy-focused.

To achieve successful and sustainable transformation, involvement of top management is crucial - without it, transformation is impossible.

The following pages look at what and whom to transform, to support middle management in their discussions with top management as required.

What to transform

Before we explore the approach for how the situation can be transformed, we need to understand which entities need to undergo transformation, and why. In the figure below we display the three entities that need to be transformed, and their relationship to each other:



The **culture** present in an organisation will determine the group mindset of the members in that organisation. The **mindset** will influence how the **processes** are developed. However, the relationship between these three entities constitutes a feedback loop: the processes will determine how people work and thus influence at least partly their mindset. The mindset, on the other hand, will play an important role e.g., in decision-making, and thus in the organisation's culture.

Therefore, no one of these three entities can be transformed without the others. If the transformation fails for one of the three, the transformation for the other two will also ultimately fail.

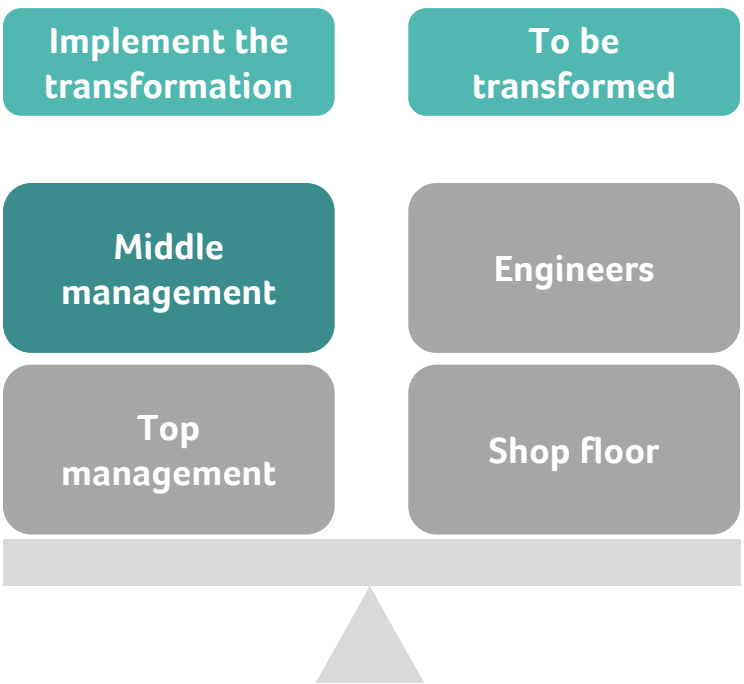
Whichever approach is chosen to achieve transformation in an organisation to address a poor quality culture situation must address all three entities: **culture**, **mindset**, and **processes**.

Whom to transform

To describe a transformation as we anticipate it here, we can use a simple 4-tier model for the organisation:

- **Top management**
- **Middle management**
- **Engineers**
- **Shop floor**

These four tiers are affected by a transformation in different ways. Whereas top and middle management must implement the transformation, engineers and shop floor are to be transformed, as depicted in the figure below:

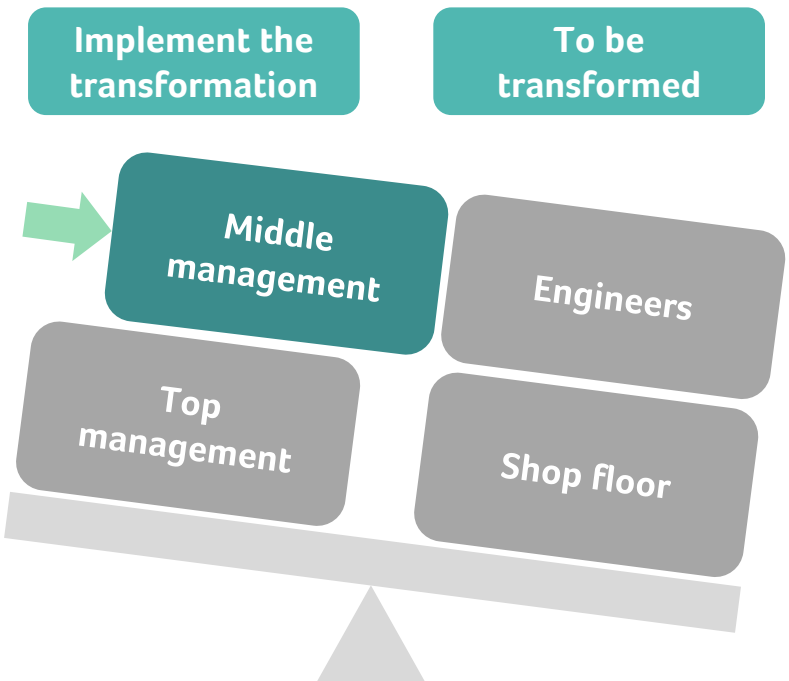


The **two management levels take an active role**, whereas the two specialist levels are more passive. This is, of course, a simplification, and we will investigate the role of the four groups during the transformation process in more detail on the next pages.

Whom to transform

The figure on the previous page indicates a balance between the four groups, which represents the "status quo" or "business as usual". So how can we unbalance this setup to induce transformation?

The key group here is middle management:



Middle management is the group that is both active in the transformation process and close to operations. Thus, the transformation must be induced via the middle management – this group is the lever that enables the transformation.

Therefore, if top management recognises the need for transformation, they should trigger transformation via the middle management. To achieve this, an **influencer** in middle management is required, who seeks confederates and multipliers and thus spreads the message and induces and drives the transformation. The influencer induces both the evolutionary and the revolutionary aspects of the transformation which we mentioned earlier. We will elaborate on the influencer role a little later, but before we do this, let us first have a look at which role the four groups in the organisation play during the transformation process.

5. Roles & tasks during transformation

Roles during transformation

Different groups within an organisation have different roles during the transformation process. In the following, we elaborate on such roles using the simple 4-tier organisation model previously introduced.

Top Management

The highest management level of the organisation or organisational unit within which the transformation shall take place, i.e., the head of the organisation or organisational unit and their direct reports.

Middle Management

Any person that has a leadership role, be it with or without direct personnel responsibility. This includes all management levels from team leads up to the highest level below top management, but also such roles as project leads and product owners.

Engineers

All technical functions like product engineers, software engineers, process engineers, usability engineers, sterility and biocompatibility experts, clinical study experts, quality engineers, supplier (quality) engineers, risk managers, quality control specialists, or even facility engineers for controlled environments.

Also, product or process-related support functions like owners of QMS processes and roles that support QMS processes (e.g., CAPA manager, change manager, auditors, regulatory specialists), even though they might not have an engineering degree.

Shop Floor (including supply chain)

Everybody directly or indirectly involved in manufacturing the product: e.g., manufacturing, logistics, purchasing.

Non-product related support functions like HR or finance are not in scope.

Tasks during transformation

Below, you'll find an overview of which tasks are assigned to each of the four groups during the transformation:

Top Management

Communicate the transformation to inform the organisation and show enthusiasm for the transformation. Such communication may be done formally (e.g., in a town hall) or informally (e.g., in conversations / meetings), depending on the situation. In most cases, informal communication is sufficient and more authentic. Periodical updates on the status of the transformation progress may also be provided.

Support the transformation not only by providing resources, but also by supportive statements etc. in their communication.

Be a role model, i.e., act in ways that are consistent with the new transformed culture and mindset.

Middle Management

Drive the transformation by encouraging and, if necessary, requesting behaviour according to the new culture and mindset, setting goals and defining actions that are necessary to achieve the transformation.

Enable the transformation by providing such support, tools, and resources as needed for the engineers to perform the transformation and act according to the new culture and mindset.

Like top management, **act as role models**.

Engineers

Actively perform the transformation by performing the respective tasks, but mainly by adopting the new culture and mindset. Many will do this happily if they see the advantages and are provided with solutions and added value.

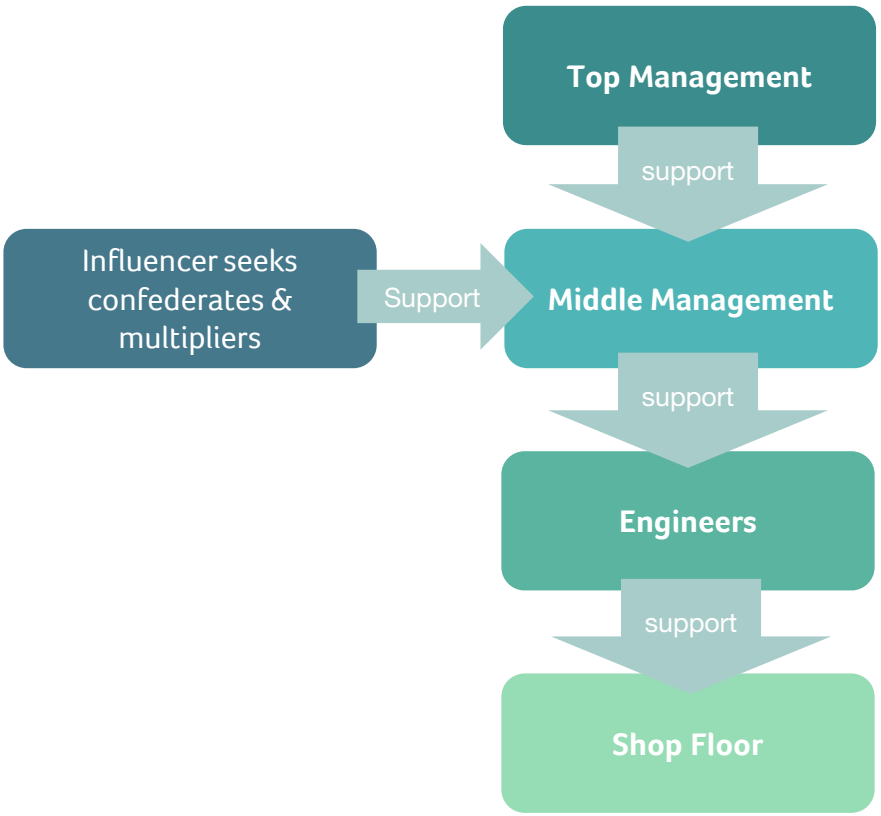
Follow the transformation, i.e., they must apply the new rules, processes, and guidance that result from the transformation.

Shop Floor

The shop floor is not always affected by such a transformation, but if so, their role is also to **follow the transformation** like the engineers.

Tasks during transformation

Besides managing their individual tasks, each level has to support and enable the next level down to perform their tasks. This also includes the influencer as mentioned previously, whose cardinal point is to support and enable the middle management. The figure below depicts this:



The figure above also indicates that for the influencer to drive the transformation, they need to find confederates and multipliers that support the envisioned transformation. This is done by talking to the key stakeholders, listening to their needs and pain factors, and then identifying key operational levers to initiate the transformation. The influencer should also be well respected and supported by the top management.

This first initial step is important to show what is possible and to demonstrate the target mindset and culture. The use of operational levers for this initial step is important, as operational levers will be present in the daily life of the engineers, be seen by middle management, and will ease at least one pain factor. In this way, the first supporters and multipliers are found.

From there, action can be taken to gather speed for the transformation process. What these actions might be, will strongly depend on the individual case. The influencer will play a key role in guiding the organisation with identifying and implementing such actions.

6. Tools for transformation

Tools for transformation

To perform these various tasks during the transformation, the different players need support and guidance, adjusted to their roles. Such support and guidance is provided by the influencer role, via four different tools, which we briefly describe below:

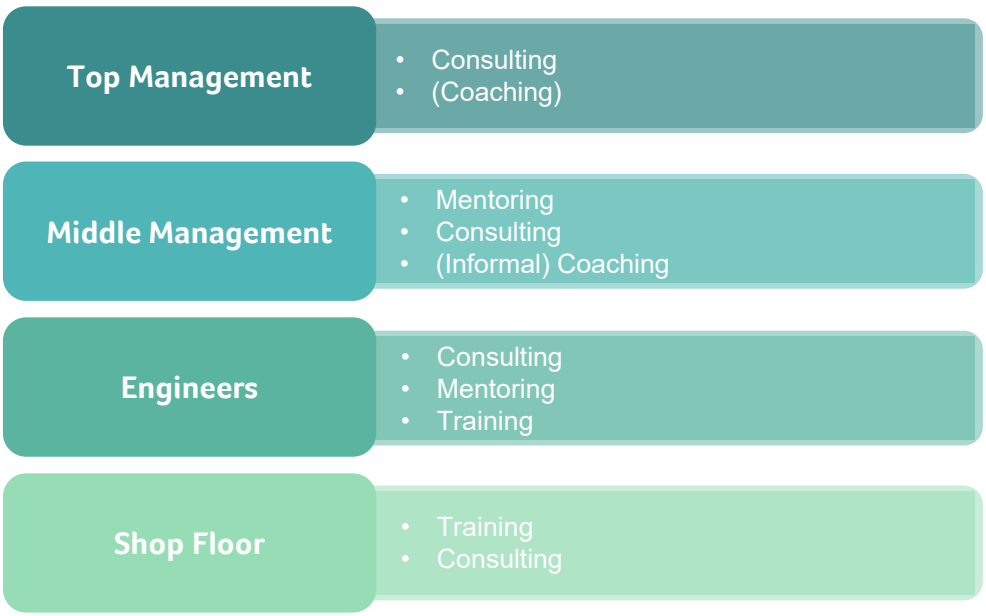
Coaching | Supporting a person in their personal development, by encouraging and supporting self-reflection, to better understand their own position, possibilities, and vision.

Mentoring | Advising the mentee on how to act and behave in a given situation, based on the experience and knowledge of the mentor, with the aim of providing the mentee with a deeper understanding of the circumstances (e.g., why the situation has arisen, why people act the way they do) and thus enabling them to make better decisions.

Consulting | Proposing (and implementing) solutions for defined topics.

Training | Providing knowledge on defined topics to enable the trainee to perform certain tasks, usually according to a process and / or instructions.

Which of these tools is typically appropriate for which level is depicted in the figure below, whereby the order represents the relative importance of the tools:



Tools for transformation

Top Management typically needs consulting towards a (high level) solution to their challenge with respect to culture, mindset, and processes within their organisation. If desired, coaching might be used in a complementary way, as support in identifying the aim of the transition, i.e., to identify target culture and mindset.

Middle Management firstly needs mentoring, in order to help them understand what causes the current situation. Based on this understanding they may be guided by mentoring to identify possible paths to alter the situation, or solutions are proposed via consulting. Also, coaching (mostly in an informal way) may be utilised to support middle management in their personal development during the transformation process and to enhance their leadership capabilities.

Engineers require mainly consulting by proposing solutions for their (operational) challenges, whereby the proposed solutions will lead to and exemplify the new mindset and culture. Additionally, mentoring should be used if deeper understanding of context is needed by the engineers. Finally, formal and informal training will be used to explain new processes and approaches and to fill any knowledge gaps, e.g., in regulatory aspects.

The Shop Floor is not always directly involved in a Quality Transformation. But if so, they mainly require training on the new processes and approaches. Additionally, they may require support in certain operational topics via consulting.

The importance of the influencer

The key role in such a Quality Transformation is played by the influencer, who will initiate, drive, and steer the transformation. The person taking this role must possess a robust set of skills and experience:

- ✓ **A true leader**
- ✓ **Able to take risk-based, pragmatic decisions**
- ✓ **Senior in quality roles in the MedTech industry, ideally in a broad variation of settings**
- ✓ **A "process person", sure of MedTech regulations**
- ✓ **Understand the products in question, technically, but also therapy-wise, and their manufacturing processes**
- ✓ **A good listener and an experienced mentor, consultant, and, to some extent, coach**

Such a combination of qualities can be difficult to find. Should an organisation not be able to find the appropriate individual internally, seeking an external professional with an outside, unbiased, fresh view of the organisation can often be advantageous.

At Congenius, we can provide persons with such abilities, skills, and experience. We have a lengthy track record of completing such Quality Transformation projects for a large variety of customers in various settings and are ready and happy to help organisations embark upon their own Quality Transformation journey. Simply get in touch to start the conversation.

Congenius

Should you have a need for a Quality Transformation, or any questions, our Quality team can help.

Simply get in touch to start the conversation.

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