HIRSH PRECISION
PROTOTYPE → PRODUCTION

DESIGNING AN AGILE & FLEXIBLE

Quality Management System

An Industry-Wide Problem

“Agile and flexible” are not words that typically come to mind when describing a traditional quality management system (QMS). Why is that?

Let’s examine the common traits displayed by the cumbersome systems that are seen across the manufacturing industry:

- They’re built for the sole purpose of passing audits
- They’re regurgitations of the ISO standard(s)
- Team members have difficulty using them
- Processes are designed to mirror the standard’s clauses
- Making changes is a slow, painful process
- They do not add value – only costs

With the majority of quality management systems demonstrating these traits, it’s no wonder a typical QMS gets a bad reputation. In addition to these system drawbacks, there are several key downsides that hinder a company’s growth, profitability, and agility.

For one, a clunky QMS struggles to handle new standards and regulations. If an entire system is built around one set of clauses, how do you integrate new requirements? If the new regulation has different clause numbers, which regulation’s formatting do you use? Further, complying with and maintaining a QMS is usually the sole responsibility of a company’s quality team, with limited to no adoption across the rest of the organization. For many manufacturers, the QMS is only given priority when the company is preparing for an audit.

The Right Way to Design a QMS

Understandably, no one wants to comply with a system or process if it adds a lot of extra work with no perceived value. Take these other drawbacks and downsides into consideration, and it's easy to see how a company's QMS can hurt them, rather than help.

A company's relationship with its QMS does not need to be this way; in fact, it shouldn't be. In fact, a well-designed, properly implemented QMS can help today's manufacturers meet the following benchmarks:

- Navigate an industry that's constantly changing
- Respond quickly to their customers' rapidly changing needs and requirements
- Anticipate market trends in order to be profitable
- Remain compliant with a wide range of regulatory requirements
- Drive down compliance-related costs

This proven, 7-step process can be used to design a brand new, agile QMS.

Summary

- Identify what you must comply with
- Define your processes
- Find the gaps
- Design the structure
- Document Processes with User-friendly Language & Formatting
- Integrate your Standards
- Build an Intuitive Process-Change System

7 Steps to Design an Agile QMS

1 Identify What You Need to Comply With

To get started designing your new QMS, compile a list of all your company's compliance needs – including any ISO/AS certifications, customer requirements, and regulatory requirements (e.g., ROHS/REACH, ITAR, EU MDR, 21CFR820). You can also include industry standards such as APQP/PPAP, AS9102B, Z540.3, etc.

Keep in mind, all of your business processes, including anything your company manufactures, must comply with the items on this list.

Once you have completed your list, make a point to understand all the specific requirements and the intricacies of each one. The better understanding you have of each requirement, the better your QMS will be. This will also make the system easier to design and certify.

2 Define your Processes

The next step is to define all of your business's key processes – those required for manufacturing, those required by certifications/regulations, and the ones your company requires to function.

Key processes can include:

- Estimation and Sales
- Engineering
- New Product Introduction
- Document and Record Control
- Quality
- Regulatory Management
- Manufacturing
- Design & Development
- Purchasing
- Customer Service
- Production Planning

Describe how each process is currently executed. Be sure to include any systems or software utilized, the inputs and outputs for each of the processes, and responsibilities.

3 Find the Gaps

Now, using the information you gathered in the first two steps, identify what gaps exist in your current processes:

- What processes need improvement?
- Are there any processes not currently documented?
- Does anything need to be changed, removed, or implemented?

This is also an opportunity to determine whether your current processes are meeting your company's needs. Are any processes ineffective? What about processes that don't exist, but should in order to improve the quality and productivity of your manufacturing operations?

While performing the gap analysis, try to make the standards fit your way of doing business. Most processes are compliant and may just need some simple tweaks or need a standard operating procedure (SOP) describing what you currently do in order to meet standards or regulations.

Consider the Cost of Compliance

The cost of federal regulations falls disproportionately on manufacturers, particularly those that are smaller.

Manufacturers pay $19,564 per employee on average to comply with federal regulations, or nearly double the $9,991 per employee costs borne by all firms as a whole. In addition, small manufacturers with fewer than 50 employees spend 2.5 more than larger manufacturers.

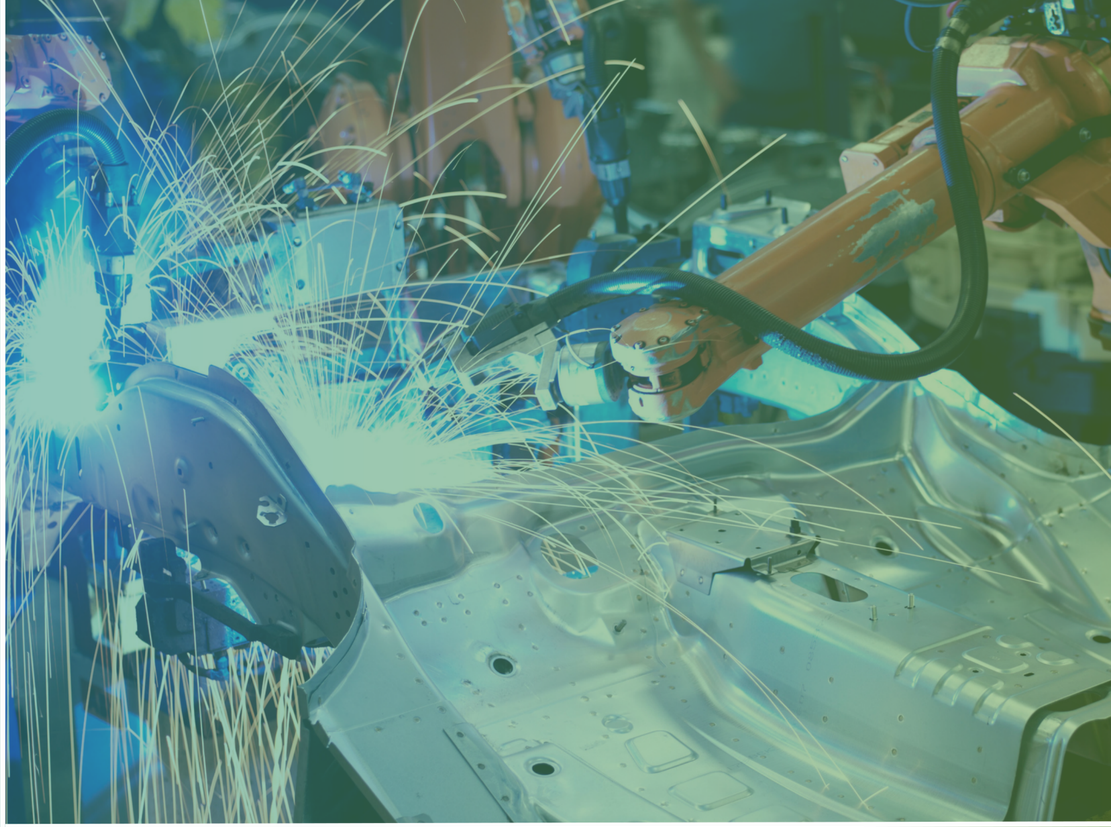
4 Design the Structure

Next, keeping process interaction and user-friendliness in mind, determine how your system will be structured:

- Organize processes in a logical manner that makes sense for your organization – this can be by department, process type, etc.
- Determine how you will structure your documentation and whether you will use software to handle certain aspects of your processes (software isn't required for managing all your processes, but it can be helpful)

ISO 9001:2015/AS9100D in Annex A.1 specifically states:

> *There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.*
>
> *The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives, and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.*
>
> *There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms that suit their operations.*[2]



Pro Tip

Do not use ISO or the standard's clauses to structure your system, as this makes future expansion very difficult. Also, failing to design your own structure will make your procedures and process instructions less useful and relevant to those who use them.

5 Document Processes with User-friendly Language & Formatting

Documentation is a critical part of compliance, and it should be written in a manner that adds value. When properly written, SOPs and process instructions reduce the amount of tribal knowledge and position a company for growth.

The key is to ensure that documentation, particularly your SOPs and work instructions, uses language that can be easily understood by the team members using it.

Some tips for writing effective, easy-to-follow procedures include:

- **Do** utilize the Federal Plain Language Guidelines for tips on writing technical documentation in a manner that is easy to understand and useful to the people who need to use and understand them [3]
- **Do** consult with the process owners and team members that perform these processes to ensure the most important parts are clearly documented in procedures and instructions.
- **Do** involve subject matter experts in writing the procedures and instructions. It will ensure buy-in for compliance after implementation.
- **Don't** regurgitate the clauses in QMS documentation; this adds zero value to your team members and only helps auditors.
- **Don't** use legalese – go even further and remove "shall" from the entire QMS. No one uses shall in daily conversations and even the U.S. Federal Government has switched to "must" for regulations as part of the Federal Plain Language Act.

6 Integrate your Standards

Integration is another important characteristic of an effective quality management system.

While integrating standards into one system is one of the more difficult steps, it simplifies both compliance and usage since processes typically don’t change when applied to different customers or industries.

Integration requires that a process meets all your standards at all times whenever feasible. This task is not as challenging as you may think, given that the bulk of the processes can be handled systematically. This also reduces the amount of human effort needed after implementation.

Holding processes to a higher standard can both strengthen the process and provide cost-saving benefits in the long run. For example, companies can cut costs by reducing the variations of a process that must be maintained and monitored in order to meet the different needs of customers and industries being served.

Pro Tip

Strike a balance with integration. Integrate as much as possible within the QMS, but if certain forms of a process are too difficult or costly to be performed for all work, opt against integration. For example, it takes a lot of resources to maintain Medical Device Files (MDF), so it makes more sense to only follow the MDF process when required.

7 Build an Intuitive Process-Change System

The manufacturing industry is changing constantly, and the final step in designing your agile QMS is to make sure it can adapt to that change, and that your team can implement changes quickly.

The parts of the system that change the most, such as work instructions, procedures, and process steps, should be easy to change – so be sure to write and design them from the beginning with this efficient process-change need in mind.

Most standards and regulations have nearly identical requirements for managing changes, and the majority of the requirements can easily be handled through a properly designed software or system.

Systems that have a good, quick, and efficient change process also become continuous improvement sponges. If any team member can easily suggest process improvements – made easier by the procedures being written in plain language – the QMS is able to constantly evolve, becoming even more agile and efficient than when it was originally implemented.

Conclusion

In the past, Hirsh utilized a very traditional quality management system that checked every box of a typical, cumbersome QMS. This old system worked well enough and (with a lot of teamwork) it was able to handle both ISO 9001:2015 and ISO 13485:2016 compliance.

When it was time to move beyond these two ISO standards and add AS9100D, 21CFR820, and ITAR, it was clear that our traditional QMS was not up to the challenge. This prompted our team to pivot and design a brand-new, innovative, and agile QMS: the Hirsh Production System.

The Hirsh Production System, or HPS as our team refers to it, is our integrated, team-built, continually improving QMS.

Hirsh has seen many benefits since adopting an agile QMS that matches the energy, focus, and drive of our team and company culture. Our redesigned quality management system has:

- Facilitated company-wide growth
- Encouraged continuous improvement
- Made compliance with regulations simple and painless
- Allowed Hirsh to serve customers across numerous industries

The Hirsh Production System has revolutionized how we handle quality. The HPS is lean, facilitates speed when necessary, allows for agility, and empowers us to meet our customers' diverse needs while staying compliant.

We followed this 7-step process to design our agile and flexible QMS, which has led to a great deal of growth (not to mention successful audits). Use these steps to level up your own team's quality management system.

HIRSH PRECISION
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For more than 40 years, Hirsh Precision has faithfully served our customers from the medical, aerospace, and technology industries.

Hirsh Precision provides a valuable set of manufacturing capabilities, ranging from manufacturability feedback to supply chain management, and rapid prototyping to end-to-end contract manufacturing. The quality of our precision manufacturing and engineering services is complemented by our strategic investment in technology and automation, ensuring increased efficiency and the ability to provide a total manufacturing solution for our customers.

To learn more about our team and manufacturing capabilities, visit **www.hppi.com**.

Endnotes

1. *Facts about Manufacturing*. NAM (n.d.). Retrieved February 10, 2023, from https://www.nam.org/facts-about-manufacturing
2. SAE International (2016). *AS9100D: Quality Management Systems - Required for Aviation, Space & Defense Organizations* [Aerospace Standard]. https://www.sae.org/standards/content/as9100d/
3. United States Government (2010). *Federal Plain Language guidelines*. plainlanguage.gov. Retrieved February 10, 2023, from https://www.plainlanguage.gov/guidelines