HTA QMS Series Part Three Webinar Summary

Risk & Efficiency Focus: ISO 13485 in Practice

Part Three of the HealthTech Activator QMS Series focused on how ISO 13485 can be used not just as a compliance requirement, but as a practical framework for building a more structured, efficient, and scalable business. Anne Arndt and guest speaker Alexander Thern emphasised that ISO 13485 helps companies organise themselves to deliver safe, high-quality products, while also supporting smoother regulatory approvals, stronger market access, better tender positioning, and greater investor confidence.

A central message throughout the webinar was that risk and efficiency are not separate ideas. A risk-based QMS means applying more control where the risk is higher, and less where the risk is lower. In practice, this means scaling processes, audits, records, reviews, and documentation to the actual level of risk. Rather than treating every activity the same, the goal is to focus effort where it is most needed and most effective.

The session also clarified that risk should be considered from the very beginning of QMS design. This starts with understanding the product itself, the business scope, the intended target markets, and the available resources. Different products entail different risks, which shape the system's design. For example, software used for diagnosis raises different concerns from those of a prosthetic or embedded AI tool, with issues such as algorithms, interoperability, cybersecurity, design controls, and mechanical performance all affecting what a business needs to manage within its QMS.

Another important point was that the scope is broader than what appears on a certificate. It includes which activities are done in-house versus outsourced, which markets the company aims for, and the regulatory role the company plays. The speakers stressed that these decisions shape the complexity of the QMS and the types of controls, documentation, and oversight required. For example, outsourced development or manufacturing often requires more deliberate process descriptions, stronger supplier oversight, and closer involvement in design review and release decisions than work done internally.

The webinar also addressed a common challenge for startups: building systems that are either too reactive or too detailed. Anne noted that many early-stage companies begin with a reactive QMS, which is understandable, but the aim should be to evolve towards a more proactive system over time. That means integrating quality into daily work, using audits as a tool for improvement, and avoiding the trap of overengineering processes too early. A recurring theme was the importance of finding the right level of detail. If a system is too vague, it is not useful. If it is too detailed, it quickly becomes hard to maintain, outdated, and disconnected from how the team actually works.

This led to a practical discussion around lean implementation. The speakers encouraged companies to use templates and standards where helpful, avoid duplication across documents and systems, and think carefully before introducing tools that may force the business into rigid ways of working. Tools should support the process, not define it. In the same way, training, approvals, and change control should all be proportionate to risk. Not every change needs a large approval board, and not every staff member needs training on every document. Instead, businesses should use role-based training and practical checks for understanding, with more formal verification reserved for higher-risk activities.

A particularly useful part of the webinar focused on embedding risk management into daily operations. Rather than adding extra meetings or layers of process, the advice was to make risk visible within existing workflows. This could include dashboards, clear risk flags, simple KPIs, short check-ins, and assigning ownership so that quality becomes part of everyday decision-making. The speakers stressed that what matters is not bureaucracy, but visibility, responsibility, and follow-through. Even simple records, if maintained consistently, can support a strong system.

The webinar also reframed what success looks like in a functioning QMS. Delaying a release because testing has identified a problem should not be seen as a failure. It is evidence that the system is working as intended. The ability of someone in the business to say no to an unsafe release, and for that decision to be respected, is a sign of quality maturity, strong accountability, and patient-centred decision-making. The idea that protecting patients is itself a positive outcome was a strong thread throughout the discussion.

The closing message was that improvement should be continuous, risk-based, and practical. Businesses do not need a perfect system from day one. What matters is building something fit for purpose, then refining it over time through small, sensible changes. As Alexander noted, much of this comes back to common sense. A strong QMS is one that is carefully designed, aligned with the business, and continually improved as the company grows.

Next steps

Following HTA QMS Series Part Three, focus on simplifying and strengthening your QMS, not adding more to it.

Sense-check your foundations, your product, target markets, regulatory role, and what sits in-house vs outsourced. Then ensure your controls are proportionate to risk, with more rigour where it matters and less where it doesn't. Look for where your system feels heavy or duplicated, and simplify it. Make quality visible in day-to-day work through clear ownership, simple metrics, and existing team rhythms.

Practical checklist

- Is our QMS aligned to our product, markets, and business model?
- Are we applying more control to higher-risk areas and keeping low-risk areas simple?
- Is our system usable, or overly complex and hard to maintain?
- Do we have clear oversight of outsourced work and responsibilities?
- Is quality visible in daily operations, with clear ownership and simple KPIs?
- Have we removed duplication, unnecessary approvals, and wasted effort?
- Is training relevant, role-based, and practical?
- Are we making small, continuous improvements over time?

Identify 2–3 changes that will make your QMS simpler, more targeted, and easier to use before the next session on audits and inspections.

We are excited to see you in the final quarter of the QMS Series. Complete the **Q3 quiz** to test your understanding and earn your certificate of completion, supporting your professional development. and explore additional tools and resources on our **QMS Series page** to support your next steps.

Looking ahead, **Q4 will focus on Audits & Inspections**, covering audit readiness, internal audit processes, CAPA, and bringing your QMS together in practice, running from April to June2026.

If you have any questions or would like support, feel free to **contact the HTA team.**

Ngā mihi,
The HTA team.