HTA QMS Series Part Four Webinar Summary

Risk-Driven Internal Audits: Turning ISO 13485 Checks into Real Insight

Part Four of the HealthTech Activator QMS Series focused on how organisations can transform internal audits from a compliance obligation into a practical tool for risk management, quality improvement, and business performance. Anne Arndt was joined by experienced auditor Brigid Glass, a highly experienced quality management specialist with decades of experience, from BSI, to explore how internal audits can be used to identify emerging risks, strengthen processes, and provide meaningful insight into the effectiveness of a quality management system.

A central message throughout the webinar was that audits should not be treated as annual checkbox exercises. While ISO 13485 requires organisations to conduct internal audits at planned intervals, risks do not emerge according to a calendar. Product issues, supplier challenges, process failures, and compliance concerns can arise at any time. The speakers emphasised that organisations gain far greater value when audit activity is directed by risk and informed by real signals coming from the quality management system.

The session explored the intent behind ISO 13485 internal audit requirements and highlighted that audit programmes should reflect the importance, complexity, and risk profile of individual processes. Rather than auditing every area with the same frequency and intensity, organisations should focus greater effort on activities that have a direct impact on patient safety, regulatory compliance, product quality, and business performance. Processes experiencing significant change, recurring issues, supplier disruption, or increasing complaints may warrant more frequent or more detailed audit attention than stable, well-performing areas of the business.
A recurring theme throughout the discussion was the importance of viewing the quality management system as an interconnected set of processes rather than a collection of isolated procedures. Brigid shared insights from her auditing experience, noting that many issues arise at the interfaces between processes, where information, responsibilities, or decisions are handed from one team to another. These transition points often represent hidden risks and can reveal weaknesses that may not be visible when individual processes are reviewed in isolation.

The webinar also examined how organisations can use existing quality data to guide audit planning. Complaints, CAPAs, nonconformities, supplier performance information, change controls, and post-market surveillance activities all provide valuable insight into where controls may be weakening or where risks may be increasing. Rather than waiting for an annual audit cycle, organisations were encouraged to use these quality signals as triggers for targeted audits. By responding to trends and emerging issues early, businesses can identify root causes and implement improvements before problems escalate into regulatory findings, customer complaints, or product failures.

Anne highlighted that auditing high-risk processes requires a different approach from auditing routine administrative activities. Effective auditors should go beyond confirming that procedures exist and instead seek evidence that controls are working in practice. This may involve following a complaint from initial receipt through investigation and CAPA implementation, tracing engineering changes through approval pathways, or reviewing how risks are assessed and managed during decision-making. The focus should be on understanding how the system operates in reality rather than simply confirming that documentation has been completed.

An especially valuable discussion centred on the concept of traceability across the quality management system. The presenters stressed the importance of following information as it moves through connected processes and verifying that outputs from one activity become effective inputs into the next. This approach not only strengthens audit outcomes but also helps organisations identify gaps, inefficiencies, and opportunities for improvement that may otherwise go unnoticed.

The session also explored the difference between training and competence. Drawing on practical examples, Brigid demonstrated how audit findings often reveal broader organisational issues than the initial observation might suggest. A problem that appears to be a simple documentation error may ultimately point to weaknesses in review processes, oversight mechanisms, or employee competence. The speakers encouraged attendees to look beyond individual findings and consider the wider system factors that may be contributing to recurring issues.

Another important takeaway was the need to write audit findings that support meaningful action. Vague observations provide little value and rarely drive improvement. Strong findings should clearly describe the requirement, the objective evidence observed, and the potential impact of the issue. This creates a stronger foundation for corrective action and enables management to make informed decisions about priorities and resource allocation.

The webinar concluded by examining how audit findings can be converted into sustainable improvement. The presenters discussed the importance of classifying findings appropriately, determining whether corrective action or formal CAPA is required, establishing meaningful performance measures, and conducting targeted follow-up activities to verify effectiveness. Metrics such as recurrence rates, CAPA closure times, complaint trends, supplier performance, and management actions can help organisations determine whether improvements have genuinely reduced risk and strengthened process performance.

Throughout the discussion, Anne reinforced that the true value of internal auditing lies not in finding nonconformities, but in helping organisations learn from their systems. When integrated with complaints management, CAPA activities, change control, supplier oversight, and management review processes, internal audits become a powerful mechanism for identifying emerging risks, strengthening operational performance, and driving continual improvement.

The closing message was simple: audit by risk, follow quality signals, and measure improvement. Organisations that embrace this mindset are far more likely to build resilient quality management systems that not only meet ISO 13485 requirements but also support long-term business success and better outcomes for customers and patients.

Next steps

- Following the final webinar in the HTA QMS Series, focus on using your internal audit programme as a tool for continuous improvement, not just compliance.
- Review your audit programme through a risk-based lens. Consider which processes have the greatest impact on product quality, patient safety, regulatory compliance, and business performance. Use complaints, CAPAs, nonconformities, supplier performance, change controls, and post-market surveillance activities to identify where audit attention is needed most.
- Identify 2–3 improvements you can make to strengthen your audit programme and better connect audit activities with risk management and continuous improvement.

Congratulations on completing the HTA Quality Management Series.

To receive your certificate of completion, ensure you have completed all four quarterly quizzes and submit your certificate request by contacting the HTA.

We encourage you to visit the QMS page to view webinar recordings, whitepapers, articles, templates, and checklists available throughout the series to support ongoing implementation of your ISO 13485 quality management system.

If you have any questions or would like support, please feel free to contact the HTA team or Anne Arndt directly.

Ngā mihi,
The HTA team