

Clinical, Medical & Diagnostic Products



How to effectively manage supplier audits in global medical supply chains

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The challenges associated with supplier audits and verification of supplier compliance are increasing alongside the growing complexity of global supply chains in the medical device sector. Supplier controls are no longer solely about meeting regulatory obligations—they are now a critical component in safeguarding product quality and ensuring that safe and effective devices reach the market. Many recalls, warning letters, and incidents like the 2012 breast implant scandal, which prompted changes to EU legislation, highlight the consequences of inadequate supplier qualification and insufficient controls. After all, supplier management is a fundamental aspect of any quality management system (QMS), such as ISO 9001, ISO 13485, or QSR

In general, the risks associated with inadequate supplier oversight are increasing as the industry becomes more global, with suppliers dispersed across multiple countries and subject to varying regulations. To maintain compliance on a global scale, manufacturers must implement a strategic and proactive supplier management process within their QMS to oversee supplier audits effectively.

Global supply chain management through a business lens

Compliance for supply chain actors - medical device manufacturers, distributors, and importers - is not just important; it is critical for ensuring device safety and achieving business success. Failure to meet these requirements can result in serious consequences, including device recalls, financial penalties, and lasting damage to a brand's reputation. A strategic approach involves ensuring the supply chain operates efficiently while adhering to the required regulatory framework.

Medical device manufacturers often depend on a diverse and geographically dispersed network of suppliers for essential components, raw materials, and services. These suppliers, operating across multiple countries, add complexity due to varying regional regulations and quality standards. This complexity extends to border regulations for delivering parts, components, pre-finished devices, and associated labelling. The challenge is further heightened by subtier suppliers - those supplying goods or services to the primary suppliers. These subtier suppliers are often less visible to manufacturers, and their failure to meet regulatory requirements can trigger compliance issues throughout the supply chain. Each tier in the chain introduces potential risks, particularly when suppliers operate under less rigorous quality management systems (QMS) or lack familiarity with medical device manufacturing regulations.

For instance, compliance with directives such as WEEE (Waste Electrical and Electronic Equipment), RoHS (Restriction of Hazardous Substances), and REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) is often mandatory for manufacturing medical devices, depending on the materials or components involved. These regulations address environmental safety, chemical usage, and recyclability. Failure to comply can halt production, delay shipments at borders, or lead to legal actions by authorities. The complexity increases with regional variations in these regulations, which global businesses must navigate and adhere to.

Additionally, processes like sterilisation - critical for ensuring the safety and hygiene of medical devices - often involve subcontractors or third-party service providers. These critical subcontractors are a key focus of supplier audits and require detailed supplier controls and thorough documentation to verify compliance with regulatory requirements

The challenges grow more significant with niche materials or components critical to the functionality and safety of medical devices. Manufacturers often rely on a limited pool of highly specialised suppliers for these components, many of whom lack the infrastructure, quality management systems (QMS), or regulatory expertise to meet international standards. For instance, a supplier might provide a rare biocompatible material essential for a device but lack the traceability documentation required to demonstrate regulatory compliance. In such cases, the supplier may not be qualified to produce materials or components for medical device manufacturers.

The golden rule remains: a medical device is only as safe as its parts. Relying on underqualified suppliers introduces significant business risks, including regulatory scrutiny, operational delays, and potential product recalls. This underscores the critical importance of thorough, risk-based supplier qualification and oversight to safeguard the supply chain and protect the business.

The regulatory view on a global supply chain

The safety of medical devices depends heavily on the quality and regulatory compliance of their components, parts, and raw materials. While regulatory frameworks worldwide may impose additional supply chain requirements, the overarching goal is consistent: protecting public health by ensuring the safety and effectiveness of medical devices.

Given the critical importance of regulatory compliance in medical device safety, effective supplier control is a core element of a global QMS. Failure to comply with regulations - such as those outlined in US 21 CFR Part 820.50 and ISO 13485 (sections 4.1 and 7.4) - can result in devices being deemed unsafe.

Manufacturers must closely manage their high-risk suppliers, also known as 'crucial suppliers' or 'critical subcontractors,' as these suppliers directly impact the safety, performance, and quality of the final product. This typically involves conducting regular audits, extensive product testing, and maintaining accurate documentation to ensure components meet the required standards. Supplier audits help detect risks early, protecting companies against potential performance and safety issues. Regulators are trained to verify adequate supplier controls (such as regular audits) to identify nonconformities or violations and take action to protect public safety. As a result, low-quality or poorly documented parts, components, or materials can lead to a medical device being classified as unsafe, resulting in significant consequences and costs.

As global supply chains become more complex and interconnected, efficient supplier oversight has evolved into both a legal requirement and a strategic priority. This process goes beyond regulatory compliance; it also involves proactive engagement with suppliers to create a culture of quality and compliance throughout the supply chain. By rigorously managing suppliers and ensuring they meet the relevant QMS standards, manufacturers can enhance operational resilience, avoid costly disruptions, and improve the overall safety and quality of medical devices.

Aligning supplier audits with global supply chain strategies

Selecting a supplier in the medical device industry requires balancing quality, cost, and risk, all within an increasingly complex regulatory environment. The business risk of supplier non-compliance grows with the size of global supply chains. Regulatory bodies worldwide are intensifying their surveillance and oversight of critical components provided by key suppliers, often through systematic database searches, enabling them to identify suppliers for audits or inspections based on defined criteria.

While this increased oversight is inevitable, companies can mitigate potential disruptions by proactively preparing for inspections through well-documented, focused supplier audits. These audits, conducted by qualified auditors with expertise in global regulations, help identify potential risks and ensure compliance before regulatory agencies intervene. The expertise of these auditors is particularly valuable when navigating specific country legislation within global supply chains.

In many cases, working with external auditors who have in-depth knowledge of local laws can provide a distinct advantage, especially when language barriers or complex regional requirements come into play. By bringing in a third-party perspective, companies gain objective, realistic feedback on potential risks that might otherwise be overlooked, offering a more comprehensive understanding of their supply chain vulnerabilities.

An alternative to formal audits is conducting a gap analysis, which offers more flexibility while still identifying areas for improvement. Unlike a regular audit, it is not conducted in a formal 'question and answer' format. This more interactive approach

allows for early discussions on corrective actions before issues escalate into non-conformities or the need for corrective and preventive actions (CAPAs). By addressing potential risks constructively, manufacturers and suppliers can collaborate to identify and resolve problems in the supply chain, thereby reducing the chances of costly compliance failures or disruptions.

Ultimately, whether through an internal audit or gap analysis, taking a proactive approach to supplier oversight empowers manufacturers to address risks before they escalate into compliance issues. By investing in regulatory expertise and obtaining objective feedback on potential gaps in the supply chain, businesses can avoid costly disruptions, maintain operational efficiency, and stay ahead of regulators

A strategic approach to mitigating supply chain risks in medical device manufacturing

A strategic approach to mitigating global supply chain risks in medical device manufacturing involves a comprehensive focus on the early identification of potential

risks and regulatory challenges. By proactively addressing these factors, companies can not only maintain compliance but also ensure product quality and safety while minimising operational disruptions. Effective management of supplier audits and controls is essential to staying ahead of evolving global regulatory landscapes. This proactive approach helps manufacturers avoid costly recalls, penalties, and reputational damage, ultimately enhancing competitiveness. Furthermore, it strengthens long-term business resilience, allowing companies to adapt and succeed in an increasingly complex and demanding regulatory environment.

About the author:

Dr Oliver Eikenberg is the Global QA/RA & IVDR Manager at Pure Global and brings over 14 years of experience in the medical device industry and 15 years in regulatory consulting, specialising in EU, US, and Australian regulations. He has deep expertise in IVD genetic tests, Companion Diagnostics, clinical performance studies, and regulatory interactions.