

INTERNAL AUDITOR TRAINING LEADS TO INVESTMENT

ABOUT TSUBAKI NAKASHIMA - ERWIN. With over 20,000 product variants, Tsubaki Nakashima is a leading producer of high-quality precision balls, rollers, and ball screws, crafted from diverse materials like ceramics and steels. Tsubaki Nakashima's extensive product range caters to diverse global customer needs across various end-market applications. For decades, Tsubaki Nakashima's commitment to excellence has driven it to achieve superior quality in rolling elements, crucial for product performance. This pursuit of near-perfect quality is evidenced by proprietary grinding and inspection machines developed in-house. Notably, Tsubaki Nakashima was the first in Japan to craft ball screws for industrial use, primarily deployed in machinery, semiconductor equipment, industrial robots, and advanced medical devices.

THE CHALLENGE. The company requested TMEP, part of the MEP National Network™, facilitate an ISO 13485 internal auditor training workshop for employees across three facilities in Tennessee. Internal auditor training serves as the foundation for internal auditors to ensure that a company's processes and procedures adhere to ISO standards, which is essential for retaining certifications and preventing potential penalties or decertification. Beyond mere compliance, trained internal auditors play a crucial role in the continuous improvement of an organization. They possess the skills to discern gaps or inefficiencies, promoting systematic enhancements. Effective internal audits, steered by well-trained auditors, enable early identification of potential risks, safeguarding the organization from unforeseen challenges and ensuring robust risk management.

MEP CENTER'S ROLE. TMEP assisted Tsubaki by conducting 16 hours of ISO 13485 internal auditor training for company team leaders, the quality management team, and internal auditors. The training was delivered online in 4.5 hour sessions and included participants from three locations. The course aimed to equip participants with a comprehensive understanding of the ISO 13485:2016 requirements and the proficiency to audit using the process approach.

Covering key aspects like terminology, quality management history, and document analysis, attendees learned effective audit questioning techniques and familiarized themselves with relevant resources. Emphasis was also placed on the audit checklist, system documentation, and the meticulous planning and execution of audits. This assistance helped the company maintain ISO 13485:2015 certification and identify several process improvement opportunities.

"All participants were pleased with the training that was received. We had a diverse group of individuals, some with limited knowledge of the training received and others that had exposure to the content at some point in their career. Upper management was satisfied with the training and eager to apply in real world applications."

-M. Branton, Quality Manager

RESULTS



\$100,000 in new investment



\$50,000 in cost savings



\$20,000 in training

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