Medistri

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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Medistri’s ISO 13485 Certification - Medistri

🚀 Medistri’s ISO 13485 Certification

The implementation of a quality management system is a cornerstone for the development and delivery of safe, effective medical devices. ISO 13485 certification ensures that every aspect of the production process aligns with international standards for quality and safety. At Medistri, this certification reflects our commitment to supporting the medical device industry by maintaining the highest levels of precision and compliance in our processes, ensuring that patient safety is never compromised.

ISO 13485 is an internationally recognized standard for quality management systems specific to the medical device industry. It provides a framework for organizations to ensure the consistent design, development, production, and delivery of medical devices that meet regulatory and customer requirements. The standard is designed to be applicable to all organizations involved in the lifecycle of a medical device, from design to post-market activities.

ISO 13485 certification is crucial to ensure that organizations meet international regulatory requirements for medical devices, facilitating market access across borders. It emphasizes risk-based thinking to help organizations identify and mitigate potential issues throughout the product lifecycle. Certification also demonstrates a commitment to quality and safety, building trust with clients and end-users, while fostering streamlined processes and continuous improvement for better resource management and cost savings.

At Medistri, we implement ISO 13485 through a meticulous and systematic process. This includes developing and maintaining a robust Quality Management System (QMS) tailored to the medical device industry's needs.

Our team undergoes continuous training to stay updated on the latest regulatory and industry standards. Regular audits ensure compliance with ISO 13485 requirements, while close collaboration with our clients aligns our processes with their specific quality and regulatory needs.

ISO 13485 encompasses various requirements. It ensures the design and development process meets safety and performance criteria. Risk management practices help identify and mitigate risks associated with medical devices. Accurate document control demonstrates compliance and traceability. Production and process controls ensure consistent product quality, and post-market surveillance monitors device performance in the market to address potential issues proactively.

Medistri is certified for the sterilization of medical devices on the basis of EN ISO 11135:2014. Whether you require full validation of your sterilization processes or support with specific quality management challenges, Medistri’s expertise ensures compliance with ISO 13485. Our accredited systems and experienced team are equipped to meet the most rigorous industry requirements, providing reliable solutions to help you bring safe and effective medical devices to market.

🎯 To learn more about Medistri’s ISO 13485 Certification, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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