

ISO 13485

QMS for Medical Devices

We have a 100% Certification Rate!



The ISO 9001 Group understands how to design, develop and implement ISO 13485 certification ready quality management systems from the ground up to meet the latest ISO 13485 standards. Our trained and experienced management system consultants will assist your organization in designing, developing, and implementing your ISO 13485 quality management system.

BENEFITS OF ISO 13485 CERTIFICATION

- ✓ Win more contracts where certification is a requirements or a competitive advantage
- ✓ Meet requirement for certification
- ✓ Improved structure, processes and procedures internally
- ✓ Better internal controls, which will improve operations and reduce risks

ISO 13485 OVERVIEW

- ✓ Medical Device File
- ✓ Management Responsibility
- ✓ Customer Focus
- ✓ Responsibility, Authority and Communication
- ✓ Management Review
- ✓ Resource Management
- ✓ Human Resources
- ✓ Infrastructure
- ✓ Contamination Control
- ✓ Planning of Product Realization
- ✓ Design and Development
- ✓ Cleanliness of Product
- ✓ Installation activities
- ✓ Servicing Activities
- ✓ Particular Requirements for Sterile Medical Devices
- ✓ Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
- ✓ Measurement, Analysis and Improvement
- ✓ Complaint Handling
- ✓ Internal Auditing
- ✓ Control of Nonconforming Product
- ✓ Corrective and Preventive Action

CLIENT TESTIMONIAL

“In order to grow as a company and cement ourselves as industry leaders , we needed to create a Quality Management System that would guide us through continuous improvement. Our consultant listened carefully to our needs, and worked with our Quality Department to offer the services we were looking for. We have begun our implementation process and have had our systems tested by current and new customers and we are proud to say that the results have been very positive. The ISO 9001 Group continues to assist us with minor questions in a prompt and courteous fashion.”

*Mike Collins, Quality Manager
Plasma-Tec Industries*

CONNECT WITH US

