

ISO 13485 Quality Management System for Medical Devices



Ensure consistent design, development, and production of your medical device

Would you want your doctor to perform surgery with medical tools not been deemed safe for their intended use?

As a medical device supplier or laboratory looking to keep and expand business, it is vital that your products be manufactured using not only the ISO 9001 quality system requirements, but also those specific to the medical industry. By conforming to ISO 13485, your operation and products will fulfill Food and Drug Administration and the Medical Devices Directive quality requirements.

Manufacturers and labs that attempt ISO 13485 implementation on their own could take up to 18 months to complete the task. Companies working with GaMEP typically take 6-9 months on average.

➤ GaMEP will:

- Conduct a gap audit and help you develop an implementation plan.
- Coach your team through ISO 13485 implementation.
- Conduct ISO 13485 training throughout the organization.
- Assist with the initial internal audits and management reviews.
- Conduct a pre-assessment audit.
- Help you correct system issues before the registration audit.

➤ By implementing ISO 13485 with GaMEP, you will:



Certify the Quality of Your Products



Increase Your Resource Utilization



Develop New Business

ISO 13485 in Action



Medical Device Manufacturer Receives ISO 13485 Certification

A Medical device startup received its 510k clearance to market products in the U.S. At the time, they also decided to go to market in Canada, which requires the adoption of ISO 13485 in order for products to be imported. The company's first attempt to obtain ISO 13485 was unsuccessful.

As a result, they contacted GaMEP to conduct a gap assessment on the ISO 13485 system, identifying areas in which they could improve and implement missing requirements. The company as a result re-tested and received certification giving them the ability to sell in its products in Canada and Europe.

Why Work with GaMEP?

Our goals are simple and impactful:

- Understand the current state of your company.
- Learn about your future goals.
- Teach your team to utilize tools and strategies to meet the needs of your organization.
- Advance your company's competitiveness and ensure a sustainable future for manufacturing in Georgia.

Each of our services resides in one of the following four key strategic solutions within the GaMEP Organizational Excellence framework:



The pillars are interconnected to maximize effectiveness. If you have multiple areas to address, request an Organizational Excellence assessment.

What Sets GaMEP Apart

Each year, GaMEP works with more than 1,000 manufacturers to implement on-site projects, conduct training, and connect manufacturers to Georgia Tech resources and our partners throughout the state. We do this through:

- Federal and state funds that help offset the cost to Georgia manufacturers, making your investment more powerful.
- Access to locally based project managers that have years of experience developing and implementing best practices for manufacturers.
- Immediate and long-term solutions that increase top-line growth and reduce bottom-line costs throughout your organization.

Service areas include: process improvement, quality, robotics, business strategy, technology integration, ISO management systems, energy, sustainability, safety integration, and more.

See what all the "Buzz" is about.

Connect with GaMEP



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