ISO 13485 outlines the requirements that are essential for organizations that need to demonstrate their ability to provide medical devices and related services that consistently meet customer and regulatory requirements. Many companies will only work with ISO-registered organizations. ISO 13485 registration shows a commitment to international quality management systems.

Why should your organization implement ISO 13485?

» Improve your process quality, transparency, and efficiency of manufacturing medical devices
» Advance and ensure the quality, safety, and performance of your medical device products
» Elevate brand reputation and gain consumer trust
» Avoid costly product recalls
» Plan, evaluate, and conduct the basis for testing and certification of medical devices

Meet manufacturing quality standards and customer needs within the medical device industry

Course Description

What exactly does ISO 13485 require? How should I implement it in my manufacturing plant? This course will answer these questions in detail using an entire Resources Section devoted to sample documents you can customize to your plant. In addition, the course provides guidance on the ISO 13485 relationship with FDA regulations and similar requirements in Canada, Europe, and South America. If you are looking to expand your market overseas, this course will show you what doors are open to you.

Learn to:

» Champion the benefits of ISO 13485 at your manufacturing plant
» Describe the requirements of ISO 13485, including those referenced within the standard
» List the common steps for implementation of ISO 13485
» Prepare an action plan to get started

For more information or to register, visit pe.gatech.edu/iso-13485