



When consumer health and safety is in the balance, ensure your medical devices meet regulatory requirements with the help of **ISO 13485** certification!

WHAT IS ISO 13485?

ISO 13485 is a sector-specific quality standard for the medical device industry.

Medical devices come in close contact with patients and range from minor support for medical conditions to lifesaving capability. As such, they demand high criteria. Companies that establish and implement an ISO 13485 quality system are taking a world-class approach to the design, development, manufacture, distribution, and servicing of medical devices. Registration to ISO 13485 requires accountability, compliance with regulations such as the U.S. Food and Drug Administration (FDA)'s Current Good Manufacturing Practices (CGMP), maintenance of documentation, and traceability of products.

Key benefits of ISO 13485 certification and implementation include:

- Attract potential new clients: many organizations require ISO 13485 in order to consider working with a medical device supplier.
- Improve company credibility and interest: demonstrate dedication to quality and safety through certification.
- Develop and improve your processes: with the help of ISO 13485 certification, gain crucial awareness of how best to optimize existing processes and develop new ones for your business.
- Reduced sales cost: with ISO 13485 certification establishing your organization's credibility and dedication to quality, explaining and demonstrating your quality system's efficacy is more straightforward, reducing the time, effort, and investment to gaining a prospective client's trust.



PJR ADVANTAGES

As a leader in the certification industry, PJR is focused on our clients' satisfaction and success! Our experienced auditors and dedicated schedulers give each client the individual one-on-one attention they deserve with detailed audit plans, flexible scheduling, and value-added auditing.

Request a **FREE** quote today and see what a difference PJR can make!

CALL (248) 358-3388 or EMAIL PJR@PJR.com