Perry Johnson Registrar's

# Quality Policy Statement

Through a strategy of continuous improvement and teamwork, and in accordance with the requirements set forth by the international standards organizations, Perry Johnson Registrars, Inc. is dedicated to differentiating itself as an effective provider of certification services, as well as ensuring that we create value for our customers, industry stakeholders, and employees.

The foundation for achieving our objective is based upon our commitment to provide our clients with the highest level of service to assist with their success in the global marketplace.

PJR understands the importance of impartiality in carrying out its management system certification activities, manages conflict of interest, and ensures the objectivity of its management certification activities. PJR further supports a policy of public access and disclosure of information regarding its certification processes and status of certified organizations, and is responsive to complaints about its activities and the activities of its certified clients.

The entire PJR team adheres to the spirit of this quality policy as well as the directives of the Quality Manual and its subordinate documents.

**Terry Boboige**
***President***

## PJR Worldwide Offices

**United States:**

Troy, MI: World HQ
Chicago, IL
Dallas, TX
Boca Raton, FL
Los Angeles, CA

**International:**

Fukuoka, Japan
Hiroshima, Japan
Nagoya, Japan
Osaka, Japan
Sapporo, Japan
Sendai, Japan
Tokyo, Japan
Monterrey, Mexico
Caserta, Italy
Monza, Italy
Bangkok, Thailand
Bangalore, India
Hyderabad, India
Toronto, Canada
Manaus, Brazil

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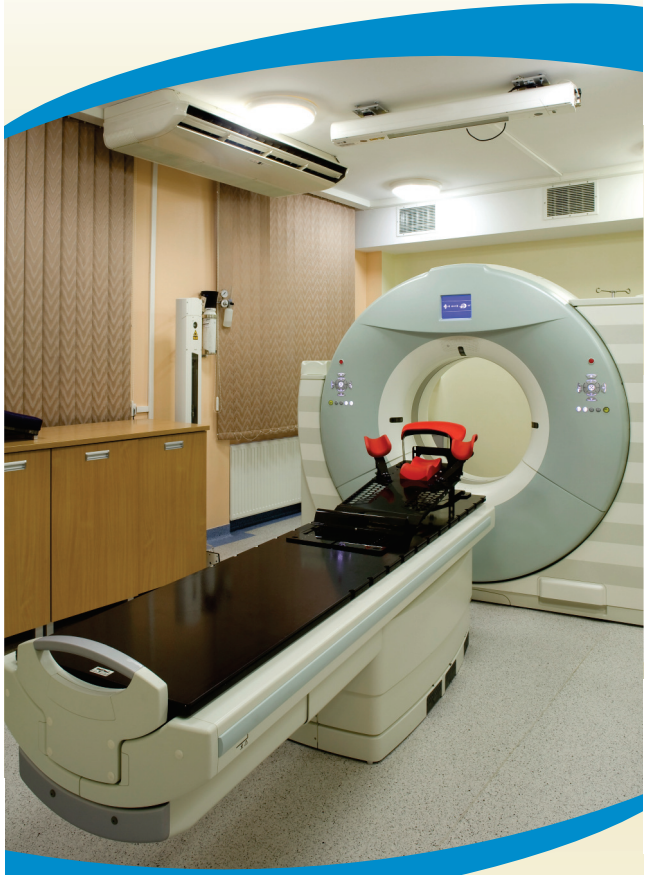
THE WORLDWIDE NAME FOR QUALITY

# ISO 13485

**A Quality Standard Focused on the Medical Device Industry**



***Your partner in ISO 13485 certification***

PERRY JOHNSON REGISTRARS, INC.

# ISO 13485

ISO 13485 is a sector-specific quality standard focused on the medical device industry. It is based off of the ISO 9001 international standard, and addresses quality system requirements for the manufacture of medical devices.

The FDA does not formally recognize ISO 13485 certification, but the requirements of ISO 13485 overlap with FDA requirements in numerous areas.

An ISO 13485 certification requires organizations to develop written policies for the following:

- Document and record controls
- Internal auditing procedures
- Controls for nonconformance
- Corrective and preventative actions
- Process and design controls, record retention
- Accountability and traceability


# Who Needs ISO 13485 Certification?

ISO 13485 extends to manufacturers and designers of medical devices. PJR is accredited by ANAB to register companies to ISO 13485.

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

# Benefits to ISO 13485 Certification

An ISO 13485 certification offers a major competitive edge for medical device companies. It can help device manufacturer's gain:

- A reduction in operational costs by bringing attention to process deficiencies, and thereby improving efficiency.
- Proven commitment to delivering quality products to customers.

# PJR, Your Certification Partner

PJR knows certification. For nearly two decades, we have provided certification services across many standards and across the globe. Here in the US, PJR was the #1 reporting Certification Body in North America in 2014.

While our range of certification services is diverse and our global research is wide, we're proud of our client-centered customer service.

- Our dedicated Project Managers welcome the opportunity to answer all of your questions as they provide you with a customized certification service plan and pricing – all free of charge.
- Once you select us as your certification partner, we continue to make the experience easier for you by providing a single point of contact for scheduling and any customer service concerns throughout the certification process.
- We offer our client-base free seminars, webinars, in-person training, and informational newsletters on a variety of topics.

**To receive a proposal for your facility contact us at:**

**1-800-800-7910**

**www.pjr.com**