ALLIANCE
International Strategic Registrar

ISO13485

MD Quality Management System

Medical Device

Quality Management system

ISO 13485 promotes harmonization of regulatory requirements for manufacturers of medical devices on an international scale.

A number of countries have incorporated ISO 13485 into their regulatory systems. Compliance with ISO 13485 can be used in support of regulatory compliance.

It incorporates many of the quality management principles and delivers the benefits of an ISO 9001 based quality management system.

KEY BENEFITS

- ISO 13485 promotes harmonization of regulatory requirements for manufacturers of medical devices.
- Ensures a consistent and effective approach to business management
- Reduces risk factors via the use of risk management techniques
- Engages top management involvement
- Provides a robust framework for assuring product consistency

We look forward to success you in the world!

Alliane Registrar-ARC

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http://www.allianceregistrars.com/

Alliance Offers a Fair Approach

THE INDUSTRY STANDARD FOR EXCELLENCE

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Certification

PROCESS

Contract Signature

Signed Application

Document Review

Audit Stage 1

Audit Stage 2

Certification

Surveillance Audits

ABOUT US-ALLIANCE REGISTRAR

Alliance International Strategic Registrar's goal is to provide the highest Management Systems assessment, so that our Clients are recognized as the industry standard for excellence. We will distinguish ourselves through dedication toward improving our Client's Management Systems.

We understand the importance of impartiality and conflict of interest to ensure objectivity of our Certification activities. We will foster developmental relationships with the Clients we serve to achieve Client satisfaction. Our logo shall be perceived as a symbol of Quality and Excellence.

Alliance is an internationally accredited Management System Registrar offering a comprehensive suite of services to those organizations wishing to achieve registration.

Alliance has been built on decades of collective experience within the manufacturing and non-manufacturing industries. Our senior staff played a major role in developing the content of the Quality System Requirements and piloting the first Quality System Requirement witness audit, setting the standard by which the industry is measured.

OUR POLICY is to provide exceptional levels of customer service combined with common sense interpretations of the Standards you wish to achieve. Based on our extensive background within the quality industry we have developed a "thorough but fair" assessment approach to the registration process. This approach, welcomed by our clients, has developed a good Improvement Partnership and earned Alliance an enviable reputation within our industry. Business leaders have put the dedication and experience of Alliance personnel to work for them and you can too

We also believe registration should be used as a development tool for your organization. Registration is only the beginning of improving your overall business. We will help by identifying opportunities for you to continue to develop your business processes to ensure not only conformance to the intent of the Standard but improvement in all aspects of the company

The logo of Alliance/ARC is the degree of public confidence and trust, which is established by customer focus, the integrity of its leadership, operating principles as well as impartial and competent assessments.

During a recent survey of ISO registrar performance, Alliance/ ARC was ranked among the top in overall customer service.