

ISO 9001:2015 Certification

What is it, why we did it, and what this means to you

What is ISO 9001:2015

- ISO – International Organization for Standardization – worldwide federation of 162 national standards bodies
“Great things happen when the world agrees”
- ISO 9001:2015 – 2015 revision of ISO standard 9001 which addresses the requirements for a Quality Management System

Where are ISO standards used?

- Medical device manufacturers
 - ISO 13485 (based on older 9001:2000 quality standard)
- Environmental management (waste reduction, energy savings)
 - ISO 14000
- Medical Laboratories information exchange and protection of data
 - ISO 15189
- All industries can benefit from ISO 9001:2015

ISO 9001 Timeline

- July 2013 – ISO 9001:2008 Awareness Workshop
- Nov 2013 – ISO 9001:2008 Internal Systems Auditor Training
- July 2014 – ISO 9001:2008 Certification
 - July 2015 – Surveillance Audit
 - July 2016 – Surveillance Audit
- July 2017 – ISO 9001:2015 Certification
 - July 2018 – Surveillance Audit Planned
 - July 2019 – Surveillance Audit Planned

ISO 9001:2015 Benefits of having a QMS

- Helps to improve our overall performance and provide a basis for sustainable development initiatives
 - Framework to assess our ability to consistently provide products and services that meet customer, statutory and regulatory requirements.
 - Focus on risks and opportunities
 - Show our ability to conform to the requirements of a specified quality management system

ISO 9001:2015 Quality Management Principles

- Customer focus
- Leadership
- Engagement of People
- Process Approach – Plan, Do, Check, Act
- Improvement
- Evidence-based decision making
- Relationship Management

ISO 9001:2015 Requirements

- Context of the Organization
 - Who we are, needs and expectations of our customers, process
- Leadership
 - Role of management, Quality Policy
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

Context of the Organization

- Our scope is “The provision of data management software for clinical research”
- Specifies the external context
 - legal, technological, geographical scope, statutory and regulatory requirements, the need to monitor and review
- Specifies the internal context
 - values, culture, knowledge
- Defines the QMS and its processes
 - Includes the evaluation of risk and opportunities

Leadership

- Management accountable for effectiveness of the QMS
- Ensure quality policy and objectives are established
- Promote risk-based thinking
- Promote improvement
- Support other relevant management roles in their areas of responsibility
- Customer focus
 - Requirements are understood and consistently met
- Enhance customer satisfaction

Planning

- Establish quality objectives
- What resources will be required
- Who is responsible
- How will results be evaluated

Support

- People
 - Organizational knowledge
- Infrastructure
 - Buildings
 - Equipment – hardware and software
 - Information and communication technology
- Environment
 - Suitable working environment
- Documented Information
 - Control of distribution, access, storage, change control, retention and disposal

Operation

- Requirements for products and services
- Design and development
- Release
- Control of non-conforming outputs
 - Problems lead to requests
- We use SDLC (software development life cycle) – User requirement, software description, evaluation (risk assessment), implementation, testing, documentation, integration testing, release

Performance Evaluation

- Monitoring, measurement, analysis and evaluation
- Internal audits
- Management Review

Improvement

- Continual Improvement
- CAPA
 - When non-conformities arise, determine the root cause and recommend corrective and preventative action

What we had to do...

- Examine our procedures for gaps
 - Things we didn't do that we needed to do to meet ISO 9001:2015 requirements
- Document our processes
- Establish monitoring and measuring methods supporting continuous improvement including internal audits and management reviews
- Demonstrate our ability to meet the 9001:2015 requirements to an independent 3rd party – trained ISO 9001:2015 auditor

Benefits to you – What Our certification means

- ISO 9001:2015 is a specified standard for a quality management system
- Certification means that we have met the requirements of the standard and have been externally audited against that standard
- You don't have to take our word for it – our certification means that we are doing everything we can to provide quality product and services to our customers in a sustainable, measurable, analyzable and effective manner
- Many recognize ISO 9001:2015 when qualifying a vendor, so there is a potential to simplify vendor audits for our customers

Questions?

