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
  o ISO 13485 (based on older 9001:2000 quality standard)

• Environmental management (waste reduction, energy savings)
  o ISO 14000

• Medical Laboratories information exchange and protection of data
  o ISO 15189

• All industries can benefit from ISO 9001:2015
ISO 9001 Timeline

• July 2013 – ISO 9001:2008 Awareness Workshop
• July 2014 – ISO 9001:2008 Certification
  o July 2015 – Surveillance Audit
  o July 2016 – Surveillance Audit
• July 2017 – ISO 9001:2015 Certification
  o July 2018 – Surveillance Audit Planned
  o 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
  o Framework to assess our ability to consistently provide products and services that meet customer, statutory and regulatory requirements.
  o Focus on risks and opportunities
  o 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
  o 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
  o Organizational knowledge

• Infrastructure
  o Buildings
  o Equipment – hardware and software
  o Information and communication technology

• Environment
  o Suitable working environment

• Documented Information
  o 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
  o 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?