Impacts of Annex SL on ISO 13485 and the Medical Device Industry

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Why is this topic important? Why am I here?

- Annex SL will change the way Regulatory Affairs Professionals think about risks – not just of the product – but on key stakeholders and the organization.
- Medical device industry is at paradigm shift, where a tick-box, compliance only approach is being superseded by a need to consider a process-based, holistic approach in looking at the entire management system.
Learning Objectives

- What is Annex SL
- Overview of Changes introduced by Annex SL
- ISO 13485 Revision – An Overview
- Relationship of ISO 13485 with Annex SL and ISO 9001
- Challenges with these forthcoming Changes
What is Annex SL?

- Annex SL (previously known as Guide 83) is an ISO/IEC directive supplement that defines the common high level structure for all new ISO standards.

- Appendix 2 of Annex SL defines the high level structure and core text for all standards as well as defining the common terms and definitions.

- All new ISO Management Systems Standards (MSS) should be consistent and compatible. This should be the end of conflict, inconsistency, duplication, confusion and misunderstanding.
Annex SL – An Overview

Already Issued

- ISO 20121
  Event Sustainability
- ISO 39001
  Road Traffic Safety
- ISO 22301
  Business Continuity
- ISO 27001
  Information Security
Annex SL – An Overview

– Each management system standard may add additional requirements and terms to the basic structure defined by Annex SL, but they cannot remove or alter the framework provided by Annex SL.

– For all assessments there will be a core set of generic requirements that need to be addressed no matter which discipline is being examined.
The Scope and Normative references will have contents specific to each discipline.

Scope is the intended outcome of the specific discipline.
Annex SL – An Overview

So what is the Significance?

- Context of the Organization
- Leadership
- Risk

Management system design will not be focused solely on conformance, but on performance as well.

Management systems will demonstrably have to be strategic tools that are integrated into the way the company does business; it has to drive improvement in performance and reduce risk.

Annex SL is essentially requiring organization’s to implement systems that are in alignment with the goals of LRQA’s Business Assurance methodology.
Context of the Organization

- Understand the business environment

- Understand the needs and expectations of “interested parties” (stakeholders)

- Determine the scope of the management system based on the items above.

- Design the management system to meet the above requirements
Interested Parties

“Interested parties” (stakeholders) are those individuals and organizations that can affect, be affected by, or perceive themselves to be affected by a decision or activity of the organization

QMS has to demonstrably determine the context of the organization
Leadership and Commitment

- Top management now have to demonstrate not only commitment to the QMS but to demonstrate leadership as well.

- While commitment can be demonstrated through the allocation of time and resources, leadership requires a more active and dynamic role for top management.
Risk Management - The yardstick for decision making

- Risk
- Org Context
- Review
- Policy
- Objectives
Revision

ISO 13485 Revision
There are now numerous definitions available in this version. Clear definitions of FSCA including descriptive text for device modification; life cycle, legal manufacturer, medical device software, post market surveillance (PMS), clinical evaluations, risk management etc.

Explicit documentation requirements for product software verification and validation.

Clause 4.2.1.2 now appears to have a very explicit description for design history files/technical files contents.

Risk/risk management is appearing in more places (in addition to design and development); including document control, quality policy, supplier evaluation, verification of purchased products, CAPA.
ISO 13485 Revision – Salient Updates

- Explicit description for design input requirements including references of safety, performance and intended uses. This also include normative references to harmonized standards such as usability (IEC/ISO EN 62366)

- Design verification and validation requirements appears to be clearer with requirements for methods of V&V, acceptance criteria, sample size requirements etc.

- Organizations now require to establish provisions for Unique Device Identification (UDI) system for device identification and traceability.

- Confidential health information appears to be considered customer property.
More details for monitoring and measuring equipment requirements; with reference to ISO 10012 for guidance related to measurement management systems.

More details for complaint handling requirements.

PMS clearly appears in clause 8.5.1

Linking risk assessment/management with CAPA process activities.
Impacts of Annex SL on ISO 13485
Challenges with Annex SL on Medical Devices Industry

– **Context of the Organization**
  Striking the right balance between business/financially driven requirements and regulators expectations for maintaining compliance.

  **Examples:**
  – Requirements and expectations from all ‘interested parties’ need to be visible within the QMS; however economical consideration during risk management will still not be acceptable by regulators.
  – Market requirements (interested parties) need to be visible in QMS; however, conflicting requirements may have to be rationalized even in design dossier/technical file management processes.

– **Role of Leadership**
  Top management has to demonstrably involve in making business as well as regulatory strategies.

– **Inclusion of Business Risk**
  In addition to safety and compliance related risks, now we have to think beyond compliance and consider business risks as well (e.g. litigation, brand).
Challenges with Annex SL on Medical Devices Industry

- Current Draft of ISO/DIS 13485 has not yet followed Annex SL Format
- ISO 9001 revision (based on Annex SL) is due to be formally published in March 2015
- It is quite possible that ISO 9001 and ISO 13485 may not be aligned for a while.

How can QMS comply with misaligned formats simultaneously?
Defining your requirements

Are there any pieces missing in your organization?

- Knowledge management process
- Risk management process
- Integrated management system
- Systematic change management
- Top management engaged and involved
- Context of your organization
- Process-based approach

Lloyd's Register LRQA
Improving performance, reducing risk
LRQA’s 7 Steps to a Seamless Transition

**Communicate**
Interested parties will appreciate your commitment to an efficient and sustainable business, as will the new clients that the transition will help secure.

**Transition**
Create a transition plan that maps out how you will manage the process to maintain certification.

**Plan**
Have an independent assurance provider conduct a thorough gap analysis to help your business understand what needs to be done.

**Engage**
Include senior management in that training, so they fully understand the importance of “Top Management” in ISO/DIS 9001:2014 and ISO/DIS 13485:2015.

**Train**
Train your people, both your internal audit team and those responsible for the development, implementation and maintenance of your management systems.

**Choose**
Select an assurance provider who is actively involved in the development and revision of standards. Their insight and expertise will help your organisation prepare for and manage a successful transition.

**Investigate**
Obtain a copy of the new ISO/DIS 9001:2014 and ISO/DIS 13485:2015. Find out about the completely new requirements and the existing ones that have been changed, as well as the proposed dates for final publication and transition schedule.
Business Assurance from LRQA helps manage your systems and risks to improve and protect the current and future performance of your organization.
Impacts of Annex SL on ISO 13485

Thanks for Listening
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