

Implementing an ISO 13485 Medical Devices Quality Management System

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A Journey Or A Destination?



Agenda

- ISO
- 13485 development & objectives
- Implementation Overview
- Implementation - Plan & Do
- Process effectiveness - Check & Act
- A Journey not a Destination
- Summary

ISO

Why implement an ISO 13485 QMS?

- contract tendering qualification
- Reduce operating overheads
- Protect customers
- Protect from legal action

ISO

- ◆ A independent “not for profit” organisation
- ◆ ISO standards are recognized in 146 countries
- ◆ Standards are designed as a business tool - to add value
- ◆ Built and agreed by technical committees from ISO countries
- ◆ Regular review

ISO 13485 development and objectives

Imperatives; ISO 13485 *is*

- A development of the world most successful *quality management* standard
- A specification for a QMS specific to organizations providing medical devices

ISO 13485 Development and Objectives

Imperatives; ISO 13485 *is not*

- Conformance does not automatically constitute conformity with national or international regulations I.e. 'GMP'
- Active understanding and compliance with medical device related regulations is required by ISO 13485

ISO 13485 development and objectives

Overview

- Generally, ISO 13485 includes both ISO 9001 requirements and new medical devices and related services requirements.

ISO 13485 development and objectives

Overview

9001 Exclusions

-continual improvement and customer satisfaction!

Why? - Most medical device regulations require process attainment and maintenance rather than process improvement. Customer satisfaction was considered by committee members to be subjective where a regulatory environment is largely quantitative.

ISO 13485 development and objectives

Overview

13485 Inclusions

More prescriptive

stipulates the use of more formal procedures to regulate and control

Allows less allowance for management discretion.

E.g. in deciding how work should be controlled.

ISO 13485 development and objectives

Management

- A tool for top management; executive directors and senior managers involving leadership, involvement and commitment.

ISO 13485 development and objectives

Internal Control

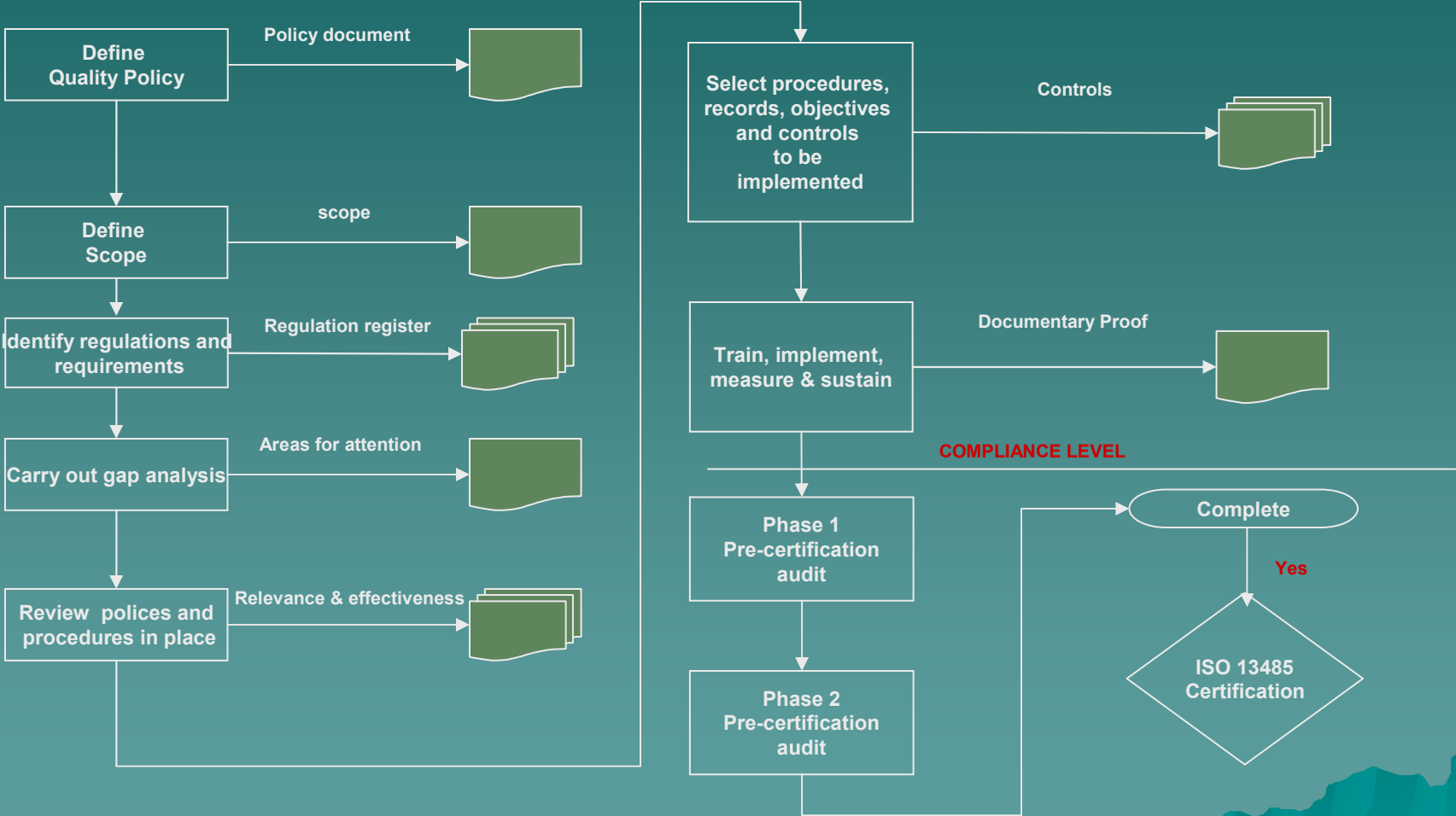
- ISO 13485 is a specification for building and operating a medical device related, quality management system, including measuring and maintaining the systems effectiveness.

ISO 13485 development and objectives

Internal Control

- A quality management system is just *part* of of an organizations internal control system.

Implementation Overview



- Management review
- Training and awareness
- Document control
- Incident management
- Internal checking
- Measuring effectiveness

Plan , Do

Business Risk

- A quality management system is designed to mitigate business risk

through a systematic, statistical and factual based approach to creating and maintaining the process which delivers the customer required product or service / business objectives

Plan, Do

Business Risk

- A high percentage of business system implementations fail!

51% - Robbins-Gioia Survey 2001

67% - KPMG Canada survey 1997

70% - OASIG Study 1995

Plan, Do

Engaging the Board

Clear direction from the top
sponsor

System owner and driver
*quality management representative appointed
by the sponsor*

Plan, Do

Communicate and spread awareness

Map or Mirror the current process
with process area owners,
discover the gaps together.

*Allow the process owner to develop and therefore own
a business effective solution to the gap*

Plan, Do

Communicate and spread awareness

Challenge every all new process activity suggested.

*Confirm system or regulatory need before any change.
Review possible solutions and ensure the most cost effective and sustainable solution is selected.*

Plan, Do

Communicate and spread awareness

Do the minimum!

*This is a starting point, a base line of essential compliance. If your business is successful and resource is already loaded delivering a regulatory compliant, consistent, product or service, **any** attempt to add activity which is not perceived as essential **will** cease at the first load spike.*

Check, Act

Monitor, Coach, Reaffirm and Modify

The Quality Management System
should reflect the business !

Having established a baseline document describing management's clear direction on the requirements and processes which produce a consistent and compliant product or service measuring and sustaining effectiveness will deliver business value

Check, Act

Monitor, Coach, Reaffirm and Modify

Expect the system to fail!

*Train in to all personnel that the system is not optional,
make sure all can access the system documentation
if in doubt of the system requirements,*

follow up and check knowledge in the first few months

Check, Act

Monitor, Coach, Reaffirm and Modify

Expect the system to fail!

Train everyone that non conformity reporting is expected where the product or process is threatened or has failed, processes will be audited - this is a good thing!

*Make the reporting easy and in proportion to the problem: - monitor and always respond
Beware of one approach, try a trial area.*

follow up and check knowledge in the first few months

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Check, Act

Monitor, Coach, Reaffirm and Modify

Expect the system to fail!

Build process and service validation, performance and conformance measures over time, be prepared to remove or down grade monitoring where there is not a regulatory requirement, evidence builds of consistent performance and a business cost is involved.

follow up and check knowledge in the first few months

Check, Act

Monitor, Coach, Reaffirm and Modify Management Review

Management review meetings provide a focal point to drive system performance measurement and sustain effectiveness.

Ensure agenda covers all ISO required required inputs and outputs

Focus on meeting culture;

Quality of information submitted

Ensure action goals are - time bound/quantifiable/responsibility/resourced

Be prepared to abandon the agenda point and even reschedule if necessary where information is incomplete or is qualitative and could be quantitative.

Follow up on actions agreed at previous meetings

A journey-not a destination

How much time and resource needed?

- ◆ QMS representative
- ◆ Management review team
- ◆ Auditors
- ◆ Site personnel

A journey-not a destination

Initial set up

- ◆ Discover
- ◆ Assess
- ◆ Document
- ◆ Communicate
- ◆ train
- ◆ Audit
- ◆ Review

A journey-not a destination

- ◆ Maintenance, monitoring, improvement
 - ◆ Management review process
 - ◆ Systematic approach to the business
 - ◆ Fact/ data analysis based decisions
 - ◆ Agree policy, objectives
 - ◆ Authority to allocate resource
 - ◆ Review progress and reset objectives
 - ◆ On-going commitment

A journey-not a destination

- ◆ Management Tool
- ◆ Deming cycle- plan, do, check, act
- ◆ Policy
- ◆ Plan
- ◆ Implement & operate
- ◆ Checking & corrective action
- ◆ Management review

Summary

- ◆ Use ISO 13485 as a framework
- ◆ A journey not a destination
- ◆ Plan the process
- ◆ Implement and operate
- ◆ Set goals
- ◆ Check and take action
- ◆ Monitor and sustain the process