ISO 13485:2016

What's new - and what does it mean?

SWEDISH STANDARDS INSTITUTE
STANDARD DEVELOPER 2016

SWEDISH Medtech

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QAdvis key competence areas

- Turn key quality systems
- Sharepoint based
- Digital signatures
- Efficient and lean
- Validated and compliant

QMS in-the cloud

- Project management
- Product software validation
- Regulated software validation
- Requirement management
- Risk management
- Verification and validation
- Process validation

System development

- Interim management
- Expert advise
- Audits/Mock audits/assessments
- Warning letter, compliance projects
- PMA, 510k, CE-mark, EC-cert
- Global regulatory support
- Vigilance, recall, post market surv.
- Clinical evaluation/clinical study

QA&RA/Clinical Consulting

- CE-marking
- ISO 13485
- IEC 62304 & IEC 82304-1
  - SW life cycle
  - SW risk management
- FDA's QSR
- Risk management
- Etc

Training/ courses

- Training and Consulting
- In cooperation with Oriel Stat-A-Matrix Inc.

Lean and Six Sigma

- Providing European representation for non-EU MedTech companies
- Active member of EAAR: European Association of Authorised Representatives

European Authorised Representation

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History and timeline for ISO 13485:2016

- Work kicked off in 2011, ISOTC210/WG1, SIS/TK355
- Purpose
  - 13485:2003 is 10+ years old
  - Scope to clarify other organization's involvement
  - Include newer regulatory expectations
  - Better compatibility with other national regulations
  - Based on ISO 9001:2008 structure

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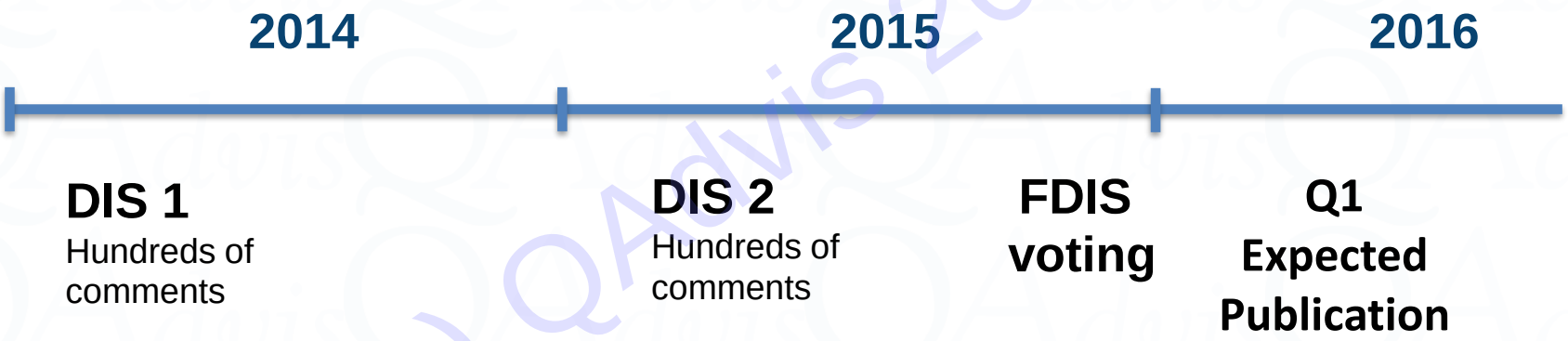
History and timeline for ISO 13485:2016



DIS: Draft International Standard

History and timeline for ISO 13485:2016

FINAL
DRAFT

INTERNATIONAL
STANDARD

ISO/FDIS
13485

ISO/TC **210**

Secretariat: ANSI

Voting begins on:
2015-10-29

Voting terminates on:
2015-12-29

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

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ISO/TC210 members

Many different opinions...

Votes by members	
Country	Member
Argentina	IRAM
Australia	SA
Austria	ASI
Belgium	NBN
Brazil	ABNT
Canada	SCC
China	SAC
Colombia	ICONTEC
Czech Republic	UNMZ
Denmark	DS
Finland	SFS
France	AFNOR
Germany	DIN
Hungary	MSZT
India	BIS
Iran, Islamic Republic of	ISIRI
Ireland	NSAI
Israel	SII
Italy	UNI
Japan	JISC
Korea, Republic of	KATS
Kuwait	KOWSMD
Luxembourg	ILNAS
Malaysia	DSM
Netherlands	NEN
Norway	SN
Philippines	BPS
Poland	PKN
Portugal	IPQ
Russian Federation	GOST R
Saudi Arabia	SASO
South Africa	SABS
Spain	AENOR
Sweden	SIS
Switzerland	SNV
Thailand	TISI
Turkey	TSE
United Kingdom	BSI
United States	ANSI

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Many added requirements all over the standard

Example

Table A.1 — Comparison of content between ISO 13485:2003 and ISO 13485:2016

Clause in ISO 13485:2016	**Comment on change compared with** ISO 13485:2003
6.2 Human resources	— New requirement for documentation processes of establishing competence, providing needed training and ensuring awareness of personnel.
6.3 Infrastructure	— Adds requirement that infrastructure prevents product mix-up and ensure orderly handling of product. — Adds information system to the listing of supporting services.
6.4 Work environment and contamination control	— Added documentation requirements for work environment. — Added requirement related to control of contamination with microorganism or particulate matter for sterile medical devices.
7.1 Planning of product realization	— Added requirements to list.
7.2 Customer-related processes	— Added requirements to list. — New requirement related to communication with regulatory authorities.
7.3.2 Design and development planning	— Added requirements to list.

To consider with 13485:2016

- Not aligned in structure with the new ISO 9001:2015
- Requires careful planning for double certified companies
- 3 year transition period

To consider with 13485:2016, examples

- Scope (Sec 1)
  - Applied to any organisation in medical device life cycle chain, Mfg, Authorized rep, importer, distr, service etc
  - Sections 6, 7 and 8 may be excluded
  - ”Regulatory requirements” - all over the text
  - ”shall” is mentioned approx 250 times, v.s. approx 220 in current version.

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To consider with 13485:2016, examples

- Terms and Definitions (Sec 3)
  - Clinical Evaluation
  - Authorized representative
  - Distributor
  - Complaint
  - Importer
  - Manufacturer
  - Life-cycle
  - Purchased product
  - Performance evaluation
  - Risk Management
  - Etc

To consider with 13485:2016, examples

- General requirements (Sec 4)
  - QMS shall also to include applicable regulatory requirements
  - Define and document the role: Mfg, Auth rep, importer, distr, etc
  - Risk based approach to control processes
  - Control of outsourcing, risk based, quality agreements
  - Procedures and records for software validation of systems used in QMS prior to initial use. New separate section

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To consider with 13485:2016, examples

- General requirements (Sec 4)
  - Establish a Medical device file, to meet 13485 and other applicable regulatory requirements
  - Revised wording for: obsolete docs, control of identification, storage, security, retrieval, retention of quality records
  - Methods for protecting confidential health information/records

To consider with 13485:2016, examples

- Management responsibility (Sec 5)
  - Clarifications
  - Quality objectives includes regulatory requirements
  - Expanded list of inputs and outputs of management review

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To consider with 13485:2016, examples

- Resource management (Sec 6)
  - Document the process for establishing competence, providing needed training and ensuring awareness of personnel
  - Training to maintain competence
  - Risk based effectivness check
  - Information systems added to infrastructure
  - Control of contamination with microorganism or particulate matter for sterile medical devices

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To consider with 13485:2016, examples

- Product realization (Sec 7) *Expanded*
  - Reference to ISO/IEC 62366, usability engineering
  - Several added requirements in customer related processes
  - Communication includes regulatory authorities
  - Requirements shall be able to be verified or validated
  - Documentation of validation plans, sample size

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To consider with 13485:2016, examples

- Product realization (Sec 7) *Expanded*
  - Documentation of validation plans, sample size
  - Design transfer clarified. New section.
  - Design and development file, New section
  - Review service records to determine any complaints
  - Process validation expanded
  - Purchasing: risk based supplier evaluation, monitoring, re-evaluation

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To consider with 13485:2016, examples

- Monitoring and measurement (Sec 8)
  - Monitor if the organization has met customer requirements, methods to be documented
  - Procedures for post market feedback
  - Reporting to regulatory authorities. New section
  - Complaint handling. New section
  - Verify that the CA & PA actions does not have an adverse effect
  - Nonconforming products expaned.

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Recommendations for next steps

- Plan for the QMS change
- Understand the need for a team work
- Get management commitment, manage any resource limitations. Link to budget process
- Create
  - Project plan, Quality plan, checklists

Do not forget upcoming new Regulations: MDR and IVDR

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Recommendations for next steps

- Obtain the new standard
- Study differences
- Guidence ISO/TR 14969 will be replaced with a Handbook
- Contact your Notified Body – plan transition timing

Recommendations for next steps

- Plan, prepare and perform gap audit, document
- Get personnel trained, incl Mgnt. Document training
- Identify responsible functions
- Assign adequate timelines for transition

Recommendations for next steps

Manage the QMS change

- Assess impact
  - Direct: QMS documents, procedures, templates, etc
  - Indirect: Training, qualifications, records, validations, etc
- Document and implement, create records
- Verify effectivness
- Correct non-conformities as needed
- Be ready for certification audit by Notified Body.

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QAdvis can support you as needed

- Complete update package:
  - Gap analysis, project plan, update/implement, training, audits, project management, supplier control, process risk management, etc
- Support with selected areas
  - Audits, alignment with QSR, make it lean/efficient, training, software risks/validation, etc

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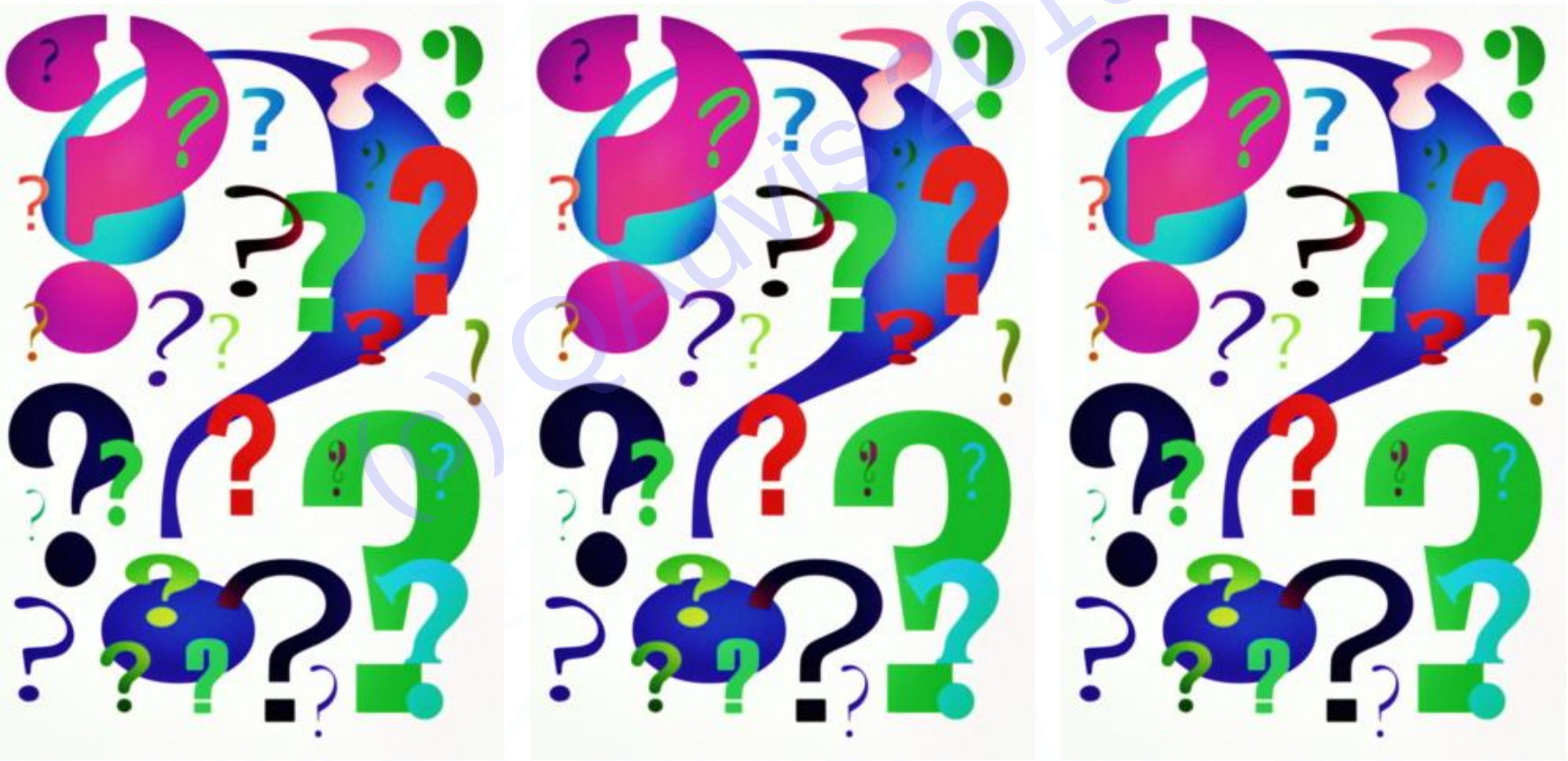
Thank you

Questions & Answers



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