ISO 13485:2016 referenced in CFR820

Medical devices — Quality management systems — Requirements for regulatory purposes

Device Good Manufacturing Practice Advisory Committee

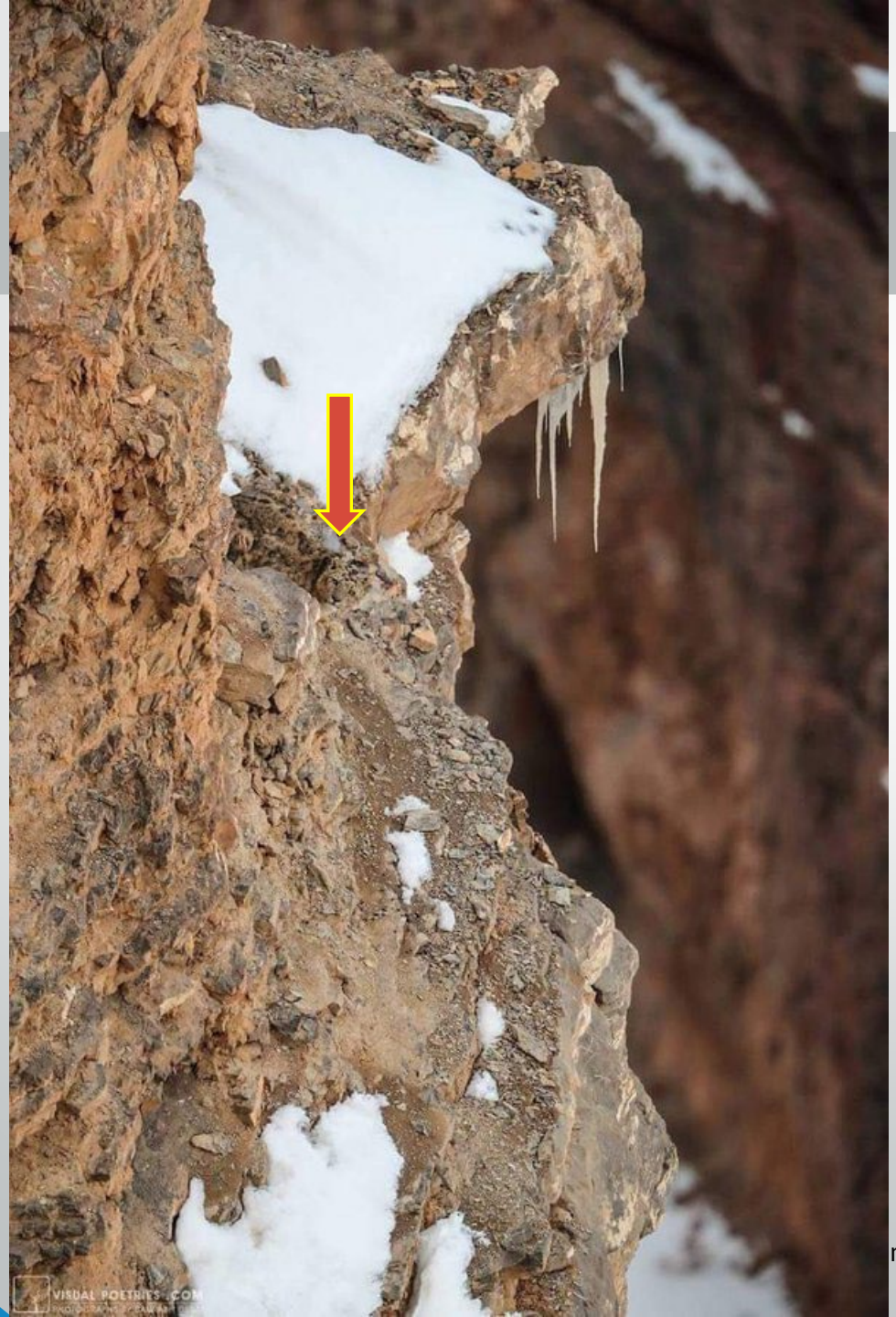
Peter Linders – chair ISO/TC 210

Device Good Manufacturing Practice Advisory Committee

Agenda

- Introduction
- What is ISO 13485:2016?
- What about that Handbook?
- Alignment between QSR and ISO 13485
- Stability of ISO 13485
- Benefits of FDA embracing ISO 13485
- Conclusion

Intro



Find the snow leopard …

Device Good Manufacturing Practice Advisory Committee

Intro

About Peter Linders

- Over 30 years involvement in IEC and ISO
- Involved in regulatory affairs since 1998
- COCIR Board member & chair of TRAC
- DITTA member Board of Directors
- Involved in GHTF, IMDRF, and AHWP
- Chair of CENELEC/TC 62 (until 01.2022)
- Chair of ISO/TC 210

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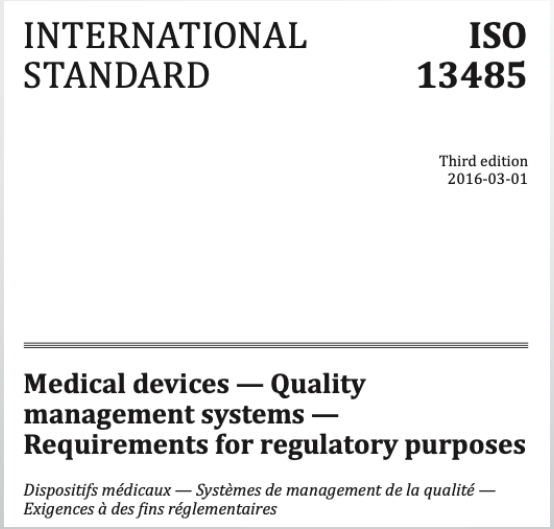
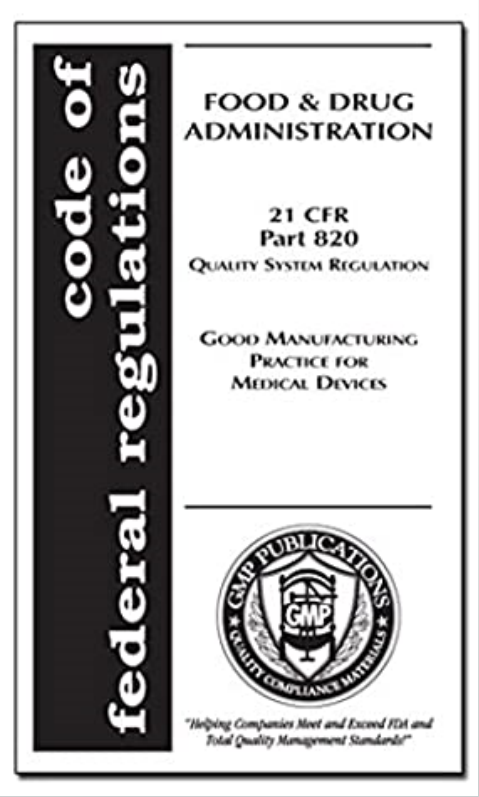
Intro

What do we talk about today?





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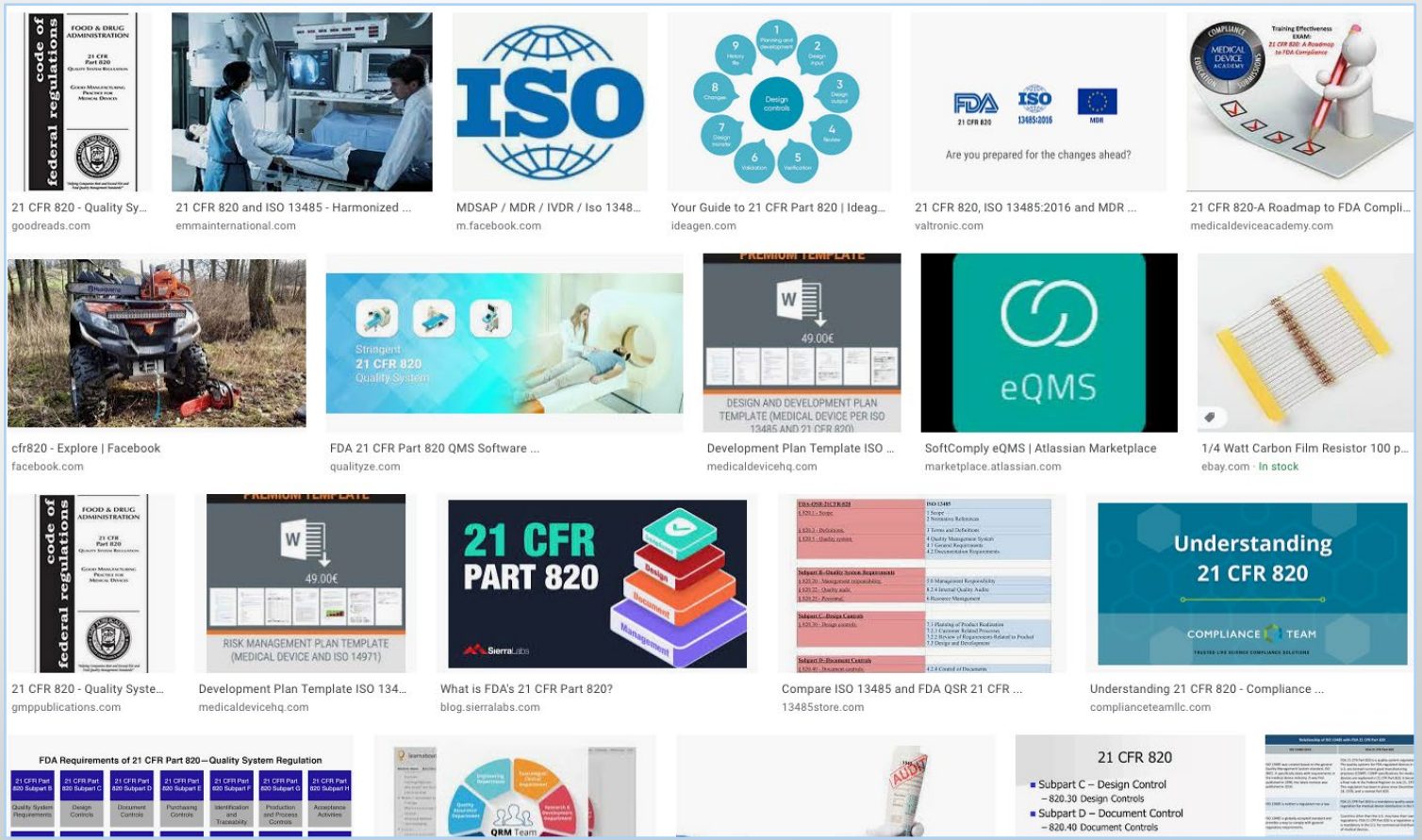
Intro

Google “CFR820” and …



ISO 13485:2016 referenced in CFR 820 - Peter Linders – 2.03.2022

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ISO 13485:2016

Scope of ISO 13485:2016

- requirements for a quality management system in medical device domain
- focus on meeting regulatory requirements for medical device QMSs
- organizations in one or more stages of the life-cycle of a medical device
- legal manufacturers AND external parties (suppliers of goods/services) *

* *Legal manufacturers may have different regulatory obligations than external parties: chain/weakest link …*

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ISO 13485:2016

Table of contents ISO 13485:2016

Clauses until #4 are mandatory
Clause 4: quality manual, documentation
Clause 5: management role
Clause 6: resources, competency
Clause 7: product creation & service
Clause 8: monitoring, post-production, non-conforming product
Annex A: ed 2016 ←→ ed 2003
Annex B: ed 2016 ←→ ISO 9001:20015

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ISO 13485:2016

ISO 13485 is a voluntary standard – sort of …

However, what is voluntary if it is required by the legislation?

Let's not focus on that question …
21CFR820 and ISO 13485 aren't that different

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Global use of ISO 13485

Use of ISO 13485 is widely spread across the globe

- ISO 13485 is one of the top selling ISO MSSs
- In 2020: it ranked #5 in top 15 MSS certificates count (*issued in 2018 – 2020*)
- Certificates issued in well over 100 countries (*data IAF survey*)

	Total valid certificates	Total number of sites
ISO 9001	916.842	1.299.837
ISO 14001	348.473	568.798
ISO 45001	190.481	251.191
ISO/IEC 27001	44.499	84.181
ISO 22000	33.741	39.894
ISO 13485	25.656	34.954
ISO 50001	19.731	45.092
ISO 20000-1	7.846	9.927
ISO 22301	2.205	4.662
ISO 37001	2.065	5.946

ISO 13485:2016 referenced in CFR 820 - Peter Linders – 2.03.2022

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Handbook

ISO/TC 210 developed "Handbook"

- ISO 13485 Handbook (officially: "A practical Guide")
- Explains, guides, supports implementation
- **Format**: text from standard, intent, and guidance
- Includes "improvement areas" software and outsourcing
- Handbook partially adopted in China as YY/T 0595-2020
- Additional insights may be provided via update (*not planned*)

Anything still unclear ? Ask the leadership in ISO/TC 210

4.1.6 The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

Records of such activities shall be maintained (see 4.2.5).

Intent

This new section makes explicit that the application of computer software used in the QMS has to be validated, consistent with product software, process control software and software used for monitoring and measurement.

Guidance

The validation of software is covered in different parts of ISO 13485 depending on the use to which the software will be put (e.g., for processes in the QMS, as an element of the product or as the product itself, for the control of production or service provision, or for monitoring and measurement). Throughout the standard, the requirements for validation of the application of computer

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Alignment

Table of contents ISO 13485:2016

Foreword

Introduction

1. Scope
2. Normative references
3. Terms and definitions
4. Quality management system
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement, analysis and improvement

Annex A, Annex B, and Bibliography

FDA-QSR-21CFR-820	ISO 13485
§ 820.1 - Scope.	1 Scope 2 Normative References
§ 820.3 - Definitions.	3 Terms and Definitions
§ 820.5 - Quality system.	4 Quality Management System 4.1 General Requirements 4.2 Documentation Requirements
Subpart B--Quality System Requirements	
§ 820.20 - Management responsibility.	5.0 Management Responsibility
§ 820.22 - Quality audit.	8.2.4 Internal Quality Audits
§ 820.25 - Personnel.	6 Resource Management
Subpart C--Design Controls	
§ 820.30 - Design controls.	7.1 Planning of Product Realization 7.2.1 Customer Related Processes 7.2.2 Review of Requirements Related to Product 7.3 Design and Development
Subpart D--Document Controls	
§ 820.40 - Document controls.	4.2.4 Control of Documents

ISO 13485:2016 referenced in CFR 820 - Peter Linders – 2.03.2022

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By reference …

What means "*Incorporation by reference*"?

"… proposing to incorporate by reference ISO 13485:2016 Medical devices--Quality management systems--Requirements for regulatory purposes, …"

21CFR820 will be amended by replacing all elements (definitions, requirements, …) with equivalent/similar elements –incl. definitions!- from ISO 13485 as dated reference, unless conflicting with 21CFR820

Stability

ISO 13485 is a stable standard

- ISO 13485 - Ed1: 1996; Ed2: 2003; Ed3: 2016; Ed4 ??
- Is the standard perfect? Well, it's pretty good - fit for a long time
- Best guarantee for ISO 13485 stability is ISO itself!
- Minor modifications may be via Handbook update

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Stability

Input from stakeholders (with syst. review i …

MDSAP Consortium Sparks Debate Over Upcoming Revisions to ISO 13485:2016

Japan NC: HLS is not suitable to be used as a base of ISO 13485

UK: ISO 13485:2016 should be confirmed for another five years to allow stability

MDSAP: careful consideration should be given to the need to revise the standard

IMDRF: Imperative that the medical device sector is engaged in any future revisions of the ISO HLS, if there is a desire by ISO TMB that the standard continue to be used for regulatory purposes.

MEDEC: we believe that the maintenance of the status quo and deferring any plans for a revision to ISO 13485 for the time being are in the best interests of both industry and regulatory stakeholders

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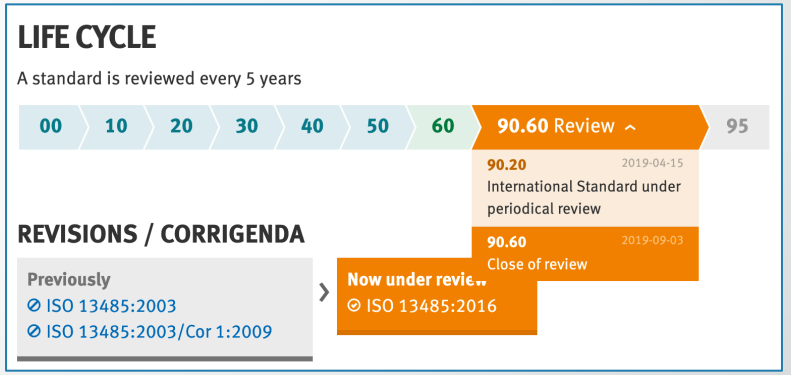
Stability

Why would ISO 13485 have to change?

- In 2020, confirmation* until 2025, *so …*
- To make ISO 13485 HAMSS compliant ?? *Nah …*
- Link with ISO 9001 ?? *No ISO 9001 revision foreseen …*
- Small updates/clarifications ?? *Ehm, maybe via the Handbook …*



Status 2019 - SR

* See document N1156 of ISO/TC 210, 17 Jan 2020

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Benefits

Amending 21CFR820 to ISO 13485:2016 is beneficial because …

- Cost saving – FDA estimate ca. 500 M USD savings for US market
- Allows USA manufacturers to export more readily *
- Will stimulate more countries to do similar
- Emphasizes the relevance of standards for global regulatory convergence

* *Helps industry with one approach to QMS, providing a least burdensome approach to global markets by focusing on a set of aligned requirements. Where as today a manufacturer has to manage 13485 and QSR. Yes there are some country differences that still have to be managed but with foundational elements aligned it let's us focus on product and market needs to serve the patient and users better.*

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Conclusion

Thank you and …