

Briefing of ISO/TC 210 progress on ISO 13485

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ISO/TC 210 progress on ISO 13485

ISO 13485:2016 is the global standard for quality management for manufacturers of medical devices, including in-vitro diagnostic devices

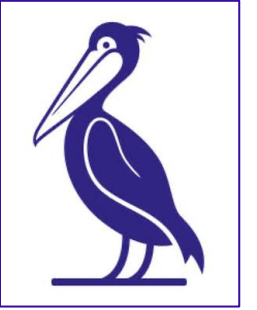
Why change?

In favor:

- ISO's Harmonized Approach (fka HLS)
- ISO 9001 is in revision
- National variations in implementation
- User survey (2023): updates desirable
- ...

Against:

- Complications with ISO/IEC Directives
- MDSAP uses ISO 13485 (convergence! reliance!)
- US FDA updated its QSR along ISO 13485
- ISO 9001 is in revision
- Implementation cost, uncertainty
- ...



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Why change? Why revise ISO 13485?

ISO's Harmonized Approach (fka HLS)

- *ISO's mandatory format & text for management system standards – like ISO 13485*

ISO 9001 is in revision

- *Revision of ISO 9001 MIGHT introduce new quality concepts. And ISO requires all quality standards to have a normative reference to ISO 9001 “in its entirety” (ISO/IEC Directives, 2024, Pt.2 with ISO Suppl., SP.5.3 a))*

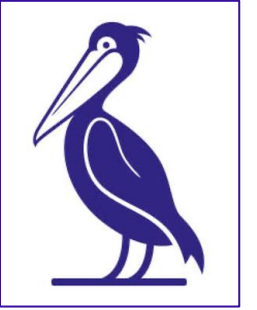
National variations in implementation

- *Can we ever get rid of these?*

User survey (2023) on ISO 13485:2016 updates desirable

- *Updates, e.g., on software, supplier, and risk based approach*





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Why **NOT** change? Why **NOT** revise ISO 13485?

Complications with ISO/IEC Directives

- *ISO's mandatory format & text for mgt. system standards conflicts with medical device regulatory concepts*

MDSAP uses ISO 13485:2016

- *IMDRF initiative helps reduce national variations in QMS requirements. Also: convergence, reliance !!*

US FDA updated its QSR and replaced by (dated!) reference to ISO 13485:2016

- *Effective date of enforcement: 2 February 2026*

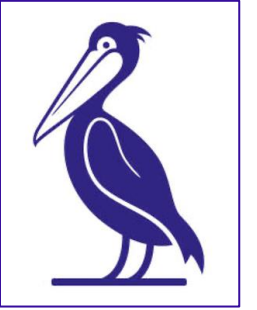
ISO 9001 is in revision

- *So, it is unclear what will come out of this process. And with a required normative reference, ...*

Implementation cost of revision, uncertainty, ...

- *All certificates invalidated, many SOPs may need revision, ...*





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Big question in WG1 of ISO/TC 210:

Revision of ISO 13485 will come at high cost ...

Can the wish for updates be met without that cost?





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Remember the “Practical Guide to ISO 13485:2016” ?

*Advice from ISO/TC 210
for the implementation
of ISO 13485:2016*





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ISO/TC 210 proposes that the “Practical Guide” be redeveloped as a TS (Technical Specification), **based on 2016 edition of the standard**

Based on user feedback:

- Clarify text where needed
- Elaborate on topics from user survey (*e.g., software, supplier, and risk based approach*)
- Underline that ISO 13485:2016 still meets the needs of regulators and industry, globally

Indication of the preferred type to be developed	
<input type="checkbox"/> International Standard	<input checked="" type="checkbox"/> Technical Specification
<input type="checkbox"/> Publicly Available Specification *	
* While a formal NP ballot is not required to start developing a PAS (no eForm04), the NP form may provide useful information for the committee P-members to consider when deciding to initiate a Publicly Available Specification.	
Proposed Standard Development Track (SDT – to be discussed by the proposer with the committee manager or ISO/CS)	
<input checked="" type="checkbox"/> 18 months	<input type="checkbox"/> 24 months <input type="checkbox"/> 36 months
Draft project plan (as discussed with committee leadership)	
Proposed date for first meeting: 2024-12-11 	
Dates for key milestones: Circulation of 1st Working Draft (if any) to experts: 2025-01-10	
Committee Draft consultation (if any): 2025-08-22	
DIS submission*: 2026-03-06	
Publication*: 2026-03-06	
* Target Dates for DIS submission and Publication should be set a few weeks ahead of the limit dates automatically determined when selecting the SDT.	
NOTE: ISO/Meetings and ISO/Projects allow you to register and continuously update the meeting dates and project target dates during the development of the project.	

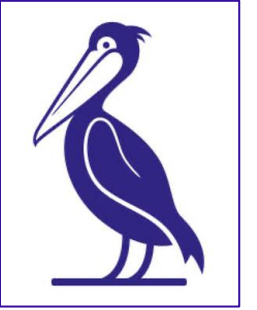




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My recommendations to GHWP members:

1. GHWP refrains from asking revision of ISO 13485:2016 in next SR
2. GHWP actively supports development of an ISO/TS, based on -and replacing- the “Practical Guide to ISO 13485:2016”
3. GHWP members collaborate in reducing national variations of QMS requirements for medical devices in support of reliance



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In a way, ISO 13485 is like a Komodo dragon ...

*Some may not like the looks
but it's an intelligent creature,
and worth to be protected!*





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