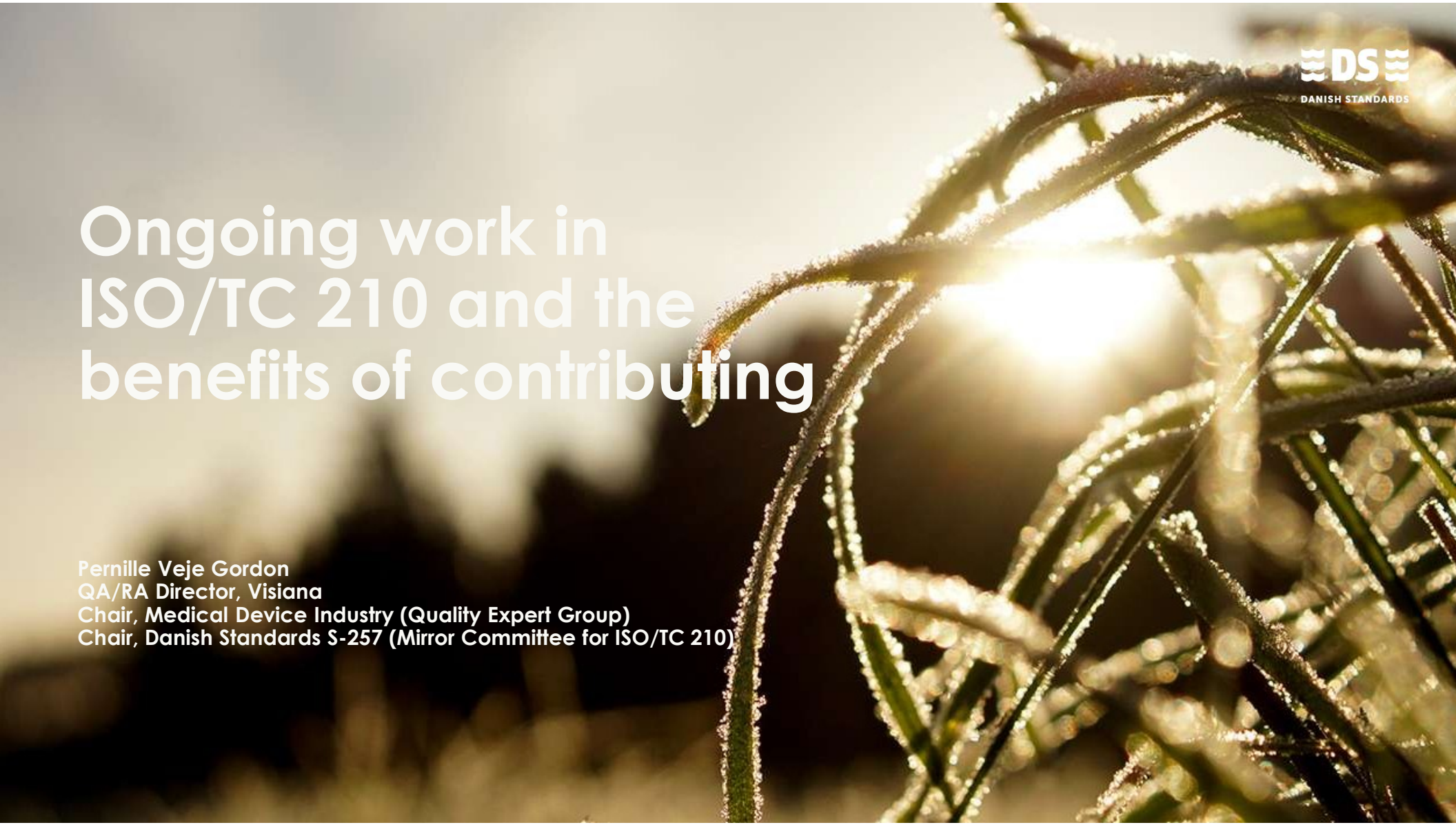

Ongoing work in ISO/TC 210 and the benefits of contributing

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Chair, Danish Standards S-257 (Mirror Committee for ISO/TC 210)

Introduction

Continue from:

Avslutning / Overgang til: Ongoing work in ISO/TC 210 and the benefits of contributing

- Standarder er felles språk
- De gjør regelverket forståelig og anvendbart
- De støtter kvalitet, sikkerhet og innovasjon i Norge
- Neste: Hva skjer internasjonalt i TC 210

Purpose of the talk:

To give insight into current ISO/TC 210 work and explain why participation matters.

Introduction

What is ISO/TC 210 ?

International Technical Committee for:
“Quality management and related general aspects for medical devices”

42 participating and 29 observing member countries

Scope includes:

- ISO 13485 (Quality management systems)
- ISO/TS 23485 (Guideline for the application of ISO 13485)
- ISO 14971 (Risk management)
- ISO/TR 24971 Guidance on the application of ISO 14971
- ISO 62366 (usability).
- ISO 20416 (post-market surveillance)
- ISO 20417 (labelling)
- ISO 15223 (symbols)
- ISO 62304 (medical device software)
- Terminology and horizontal standards

Introduction

Structure of ISO/TC 210

Working groups (WGs) – example:

WG1: Quality management systems (ISO 13485)
WG2: Risk management (ISO 14971)
WG3: Usability (IEC/ISO 62366)
WG6: Post-market surveillance guidance

ISO/TC210 is attended by:

Regulators
Industry leaders
Technical experts
Notified bodies

Organized in relevant working groups – covering most of the elements

* number includes updates

Structure | Liaisons

Reference ↑	Title
ISO/TC 210/AHG	Ad-hoc group for ISO 22740
ISO/TC 210/AHG 4	Assessment of ISO 13485
ISO/TC 210/AHG 5	Collaboration with IMDRF on guidance documents
ISO/TC 210/ATTF	Arabic translation task force
ISO/TC 210/CAG	Chair Advisory Group
ISO/TC 210/JWG 1	Joint ISO/TC 210-IEC/SC 62A WG : Application of risk management to medical devices
ISO/TC 210/JWG 2	Joint ISO/TC 210-IEC/SC 62A WG : Medical device software
ISO/TC 210/JWG 3	Joint ISO/TC 210-IEC/SC 62A WG : Medical device usability
ISO/TC 210/JWG 4	Joint ISO/TC 210 - IEC/SC 62D WG: Small bore connectors
ISO/TC 210/STTF	Spanish translation task force
ISO/TC 210/WG 1	Application of quality systems to medical devices
ISO/TC 210/WG 2	General aspects stemming from the application of quality principles to medical devices
ISO/TC 210/WG 3	Symbols and nomenclature for medical devices
ISO/TC 210/WG 5	Connectors for reservoir delivery systems
ISO/TC 210/WG 6	Application of post market surveillance systems to medical devices
ISO/TC 210/WG 7	Good engineering maintenance management

Ongoing Work in ISO/TC 210

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Current Revisions and Projects – Highlights:

No revision to ISO 13485

ISO/TS 23485

New work on post-market surveillance

TS related to ISO 14971

Increased focus on software and digital health

Standard and/or project under the direct responsibility of ISO/TC 210 Secretariat ↑	Stage
ISO/DTS 5137 [Under development] Medical device maintenance management programme for healthcare delivery organizations (HDO)	50.20
ISO/CD 15223-2 [Under development] Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation	30.00
ISO/AWI 18250-3 [Under development] Medical devices — Connectors for reservoir delivery systems for healthcare applications — Part 3: Enteral applications	20.00
ISO/AWI TR 20416 [Under development] Medical devices — Post-market surveillance for manufacturers	20.00
ISO/FDIS 20417 [Under development] Medical devices — Information to be supplied by the manufacturer	50.00
ISO/AWI 23421 [Under development] Medical devices — Terminology — Terms used in the field of quality management and corresponding general aspects for products with a health purpose including medical devices	20.00
ISO/WD TS 23485 [Under development] Medical Devices — Quality management systems — Guideline for the application of ISO 13485:2016	20.60
ISO/TS 24971-2 [Under development] Medical devices — Guidance on the application of ISO 14971 — Part 2: Machine learning in artificial intelligence	60.00
ISO/AWI TS 24971-3 [Under development] Medical devices - Guidance on the application of ISO 14971 — Part 3: Combination products	20.00
IEC/CD TS 62366-2 [Under development] Medical devices — Part 2: Guidance on the application of usability engineering to medical devices	30.60
IEC/AWI 80369-5 [Under development] Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applicatior	

Ongoing Work in ISO/TC 210

Trends Driving the Work

- Regulatory tightening (MDR/IVDR, FDA updates)
- Increased focus on patient safety
- Digitalisation & software-heavy devices
- Global consistency / harmonisation
- Better clarity for audits
- Reducing unnecessary complexity in standards

Benefits of Contributing

Why Participate in ISO/TC 210?

- **Influence the development of the standards you must comply with**
- **Gain early insight into changes**
- **Understand the intent behind requirements**
- **Enhance internal interpretation and implementation**
- **Build strong expert networks**

Benefits of Contributing

Benefits for Companies

- Reduced compliance risk
- Improved audit outcomes
- Faster adaptation to new standards
- Better understanding of expectations from regulators
- Opportunities for internal competence building
- Competitive advantage

Benefits of Contributing

Practical Impact:

- **Clarifying unclear requirements in drafts**

- **Influencing on International Standards**

  Participation gives your organization the ability to:

  - Suggest changes
  - Comment on drafts
  - Vote on key decisions

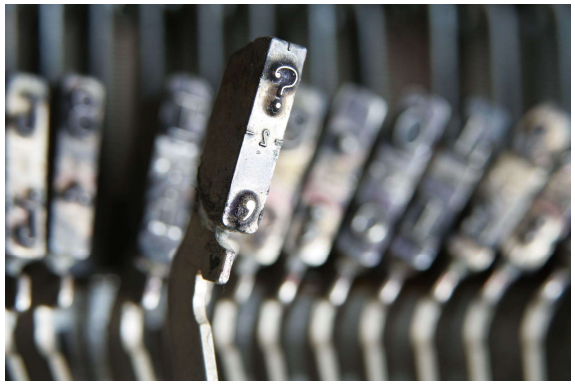
  This influence ensures that standards remain practical, implementable, and aligned with real-world industry needs.

- **Bringing industry experience into the standard**
- **Helping avoid over-regulation or unrealistic demands**

Benefits of Contributing

How Individuals and Companies Can Engage

- Join the national mirror committee
- Participate in working groups
- Review and comment on drafts
- Attend meetings (virtual/in-person)
- Bring real-world issues forward



Closing

Summary

ISO/TC 210 is central to medical device quality and safety
Current work is highly relevant for industry and regulators
Contributing ensures influence, insight, and readiness
National participation through S-257 strengthens Danish impact

It’s one of the best global arenas for staying close to the regulatory landscape related to medical device

Information

Technical Committee: ISO/TC 210 develops international standards related to quality management, risk management, usability, and safety for medical devices.

Link to publicly Strategic Business Plan: ISO-TC 210 -Quality management and corresponding general aspects for medical devices- (3).pdf

Scope and Structure

- Work is conducted through various groups, including working groups, joint working groups, and task forces, with input from numerous stakeholder organizations.
- The committee has 32 published standards and 11 under development (status 02-12-25), collaborating with other ISO and IEC committees.

Vision and Mission

- The vision is to create a globally relevant program of consensus standards that enhance patient safety and public health.
- The mission includes providing a collaborative forum, anticipating emerging technology needs, ensuring regulatory readiness of standards, and promoting global harmonization.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