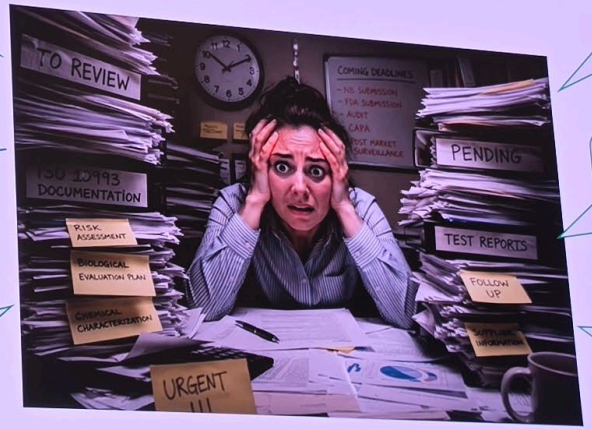
The update is raising urgent questions

- Manufacturers are overwhelmed by the breadth of ISO 10993-1:2025

What are Notified Bodies or FDA expecting?

Do legacy products need reassessment?

How should bioaccumulation be evaluated?



How should risk estimation be implemented?

What constitutes systemic reasonably foreseeable misuse?

and many more ???

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TC 194 Work program

RISK MANAGEMENT ASPECTS

ISO/CD TR 24850	Sources of constituent hazard information
ISO/CD TS 26177	Guidance on risk estimation and evaluation

CHEMICAL CHARACTERIZATION

ISO/AWI TS 11967	Guidance on commissioning scientifically robust chemical characterization testing in accordance with ISO 10993-18
ISO/CD 8250	Characterization of residuals
ISO/AWI 10993-13	Characterization of polymer degradation products
ISO/AWI 10993-14	Part 14: Characterization of ceramic degradation products
ISO/FDIS 10993-16	Part 16: Toxicokinetic evaluation of degradation products & leachables
ISO/CD TS 20324:	Extracts for chemical analysis for Toxicological risk assessment
ISO/WD TR 21582:	Pyrogen testing
ISO/DTS 25364-1:	Identification of organic extractables in non-targeted analysis (NTA)
ISO/CD TS 25364-2.2:	Quantification of extractables and leachables using NTA
ISO/CD TS 25364-3:	Requirements for NTA evaluation
ISO/AWI TS 25364-4:	Critical aspects of extract viability in extractables and leachables testing t

DOMAIN STANDARDS

ISO/DIS 10993-4:	Haemocompatibility test selection
ISO/DIS 10993-11.2:	Systemic toxicity testing
ISO/FDIS 18969	Clinical evaluation principles
ISO/AWI 14155	Devices Good clinical practice
ISO/DIS 10993-2	Animal welfare requirements

STILL TO DO

- Application of ISO 10993-1 throughout the **medical device lifecycle** including shelf-life considerations
- Determination of **Bioequivalence**
- Conduct of **literature review** to support biological evaluations

BIOACCUMULATION

ISO/CD TS 26420	Guidance on bioaccumulation

TOXICOLOGICAL RISK ASSESSMENT

ISO/DTS 21726:	Threshold of toxicological concern (TTC)
ISO/AWI TS 24830:	In-silico/read-across approaches

ABSORBABLE DEVICES

ISO/WD TS 37137-2:	Testing of absorbable devices for soft tissue repair

BIOLOGICAL MATERIALS

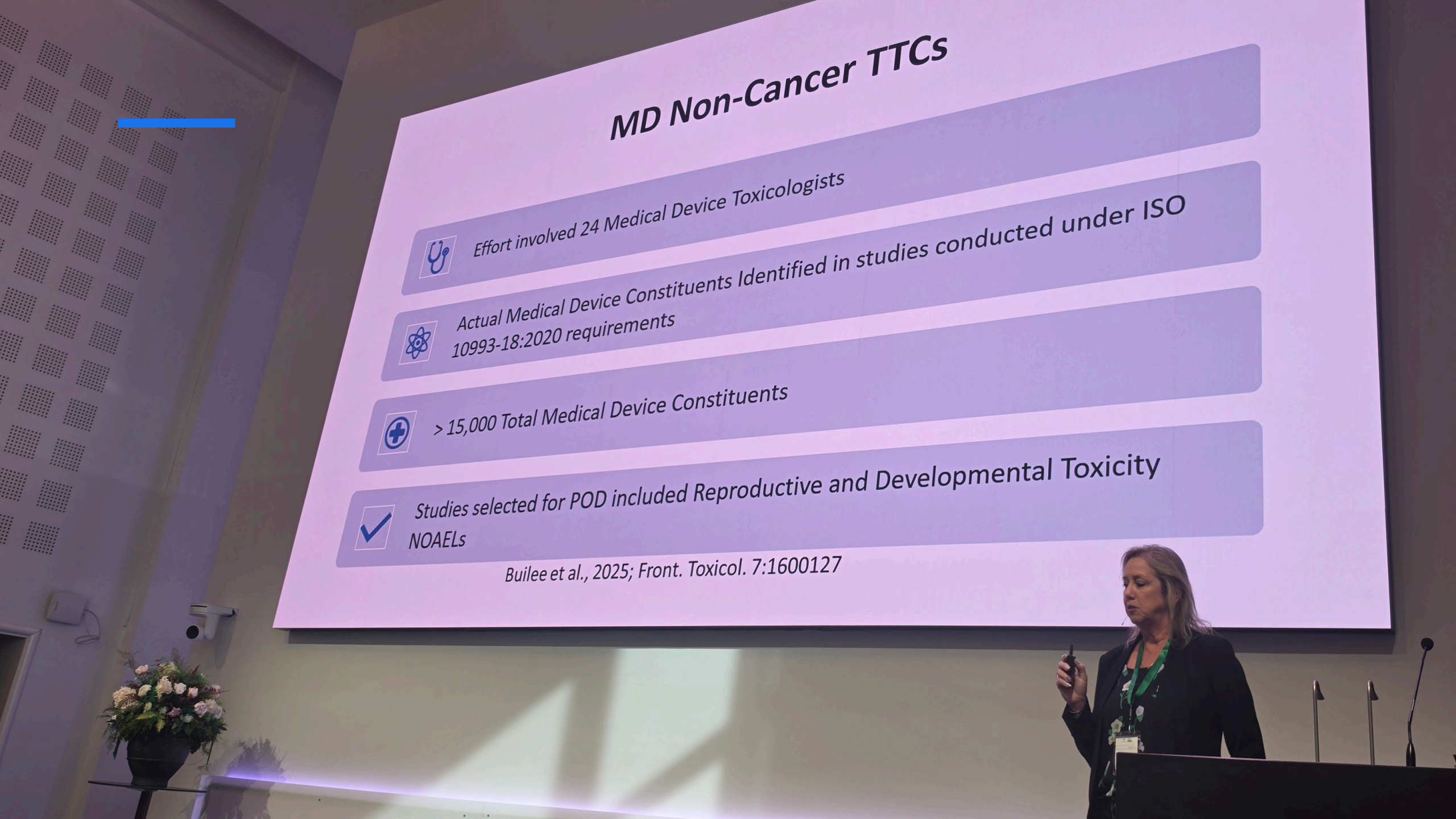
ISO/FDIS 21762:	Application of risk management for non-viable human materials
ISO/AWI 22442-1:	Application of risk management for tissue derivatives
ISO/AWI 22442-2:	Controls on tissue sourcing, collection and handling
ISO/AWI 22442-3	Validation of the elimination/inactivation of viruses and TSE in animal materials
ISO/CD 25695:	Application of risk management to bioengineered biological substances




SCIENCE
BUSINESS
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BETTER SCIENCE. REAL-WORLD IMPACT. PATIENTS FIRST.


Four Hats.
Greater Impact.
DIFFERENT PERSPECTIVES.
ONE CONVERSATION.
BETTER OUTCOMES.
- VALUE
- ACCESS
- SUSTAINABILITY
- REAL-WORLD IMPACT
THE KEY ADDITION
- PATIENT NEEDS
- CLINICAL REALITY
- SAFETY & EFFICACY
- QUALITY OF LIFE
- COMPLIANCE
- RISK MANAGEMENT
- ETHICS
- GLOBAL HARMONISATION
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FEASIBLE SOLUTIONS
MEANINGFUL PATIENT OUTCOMES
TRUSTED & COMPLIANT
BETTER
BIOCOMPATIBILITY SCIENCE
FOR REAL PATIENT IMPACT


• Regulatory hurdles
Is the science ready to give the confidence to move away from our reliance on animal studies?
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IDA
Conference


MD Non-Cancer TTCs
Effort involved 24 Medical Device Toxicologists
Actual Medical Device Constituents Identified in studies conducted under ISO 10993-18:2020 requirements
> 15,000 Total Medical Device Constituents
Studies selected for POD included Reproductive and Developmental Toxicity NOAELs
Builee et al., 2025; Front. Toxicol. 7:1600127




US KEY REGULATORY ISSUES FOR MANUFACTURERS
HISTORICAL FEAR !
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BI 2026
Biocompatibility Expertise
Make Biological Evaluation Decisions with Confidence
Risk-based evaluation strategies
Evidence-driven


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AVERSION
FEAR OF
FAILURE
FEAR OF
CHALLENGING
THE NORM
FEAR OF
REGULATORY
UNCERTAINTY
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COMMERCIAL
RISK
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WRONG
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WILL OTHERS
THINK?
IT'S ALWAYS
BEEN DONE
THIS WAY
FEARS
LEAVE THEM BEHIND
BETTER
PATIENT OUTCOMES
SMARTER
SOLUTIONS
BOLDER
SCIENCE
BRAVER
CONVERSATIONS

