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Terveysteknologian CE-merkinnän vaiheet Euroopassa

Tampereen ammattikorkeakoulu 7.3.2023

Heikki Pitkänen

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Senior Expert, Regulations & Quality CEO & Founder of Lean Entries

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AGENDA 7.3.2023

- Sääntelyn viitekehys ja CE-merkintä Euroopassa: MRD & IVDR
- Lääkinnällinen laite ja sen käyttötarkoitus
- CE-merkintä ja vaatimustenmukaisuuden vakuutus
- Laitteen määrittely ja luokittelu (ml. lääkinnälliset ohjelmistot)
- Sovellettavat regulaatiot ja standardit
- Strategia säännösten noudattamista ja markkinoillevientiä varten
- Vaatimustenmukaisuuden arviointi ennen markkinoille asettamista
- General Safety & Performance Requirements: Kliinisen evaluaation ja riskienhallinnan tasapaino
- Vaatimusten suhde liiketoimintaan ja lessons learned
- Tuotekehitys regulaatioiden ja standardien ohjaamana
- Roolit ja vastuut
- Laadunhallintajärjestelmän perusteet



SAFETY AND EFFICIENCY: NON-NEGOTIABLE

The core of regulatory requirements, and the baseline for business in healthcare:

Devices shall achieve the performance intended by their manufacturer...

They shall be safe and effective and not compromise the clinical condition or safety of patients or other persons...

Risks, when weighed against benefits, are compatible with a high level of protection of health and safety...

...taking into account the generally acknowledged state of the art. *

*) MDR and IVDR, Annex I General Safety and Performance Requirements, Chapter I (1)

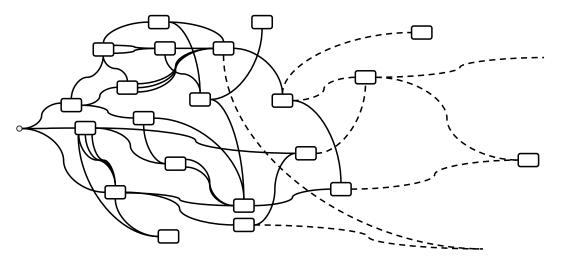
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THE EARLY STAGE REGULATORY HURDLE

"Medtech innovation is driven by small companies and startups on the cutting edge of improving patient care. In the best of times, these heavily R&D-focused firms struggle to find the financing and resources they need to navigate tough regulatory and reimbursement pathways in order to bring a new device or diagnostic to market, and that challenge has been magnified by the pandemic."

AdvaMed Press Release - 5 Aug 2020

REGULATIONS CAN BE COMPLEX



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MEDICAL DEVICE DIRECTIVE 93/42/EEC

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

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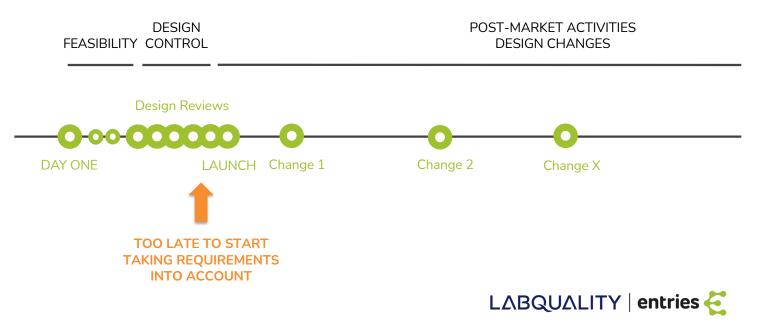


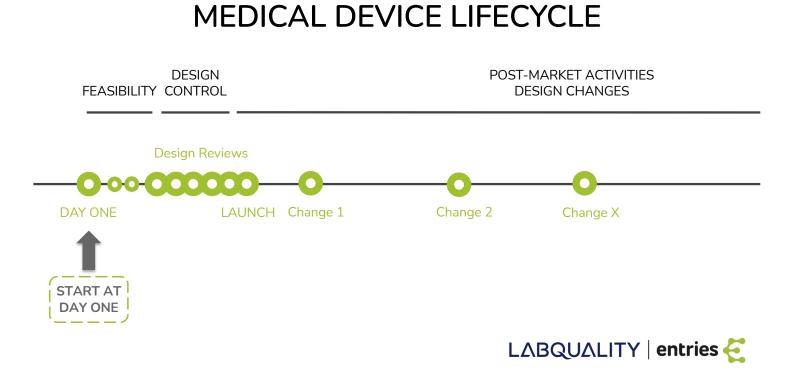
A LOT TO COMPLY WITH

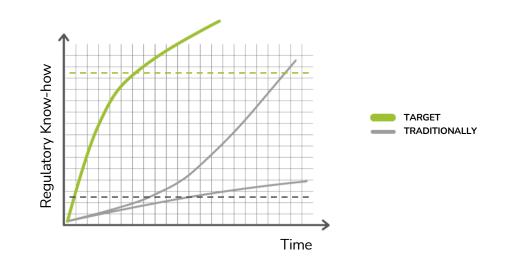
Medical Device Regulation (MDR) 2017/745 - or - IVD Medical Device Regulation (IVDR) 2017/746) US FDA Code of Federal Regulations (CFR) Title 21

ISO 13485:2016 - Quality Management System FDA CFR Part 820 - Quality System Regulation (QSR) MEDDEV 2.7/1 (June 2016) - Clinical Evaluation ISO 14155:2020 - Clinical Investigation / Good Clinical Practice (GCP) ISO 14971:2019 - Risk Management IEC 62366-1:2015/A1:2020 - Usability IEC 62304:2006/A1:2015 - Software Life Cycle IEC 60601-1:2005/A2:2020 - Electrical Safety (series) ISO 10993-1:2018 - Biocompatibility / Biological Evaluation (series) ISO/TR 20416:2020 - Post-Market Surveillance and Clinical Follow-up Etc. LABQUALITY | entries 🧲

MEDICAL DEVICE LIFECYCLE









NOONA HEALTHCARE

PASI HEISKANEN, COO & CO-FOUNDER

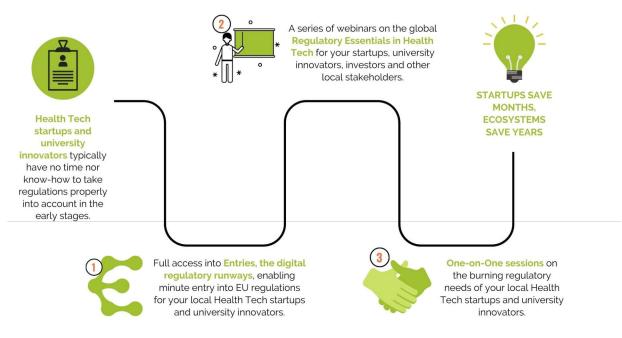
"Having identified a pile of business risks, risking compliance was clearly not one we could afford.

Everything we do for the sake of compliance, starting from risk management and clinical evaluation, translates into smart and efficient business and highly valuable marketing material.

We're now acquired by the multinational health tech giant Varian.

8. KEY PARTNERSHIPS	7. KEY ACTIVITIES	2. VALUE PRO	OPOSITION	4. CUSTOMER RELATIONSHIPS	1. CUSTOMER SEGMENTS
Top university hospitals and clinics globally Development & UX subcontractors Regulatory & Quality	 Development & upkeep UX design Clinical evaluation Compliance & Risk management Sales 	Substantial increase in care output and quality with half of the resources compared to state-of-the- art care		Pilots and workshops with clinics Co-operating clinics	Healthcare professionals Patients
support services Clinical Research Organizations (CRO's)	 6. KEY RESOURCES Development UX expertise Clinical expertise Regulatory & Quality expertise Sales expertise 			3. CHANNELS SaaS for patients Installations for clinics	
9. COST STRUCTURE €		•	5. REVENUE STREAMS €		
Development & upkeep Marketing & Sales			Annual fee from the clinics		
Compliance	Etc.				
Clinical investigations			LABQUALITY entries 🧲		

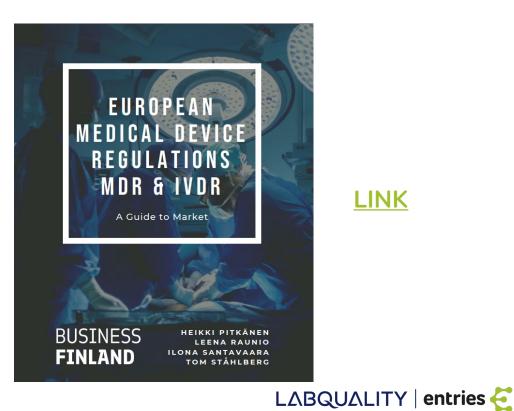
THE KNOWLEDGE TRANSFER CONCEPT



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REGULATORY ESSENTIALS IN HEALTH TECH

(Session 1 – Compliance as a Business Advantage	Thu 16 Mar 2023
Í.	Session 2 – Early Development and Management	Tue 21 Mar 2023
	Session 3 – The Core of the Regulatory Requirements	Thu 23 Mar 2023
	Session 4 – Design Control and the Regulatory Environment	Tue 28 Mar 2023
	Session 5 – Regulatory Essentials of In Vitro Diagnostics	Thu 30 Mar 2023
	Session 6 – Medical Device Software	Tue 18 Apr 2023
	Session 7 – Risk Management in Practice	Thu 20 Apr 2023
	Session 8 – FDA	Tue 25 Apr 2023
	Session 9 – Usability and Labelling	Thu 27 Apr 2023
	Session 10 – Biological and Electromedical Safety	Tue 2 May 2023
	Session 11 – Clinical Evaluation in Practice	Thu 4 May 2023
	Session 12 – Clinical Investigations in Practice	Tue 9 May 2023
	Session 13 – Post-Market Surveillance & Clinical Follow-up	Thu 11 May 2023
	Session 14 – Person Responsible for Regulatory Compliance	Tue 16 May 2023 LABQUALITY entries 🗲



LINK

AGENDA 7.3.2023

- Sääntelyn viitekehys ja CE-merkintä Euroopassa: MRD & IVDR •
- Lääkinnällinen laite ja sen käyttötarkoitus •
- CE-merkintä ja vaatimustenmukaisuuden vakuutus
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- Vaatimusten suhde liiketoimintaan ja lessons learned
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- Roolit ja vastuut
- Laadunhallintajärjestelmän perusteet



THE EARLY FOCUS IN HEALTH TECH

Regulations and Standards = D

= Decades of wisdom condensed

- 1 Intended Purpose
- The heart of your medical device

- The level of proof required (Conformity Assessment options)

- 2 Device Classification
- 3 List of Standards
- 4 Regulatory Strategy
- The baseline for state-of-the-art safety requirements
- Roadmap for market entry

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COMPLIANCE AND BUSINESS NEEDS

ANNEX I: General Safety and Performance Requirements

= The heart of the MDR & IVDR



- 1 Clinical Evaluation from Literature Review to Post-Market Surveillance
- 2 Risk Management from Risk Analysis to Benefit-Risk Analysis
- 3 Device Life Cycle from Feasibility Studies to Design Control
- 4 Supplier Evaluation from Contracts to Design Control

Align compliance with your Business, Marketing & Sales needs!

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BUSINESS, MARKETING & SALES NEEDS

1 Literature Review

- To know the clinical state-of-the-art, benchmarks, competition, the basis for your value proposition and sales & marketing materials
- \circ $\,$ Major source of both design inputs and business considerations $\,$

2 Risk Analysis

- To know your business risks, not just device safety risks
- Major source of both design inputs and business considerations

3 Feasibility Studies

• To minimize repetition during Design Control (exposing to slow failure)

4 Contracts

- To ensure all parties involved are capable of fulfilling the requirements
- A great risk, if the manufacturer AND the supplier are BOTH unaware of the requirements



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LESSONS LEARNED

Typical reasons for major losses in funds and time, causing many slow failures

- Regulations not taken into account early on
- False classification of the device
- Wrong standards chosen
- Too few resources or no earlier knowledge on regulations
- Change in the Intended Purpose of the device without checking the effect of regulations
- Focus on technology -> Too little focus on requirements and business
 - Shortcomings in clinical evaluation (incl. Clinical investigations) & risk management etc.



URISENS SMART DIAPER - R2B PROJECT

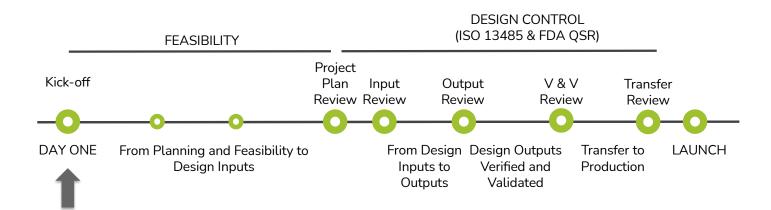
OGUZ TANZER, PHD, BIODESIGN INNOVATION FELLOW, AALTO UNIVERSITY & SPARK FINLAND

"Before exploiting these regulatory tools I was daunted by the complexity of regulatory compliance. Now I feel relief and understand how our project can harness regulations and standards to our benefit and avoid the regulatory pitfalls.

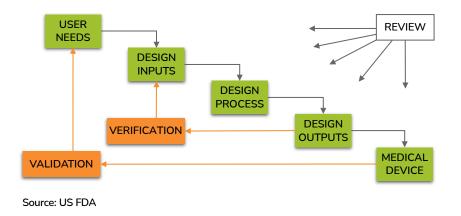
The Entries tool in itself is very effective in transmitting knowledge. I have experienced nothing comparable to it as an educational hands-on application. I've certainly saved weeks worth of my time in reaching this new level of regulatory knowledge and find confidence in moving forward."

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FEASIBILITY & DESIGN CONTROL PHASES



DESIGN CONTROL EXPLAINED 1/2



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DESIGN CONTROL EXPLAINED 2/2

Why apply Design Control (the FDA origins)? And why apply an entire QMS?

- Maintaining constant high quality of products
- Avoiding adverse events
- Improved communication of the development team
- Earlier recognition of problems
- Systematic preparation for Design Transfer through Process Validation
- Increased likelihood of the transferred products to meet the Intended Purpose
- Complete data for the records, production, conformity assessments and market approvals
 - Design History File (DHF)
 - Device Master Record (DMR)
 - Technical Documentation (TD) / Technical File (TF)

