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Terveysteknologian CE-merkinnän vaiheet Euroopassa

Tampereen ammattikorkeakoulu
7.3.2023

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

AGENDA 7.3.2023

- Sääntelyn viitekehys ja CE-merkintä Euroopassa: MRD & IVDR
- Lääkinnällinen laite ja sen käyttötarkoitus
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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

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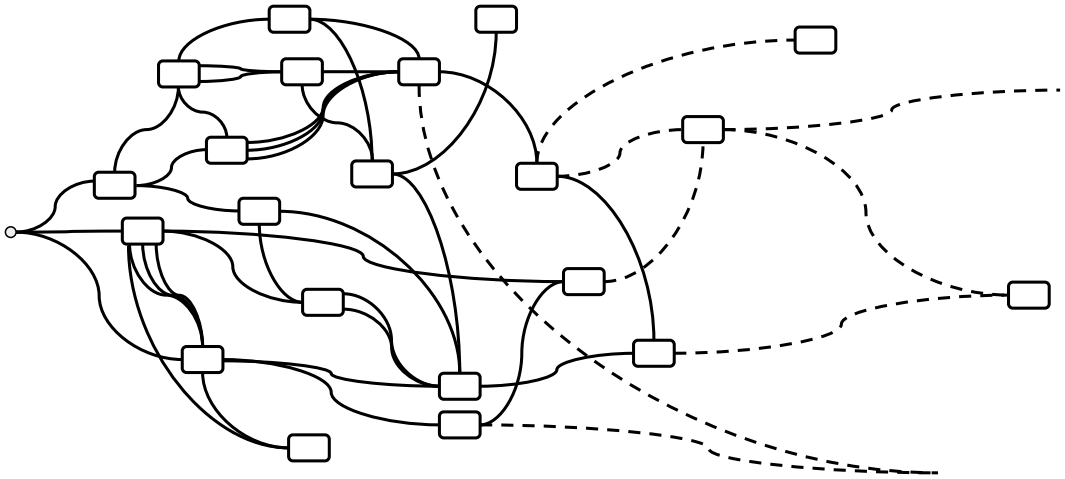
REGULATIONS CAN BE COMPLEX



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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.

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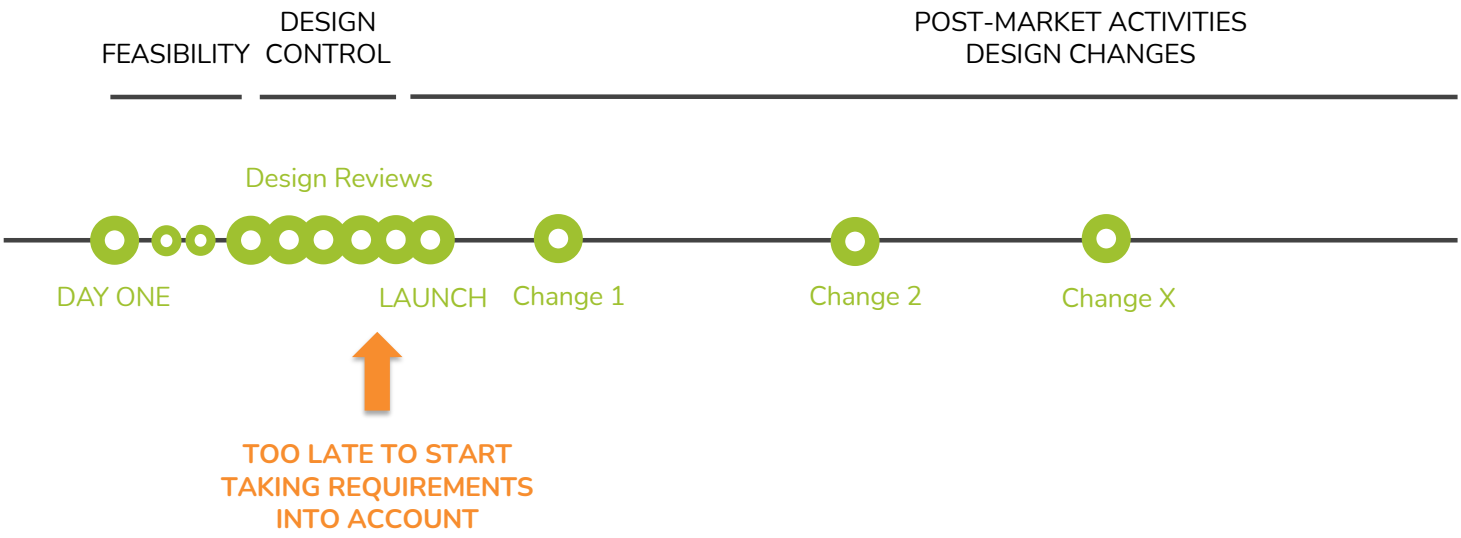
MEDICAL DEVICE LIFECYCLE



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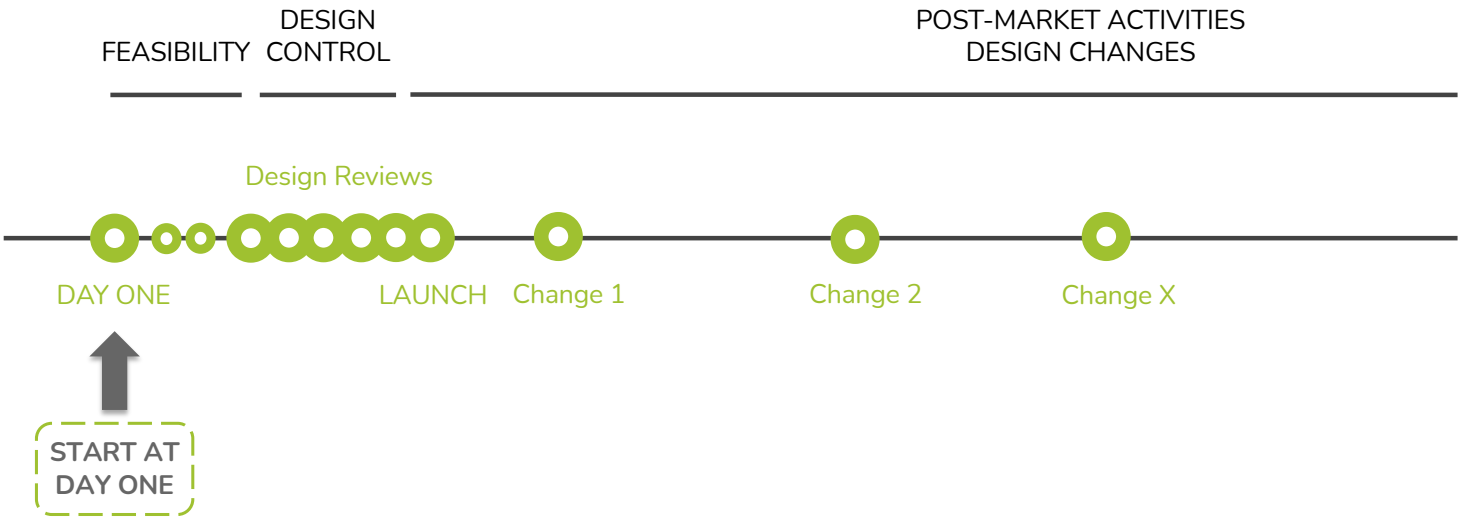
MEDICAL DEVICE LIFECYCLE



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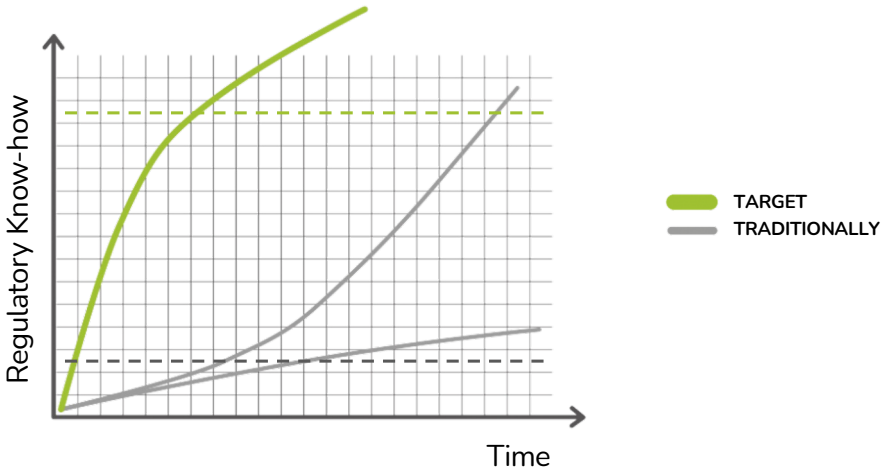
BASELINE OF REGULATORY KNOW-HOW



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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.

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8. KEY PARTNERSHIPS	7. KEY ACTIVITIES	2. VALUE PROPOSITION	4. CUSTOMER RELATIONSHIPS	1. CUSTOMER SEGMENTS
Top university hospitals and clinics globally Development & UX subcontractors Regulatory & Quality support services Clinical Research Organizations (CRO's)	• Development & upkeep • UX design • Clinical evaluation • Compliance & Risk management • Sales 6. KEY RESOURCES • Development • UX expertise • Clinical expertise • Regulatory & Quality expertise • Sales expertise	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 3. CHANNELS SaaS for patients Installations for clinics	Healthcare professionals Patients

9. COST STRUCTURE €		5. REVENUE STREAMS €
Development & upkeep Compliance Clinical investigations	Marketing & Sales Etc.	Annual fee from the clinics

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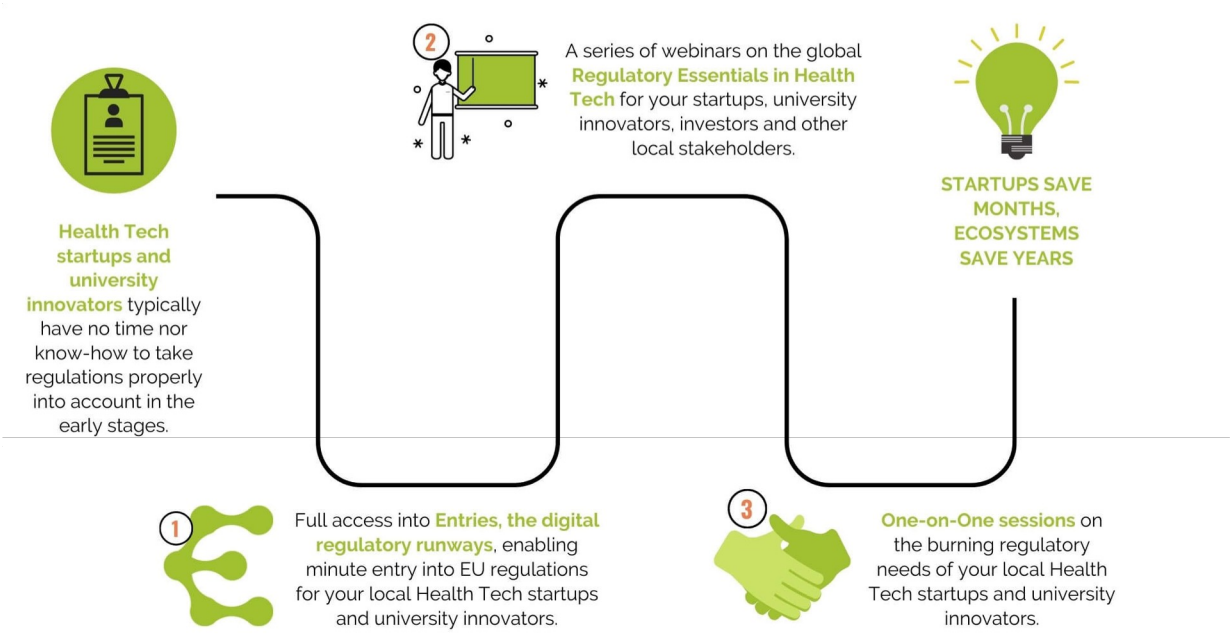
THE KNOWLEDGE TRANSFER CONCEPT



REGULATORY ESSENTIALS IN HEALTH TECH

Session 1 – Compliance as a Business Advantage	Thu 16 Mar 2023
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

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THE EARLY FOCUS IN HEALTH TECH

Regulations and Standards = Decades of wisdom condensed

1 Intended Purpose - The heart of your medical device

2 Device Classification - The level of proof required (Conformity Assessment options)

3 List of Standards - The baseline for state-of-the-art safety requirements

4 Regulatory Strategy - 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
   - 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

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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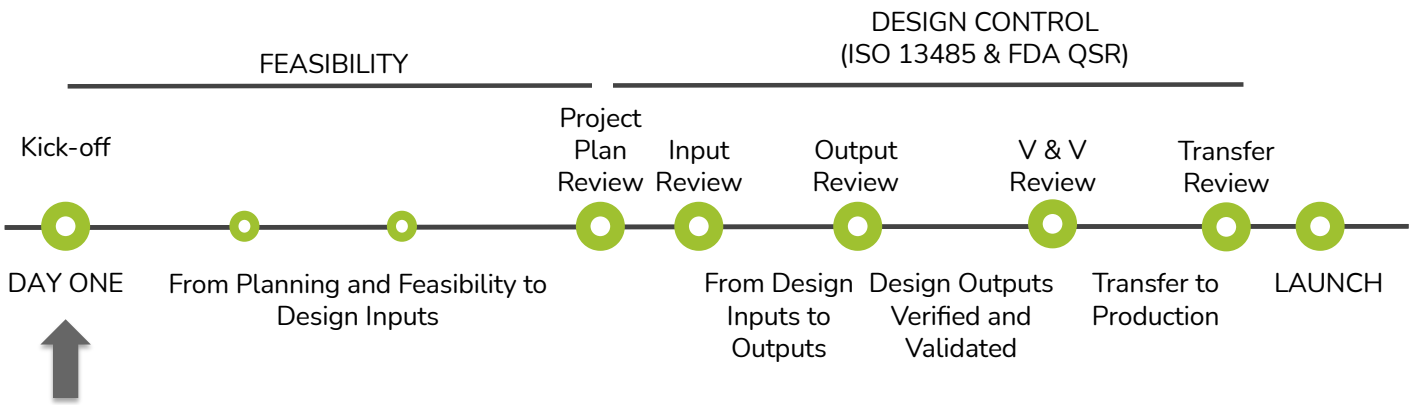
FEASIBILITY & DESIGN CONTROL PHASES



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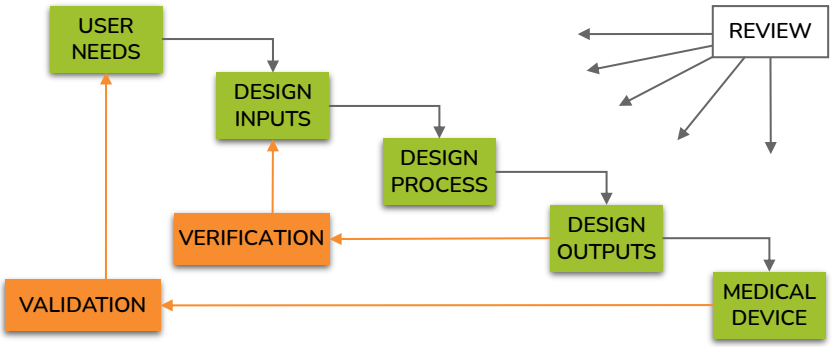
DESIGN CONTROL EXPLAINED 1/2



Source: US FDA

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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)

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