Establishing a regulatory strategy

James Pink

What is a regulatory strategy?

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‘A regulatory strategy can be defined as a science-driven assessment of a product’s development options, key considerations and likely regulatory outcome’.

Walker, C & Soulis, T (2020). Regulatory Strategy. In Global Pharmaceutical and Biologics regulatory strategy 2nd ed, RAPS.,pp.187

What is a regulatory strategy?

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The “cunning plan” to get from bench to bedside

Why should I invest my time in developing a regulatory strategy?

This happens…

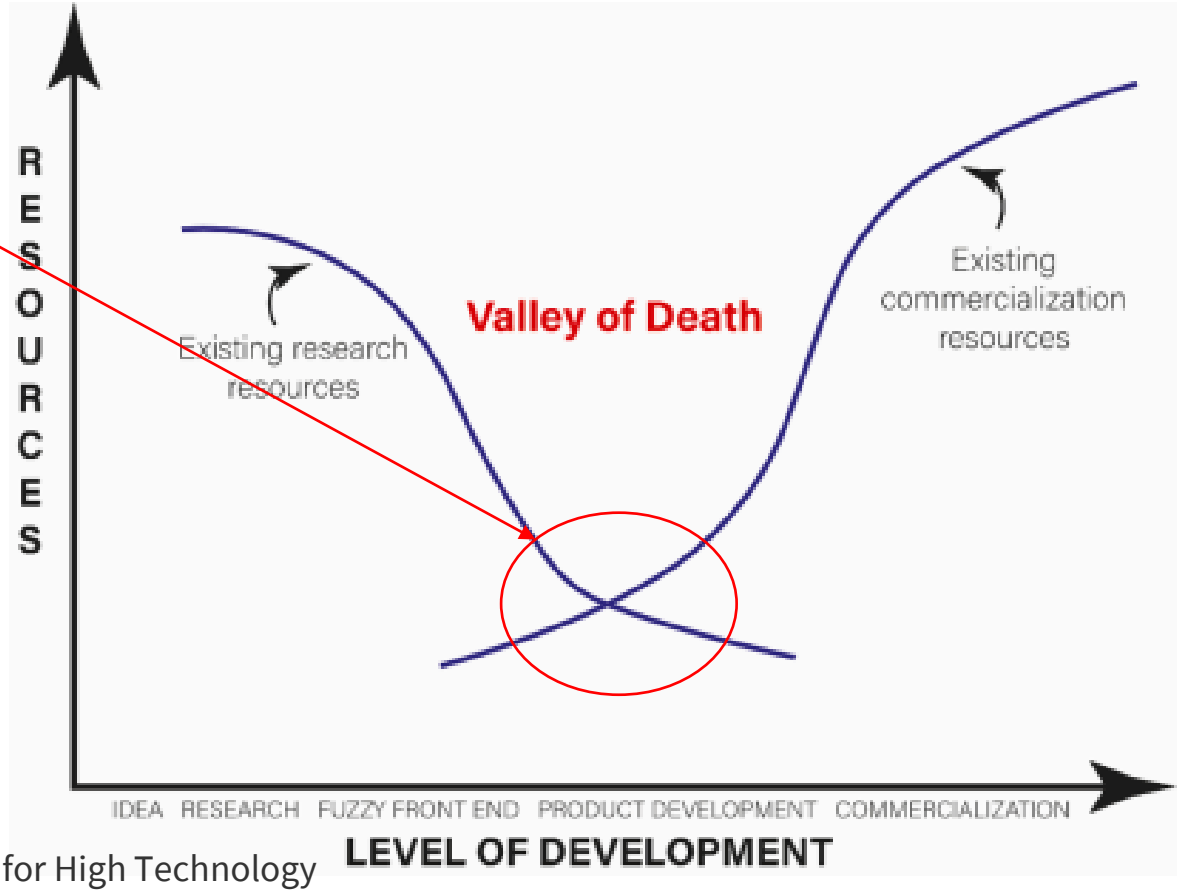

Fig. 1. Valley of Death.

Gbadegeshin et al, Overcoming the Valley of Death: A New Model for High Technology Startups,
Sustainable Futures, Volume 4, 2022, 100077, ISSN 2666-1888

Why should I invest my time in developing a regulatory strategy?

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Because of this…

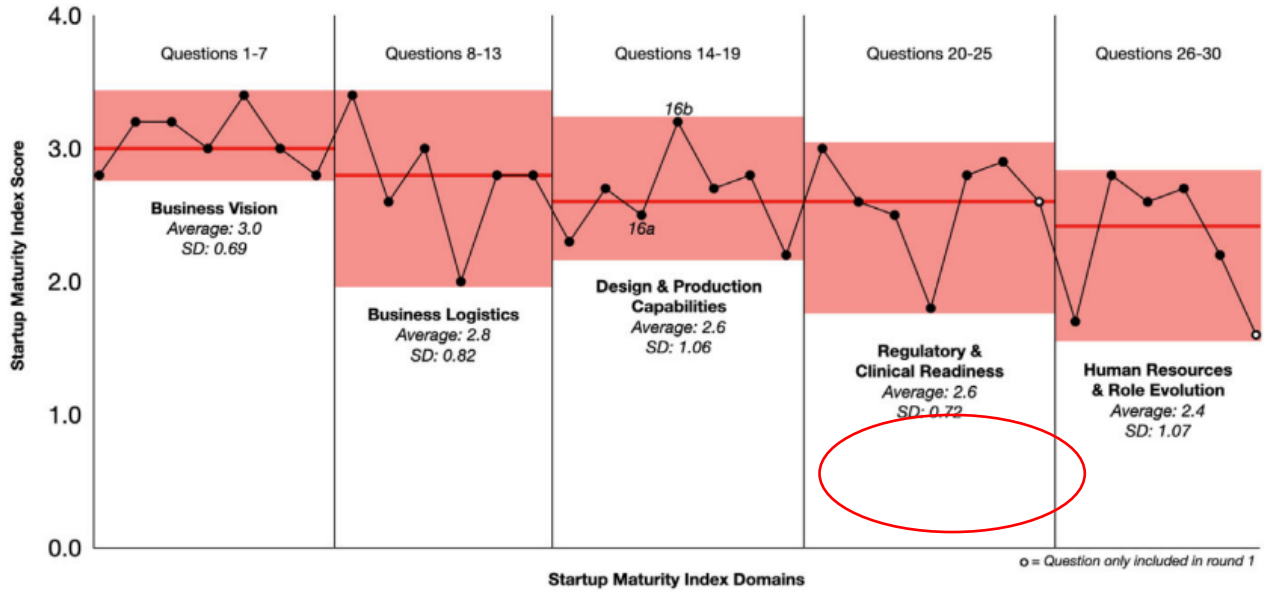

Fig. 1. Graphical summary of Startup Maturity Index (SMI) Scores across five domains. The x-axis indicates SMI questions 1–30 and y-axis the corresponding SMI scores. The red horizontal bars represent the section average score, while the red highlighted area represents the range of scores. Each individual point represents the average score across all companies for a given question, sequentially from left to right. The two points with a white center represent questions that were only included in the first round of interviews. SD = Standard deviation.

: Richmond Fj et al. A novel maturity index for assessing medical device startups. Journal of Clinical and Translational Science 6: e99, 1–9. doi: 10.1017/ cts.2022.436

Why should I invest my time in developing a regulatory strategy?

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Leading to this…

Startling Statistics: Cost, Failure Rates, and Time

Given the complexity of the process involved in bringing a new device to market, it is no surprise that doing so is expensive. The average cost to bring a 510(k) product from concept to market is in excess of $31 million, with greater than 77 percent of the cost – approximately $24 million— spent on regulatory and FDA-related activities. The cost of an FDA premarket approval (PMA) averages $94 million, with $75 million spent on FDA-linked stages—nearly 80 percent of the total amount. (**https://www.massdevice.com/exploring-fda-approval-pathways-for-medical-devices/**).

The failure rate for medical startups should not come as a surprise either. As of 2019, startup failure rates were around 90%; 21.5% of startups fail in the first year, 30% in the second year, 50% in the fifth year, and 70% by Year 10. One article states that **75% of US-based medical device start-ups fail,** and 98% of digital health startups fail. Seventy-five percent of venture-backed companies never return cash to their investors, and in 30% to 40% of cases, investors lose their entire initial investment (**https://www.embroker.com/blog/startup-statistics/**).

Why should I invest my time in developing a regulatory strategy?

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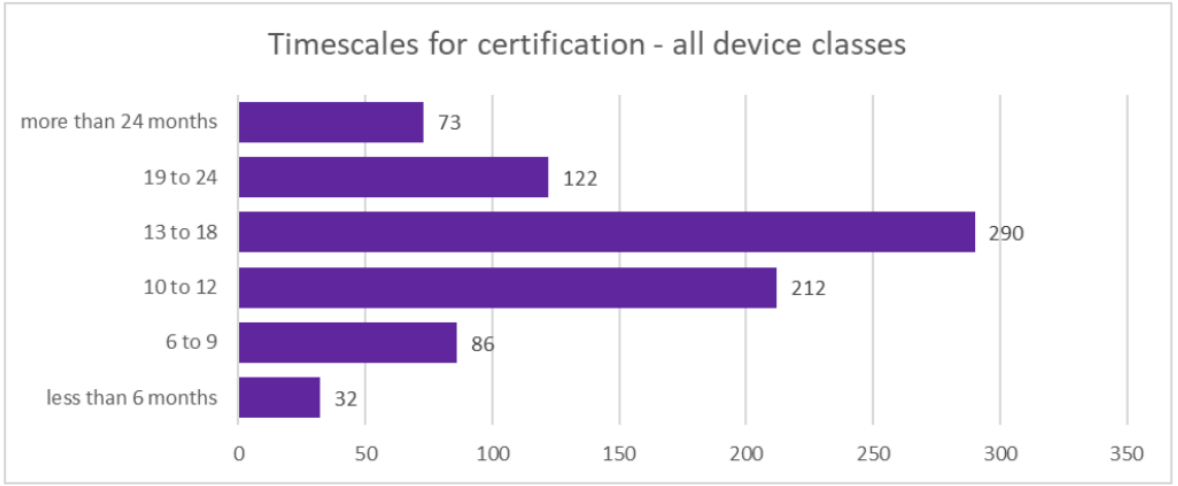
and this…

14 July 2022

MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation

3) SMEs are more impacted by the MDR than larger companies.

- Up to 30% of SMEs have either no Notified Body (15%) and/or have a Notified Body that is not yet designated to MDR (15%).
- Progress to certification is slower than average: only 7% of MDR certificates have been issued for SMEs compared to 13% on average.
- According to the survey data, while SMEs account for 26% of the total number of devices expected on the market by 26 May 2024, they will require 40% of the total certificates needed.



How do I start?

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Start with the end in mind

"The clinical and regulatory barriers"

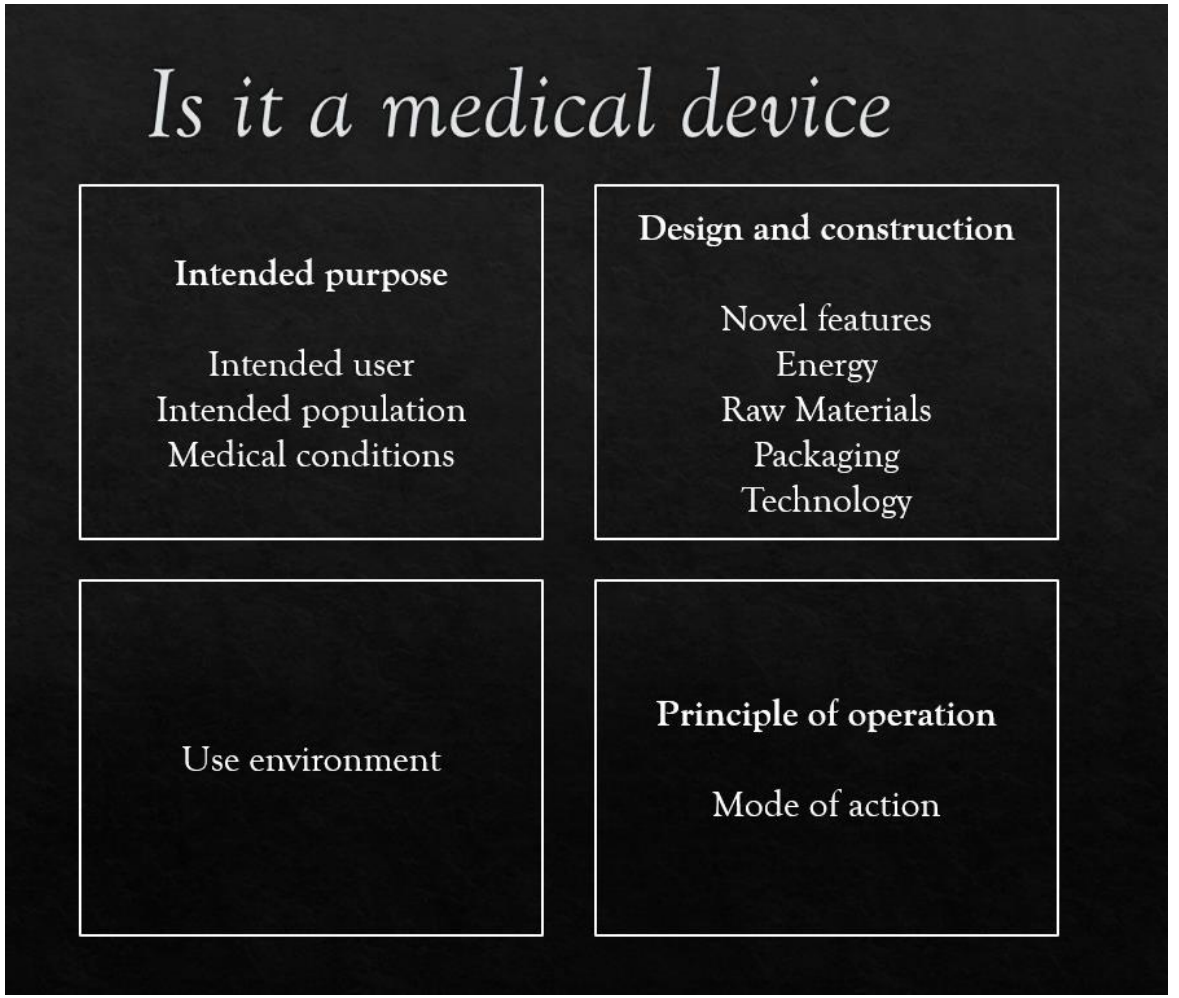
- Is it a medical device and what laws apply
- What is its classification and which rules apply
- What are the product requirements, risks and standards
- What are the likely regulatory and quality processes
- What clinical and non-clinical evidence will I need to generate
- What are the business administrative entities I need
- What is the conformity assessment route to market
- What evidence is required for market adoption
- What is the likely overall cost and timeline
- What options are available optimise my pathway to market
- How will my product be reimbursed

"The regulatory strategy"

"The market"

How do I start?

Define and refine the intended purpose and principle of operation / mechanism of action



How do I start?

Environment scan the intended market ecosystem

NOTE
Regulatory strategy addresses how each aspect will be addressed based upon the product intended purpose, risk classification and evidence requirements

"I want to sell in the US market".

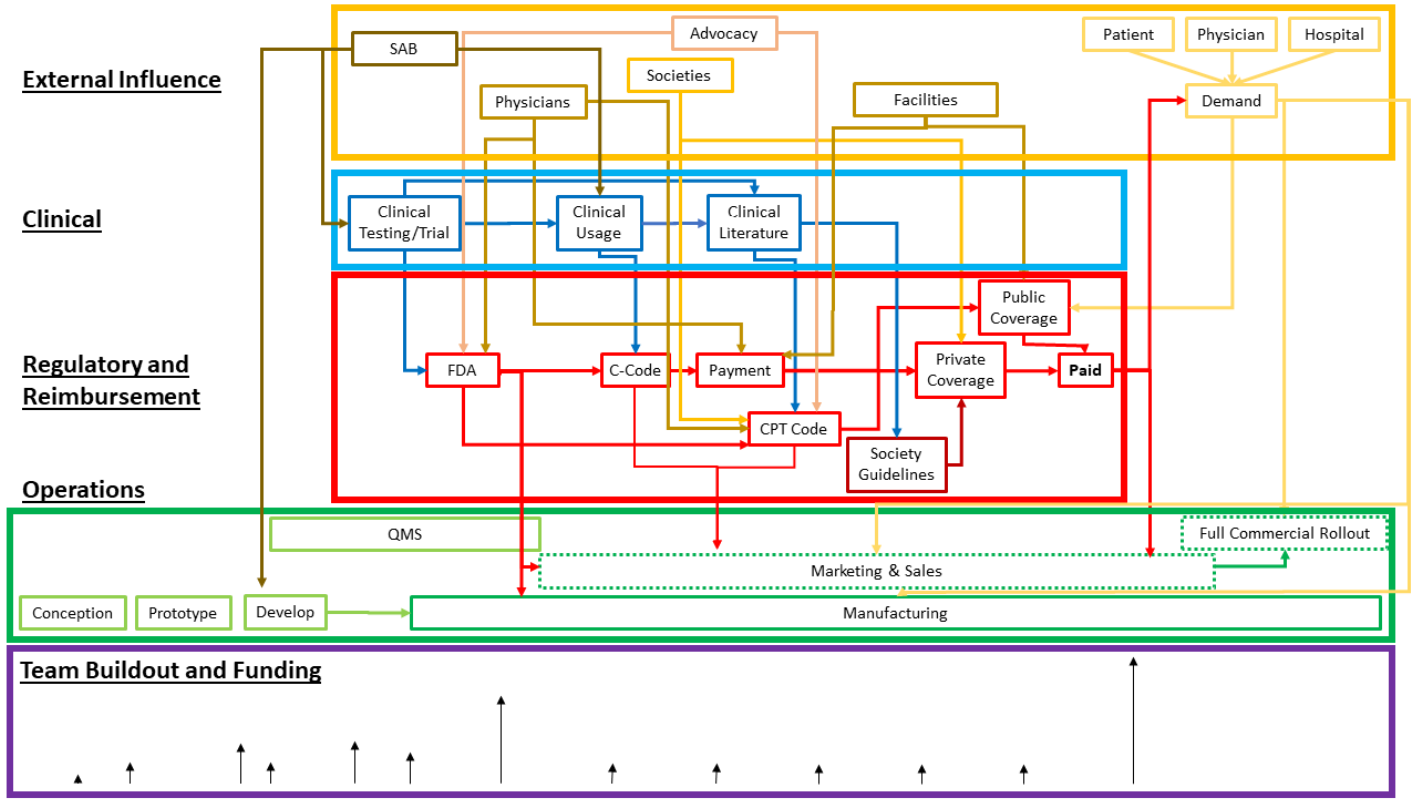


Figure 1: The complete integrated pathway and timeline for a new medical device, from conception through to commercial rollout, including relative level of financing required.

Source, Online "Why It Takes So Long to Develop a Medical Technology (Part 1) - Focused Ultrasound Foundation (fusfoundation.org)"

How do I start?

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Step 1: Qualification as a medical device within the regulatory jurisdiction (market)

Step 2: Regulatory risk classification of the medical device

Step 3: Safety risk classification of the medical device

Step 4: Conformity assessment options and pathways available

Step 5: Applicable standards, guidelines and regulatory requirements associated with safety and performance

Step 6: Known hazards associated to the device characteristics, intended use and user environment

Step 7: Known methods used to reduce hazards to an acceptable level

Step 8: Determine clinical novelty and evaluate clinical evidence generation (clinical development plan)

Step 9: Technical documentation requirements

Step 10: Quality management system requirements

Step 11: Legal and business administration requirements

Can I change my mind?

Of course!

Refinement of claims, adapting technologies, eliminating / removing risks all have positive impacts on the market access and adoption barriers.

Can I change my mind?

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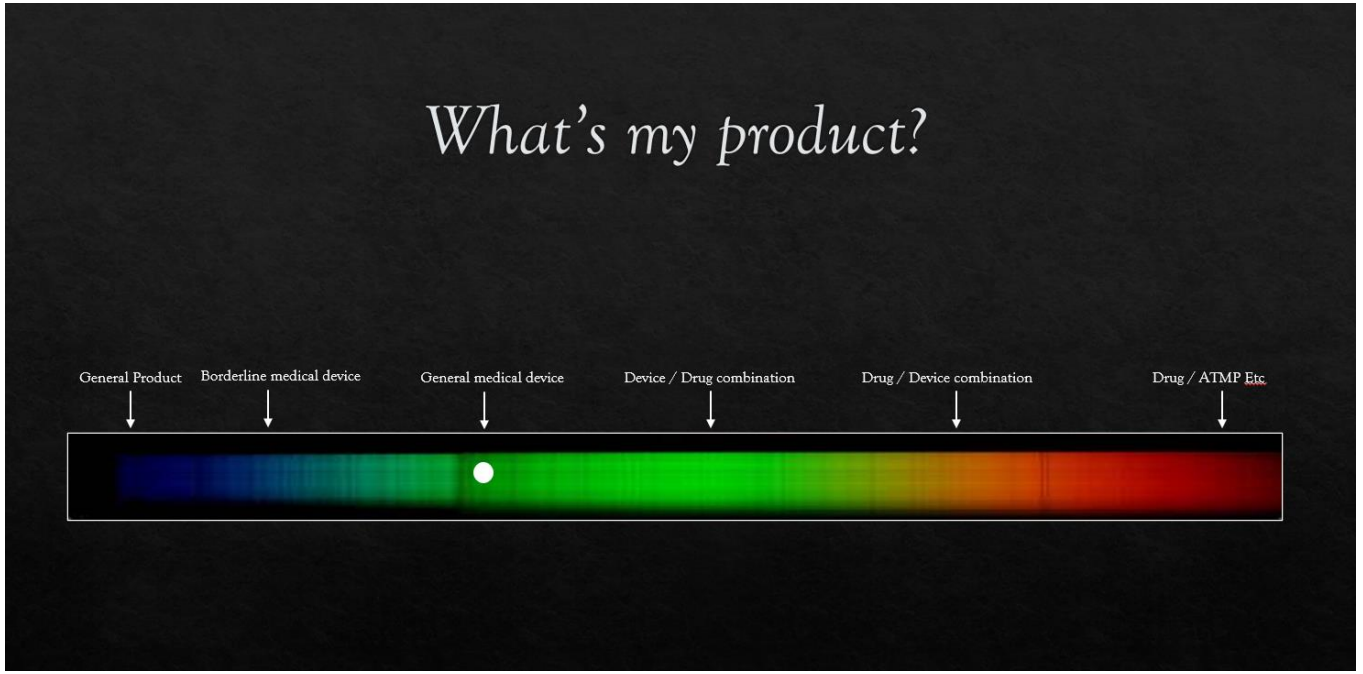
Defining and refining intended purpose may lead to less, more or different market access and regulatory barriers.



Can I change my mind

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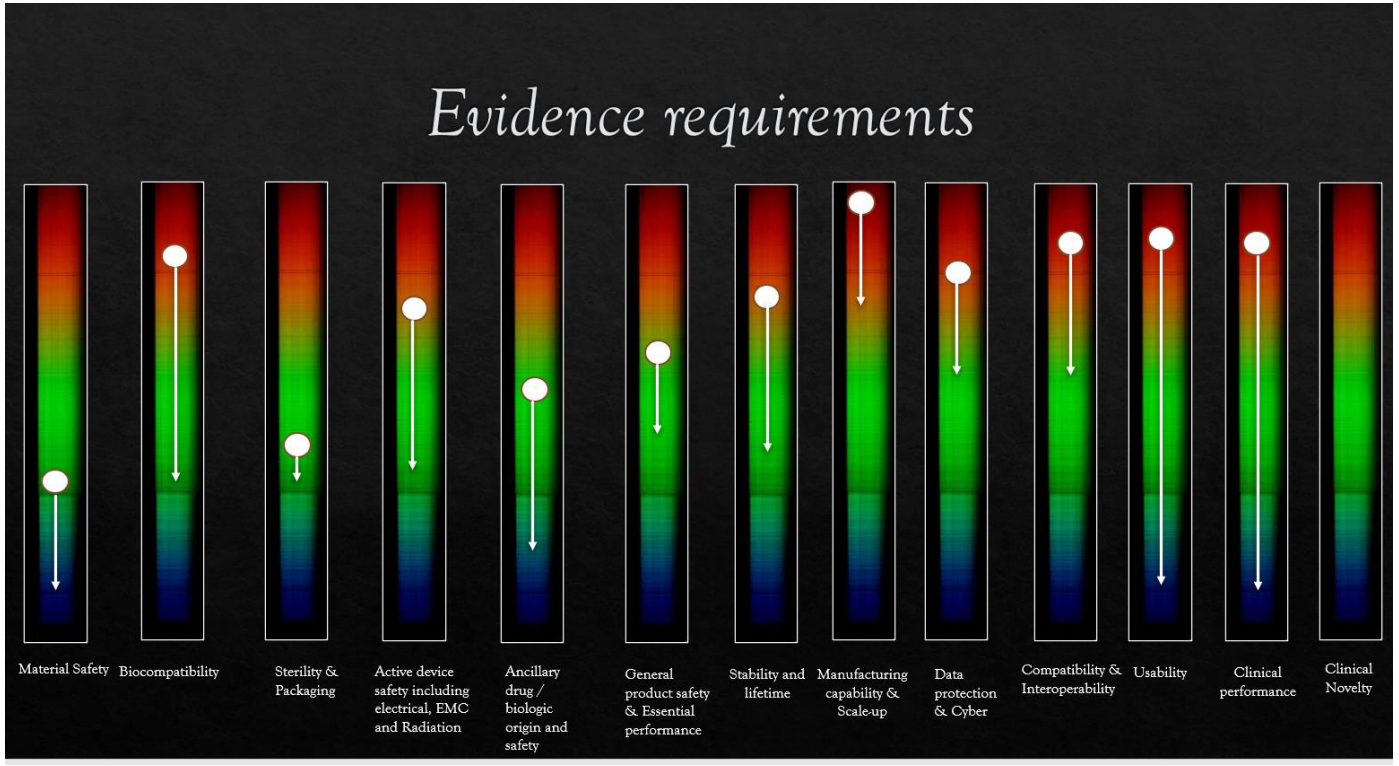
Adapting technologies, ensuring substantial equivalence or removing / eliminating risks may change evidence requirements



Can I change my mind?

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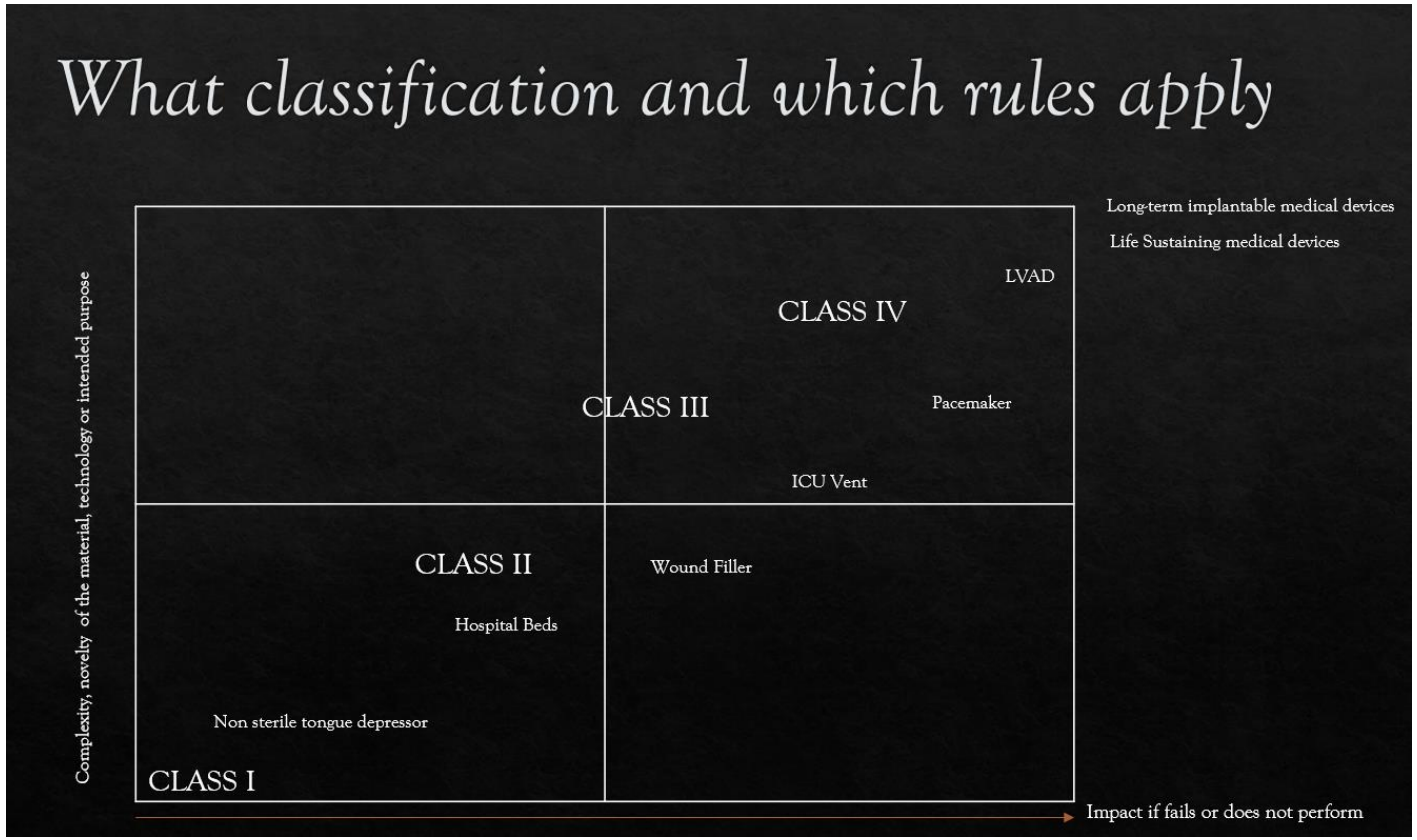
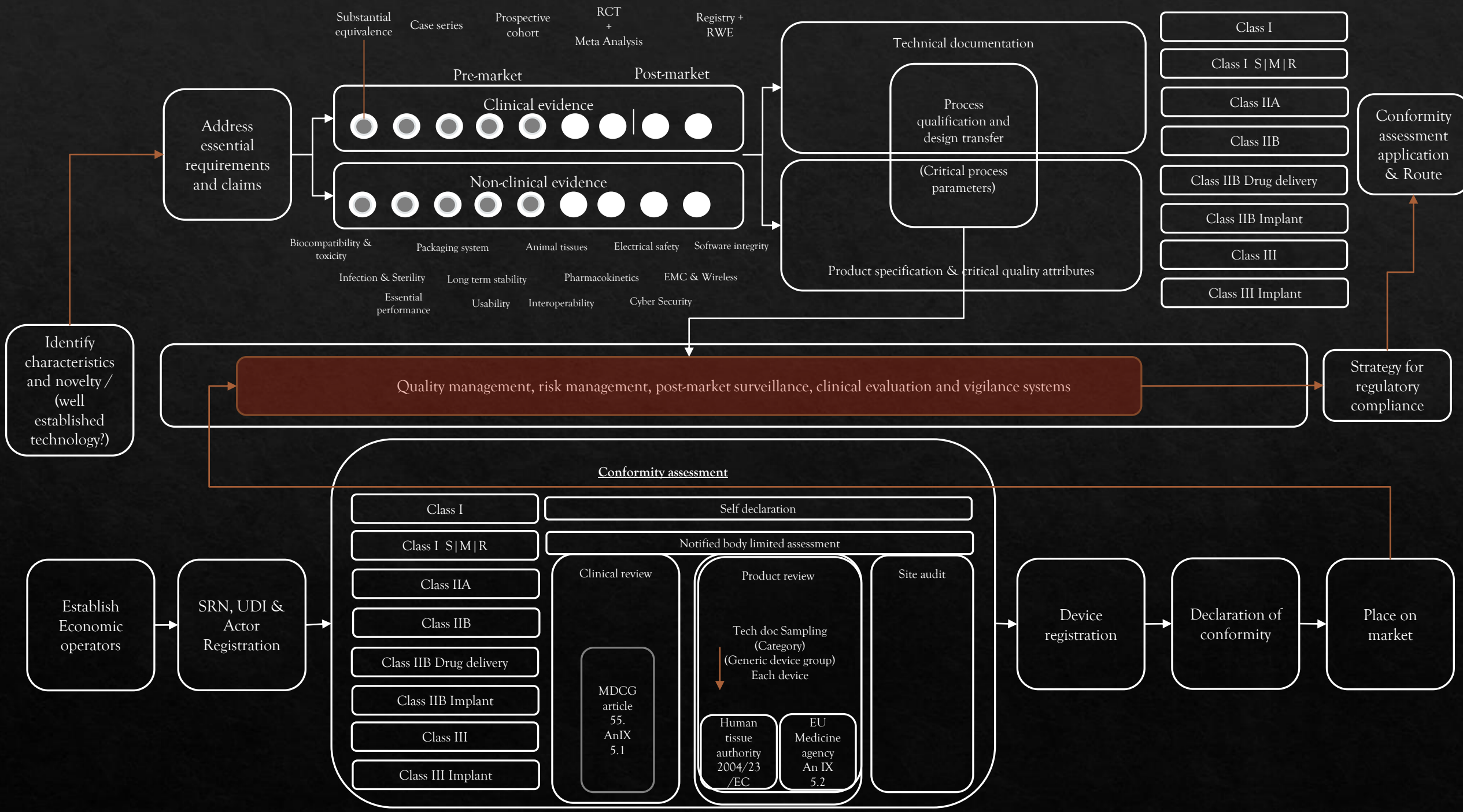
Refining intended purpose or adapting product characteristics may change both the regulatory and safety risk classifications.




Substantial equivalence
Case series
Prospective cohort
RCT + Meta Analysis
Registry + RWE
Pre-market
Post-market
Clinical evidence
Non-clinical evidence
Address essential requirements and claims
Biocompatibility & toxicity
Packaging system
Animal tissues
Electrical safety
Software integrity
Infection & Sterility
Long term stability
Pharmacokinetics
EMC & Wireless
Essential performance
Usability
Interoperability
Cyber Security
Technical documentation
Process qualification and design transfer
(Critical process parameters)
Product specification & critical quality attributes
Class I
Class I S|M|R
Class IIA
Class IIB
Class IIB Drug delivery
Class IIB Implant
Class III
Class III Implant
Conformity assessment application & Route
Identify characteristics and novelty / (well established technology?)
Quality management, risk management, post-market surveillance, clinical evaluation and vigilance systems
Strategy for regulatory compliance
Conformity assessment
Class I
Class I S|M|R
Class IIA
Class IIB
Class IIB Drug delivery
Class IIB Implant
Class III
Class III Implant
Self declaration
Notified body limited assessment
Clinical review
MDCG article 55. AnIX 5.1
Product review
Tech doc Sampling (Category) (Generic device group) Each device
Human tissue authority 2004/23 /EC
EU Medicine agency An IX 5.2
Site audit
Establish Economic operators
SRN, UDI & Actor Registration
Device registration
Declaration of conformity
Place on market

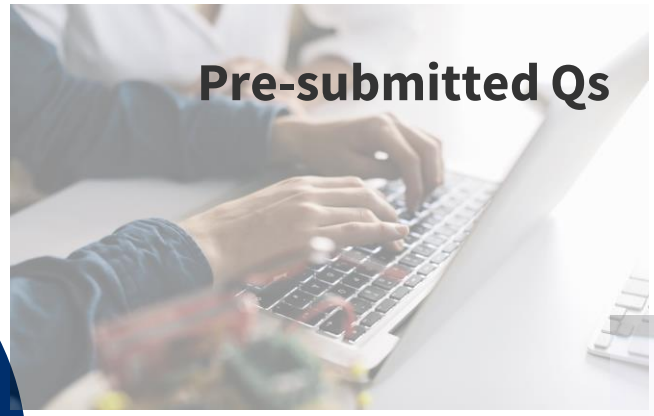
Tools and support

- Professional associations
  - TOPRA, RAPS (Europe)
  - Industry associations
  - ABHI, BIVDA, MedTech Europe, Advamed
- Regulatory agency websites and learning portals
- Consultancies
- Medical technology innovation services
  - MDIC (US), Innovate UK, NIHR and many more here today!!

Q&A

James Pink, MBA
Director, Medical

James.Pink@element.com



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