# **From concept to patient**: 5 key factors for successful Medical Device Development

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6 februari 2024 | Van der Valk Vianen

**2003 - Theranos founded**

2004 - $6.9 mln funding - $30 mln valuation

2007 - $42.2 mln funding - $197 mln valuation

**2010 - $1 billion valuation**

2013 - International launch

2014 - $400 million funding - $9.0 billion valuation

2015 - Capital BlueCross choses Theranos as preferred provider

**2015 - Wall Street Journal article**

2015 - FDA warning (483 form)

2015/17 - Articles, reports and lawsuits

2018 - SEC charges Theranos and CEO Elizabeth Holmes with fraud

**2022 - Elizabeth Holmes sentenced to 11 years in prison**

THE WALL STREET JOURNAL.

## Hot Startup Theranos Has Struggled With Its Blood-Test Technology

Silicon Valley lab, led by Elizabeth Holmes, is valued at $9 billion but isn't using its technology for all the tests it offers

*By John Carreyrou* Follow

*Updated October 16, 2015*

# What did go wrong with this Medtech company?

*Technology didn't work*

And what can we do about it?

↓

*Patients received wrong diagnosis*

↓

*Company goes out of business*

↓

*Investors loose money*

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# 1) The power of Proof of Concepts (PoC)

**What?**

The main goal of a PoC is the **verification** of the **core idea** or **function.**

(It’s not a prototype or a market-ready solution!)

**Why?**

Reduce risk. Save time and money instead of investing in a flawed concept

**How?**

1. Break-down your concept into core functions
2. Identify the ones with the highest risk
3. Define a test setup. What are the intended outcomes and how do you measure them?
4. Execute
5. Evaluate and decide (all fact-based!)

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# 1) The power of Proof of Concepts (PoC)

**What are the benefits of a good PoC?**

1. Demonstrate feasibility based on evidence
2. Gain buy-in from stakeholders and obtain approval for development
3. Enhanced trust
4. Product development timeline and costs become more predictable

# 2) Strong product definition, validated with stakeholders

**Some characteristics of Medtech development:**

1) A great idea is not always a great business

2) Pivoting is quite impossible

3) Commercialization is often underestimated

**4 views:**

1) **Patient / User**: ***great idea*** versus ***patient needs***
2) **Competitors**: how to differentiate from existing products?
   risk of IP infringement…
3) **Reimbursement**: who will pay?
4) **Suppliers**: viable and feasible?

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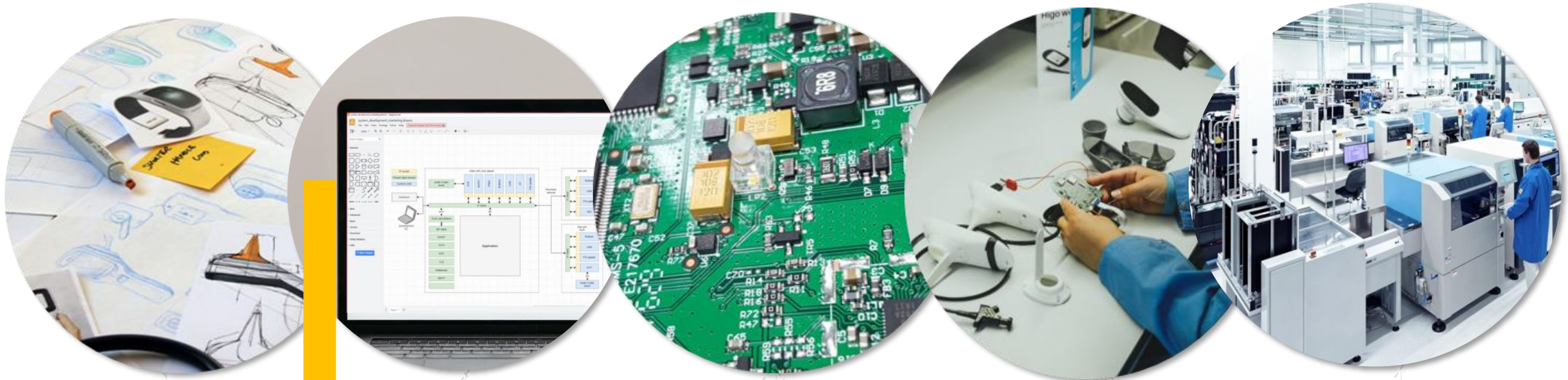
# 3) Team extension through early supplier involvement

# Typical product development process



Idea & concept

System design

Implementation

Industrialization

Mass Manufacturing

**Early supplier involvement**

# 4) The importance of verification & validation

- **Verification:** confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

- **Validation:** establishing by objective evidence that device specifications conform with user needs and intended use(s)

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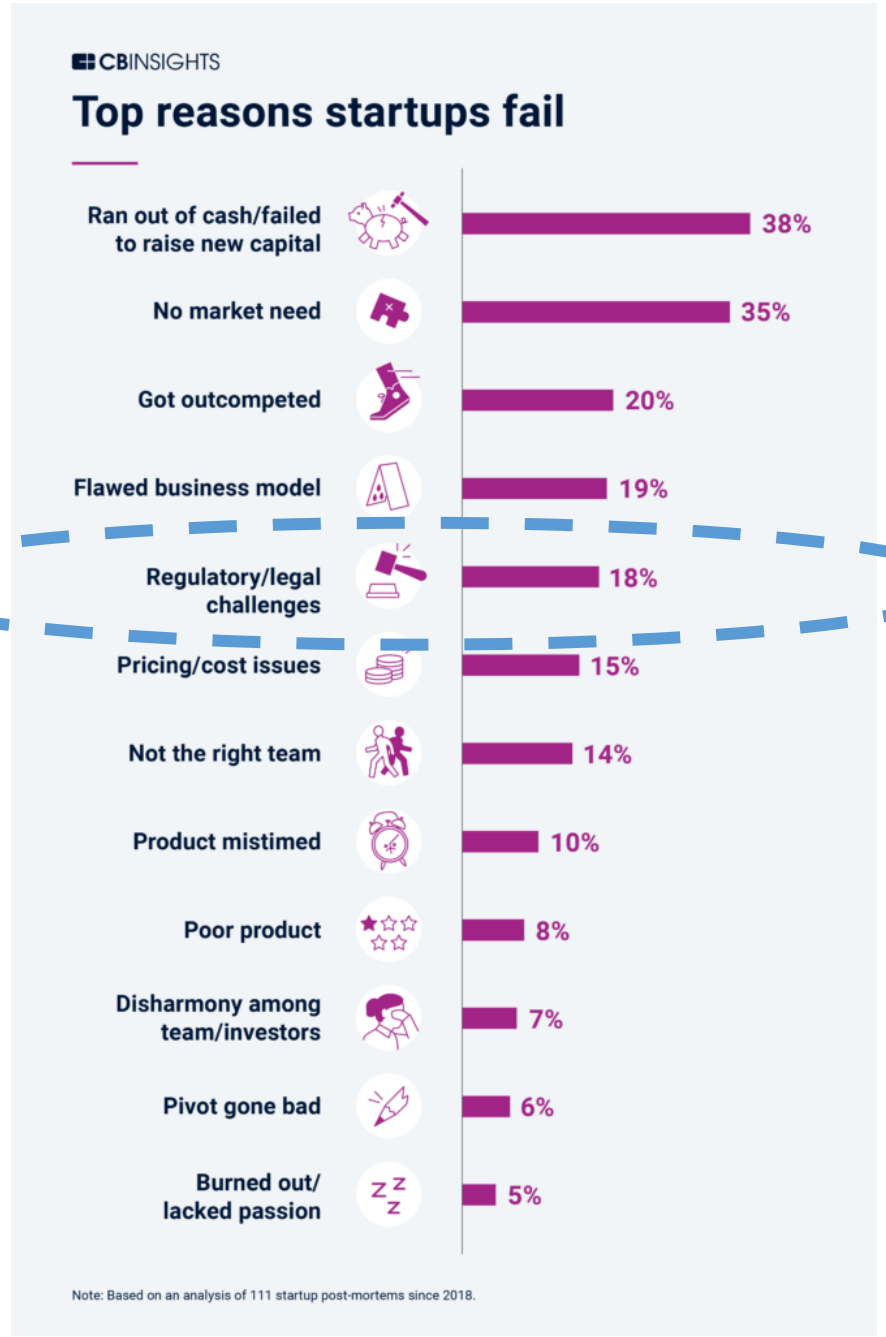
# 5) Without a realistic regulatory strategy there is no successfull market introduction




*Source:*
*https://www.cbinsights.com/research/report/startup-failure-reasons-top/*

# Strengere Europese regels voor medische hulpmiddelen brengen ziekenhuizen in problemen

deVolkskrant

27 October 2023

## Case study finds regulatory challenges are affecting MedTech innovation in the UK

Researchers from the King's School of Biomedical Engineering & Imaging Sciences have published a new study analysing the impacts of regulatory challenges on medical technology development projects in the UK.

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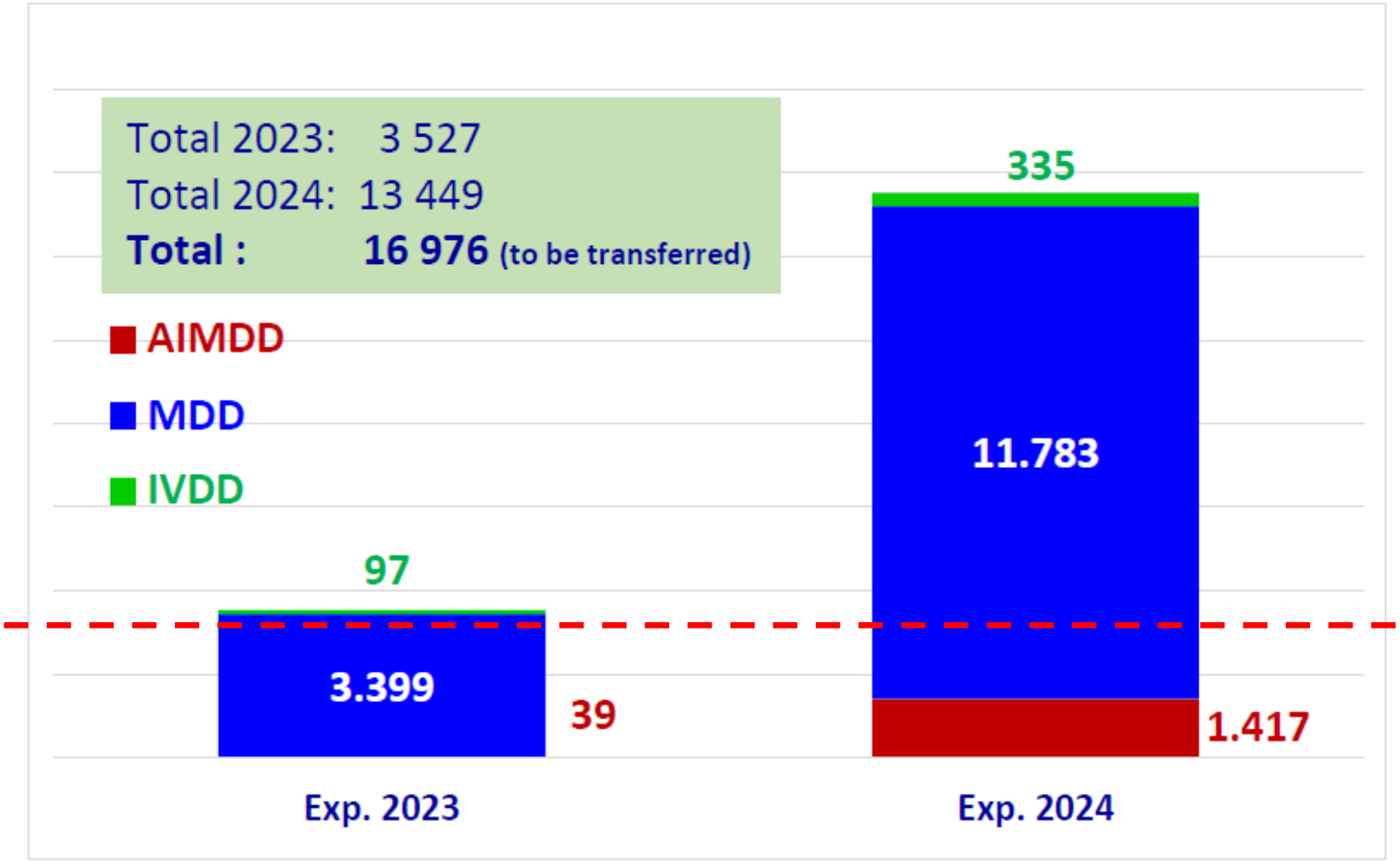
The European Association for Medical devices of Notified Bodies




**Estimated capacity 3200 per year**

*Source:*
*https://www.team-nb.org/wp-content/uploads/members/M2023/Team-NB-MD-Sector-Survey-PressRelease-20230411.pdf*

# 5) Without a realistic regulatory strategy there is no successful market introduction

**8 recommendations:**

a) Who is responsible for **Quality** & **Regulatory**?

b) Implement Quality Management System (**QMS**) according to **ISO 13485-2016**

c) Consider different regulatory submission strategies (ie. **MDR** vs **FDA**), gain advice!

d) Select and contract a Notified Body (**NB**)

e) Understand the core concepts of:
- ISO 14971 – Risk management for medical devices
- IEC 60601 – Safety and performance requirements for electrical medical devices
- IEC 62366 – Human factors engineering (usability)
- IEC 62304 – Medical device software

f) Start with Technical File **(DHF)** right from the beginning, not at the end… (and check your supplier)

g) Setup **Quality Agreement** with your supplier(s)

h) Validation of manufacturing processes **(IQ/OQ/PQ)** should not be underestimated

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# From concept to patient:
# 5 key-factors for succesful Medical Device Development:

1) The power of Proof of Concepts (PoC)
2) Strong product definition, validated with stakeholders
3) Team extension through early supplier involvement
4) The importance of verification & validation
5) Without a realistic regulatory strategy there is no successfull market introduction

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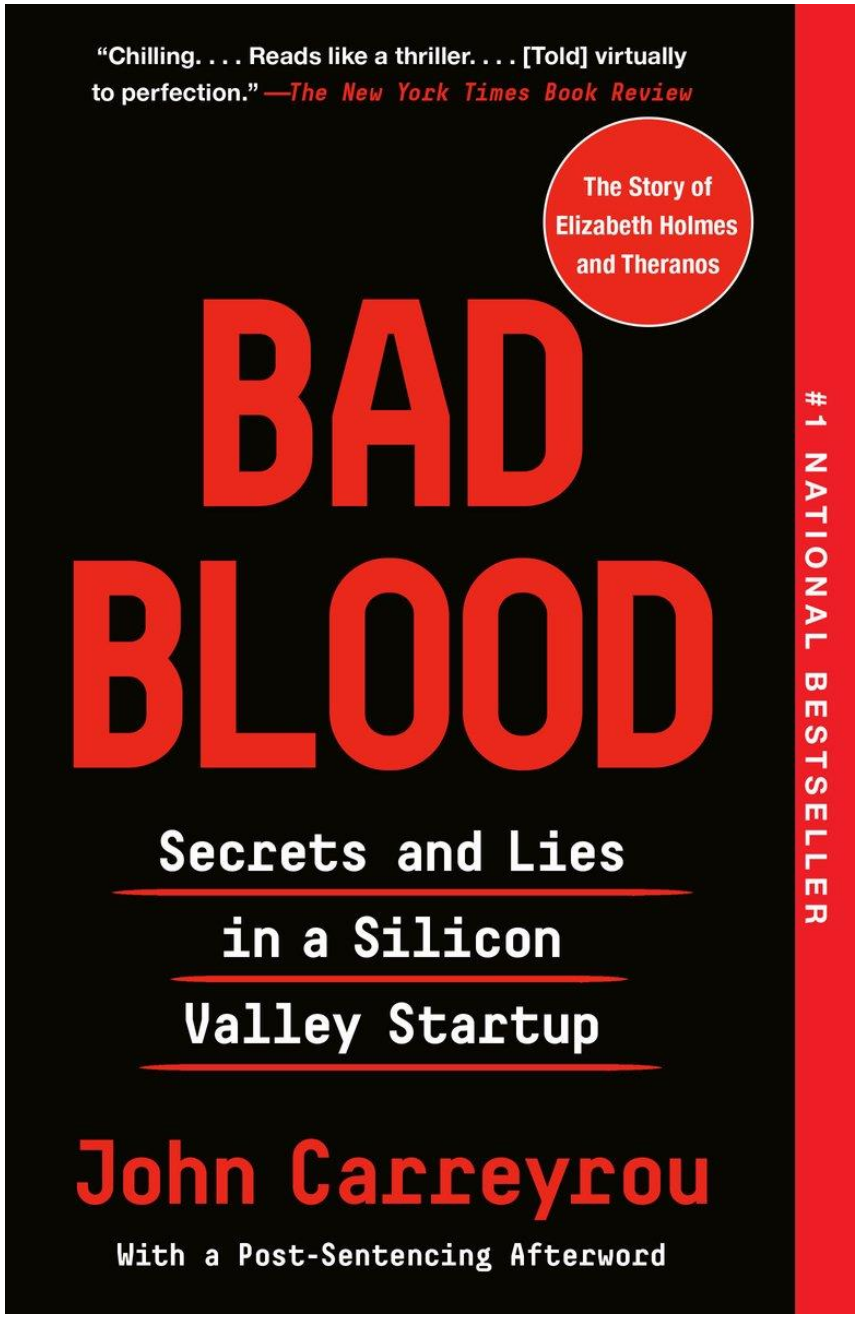



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**'The Inventor: Out for Blood in Silicon Valley'**

**Now Streaming on HBO Max**

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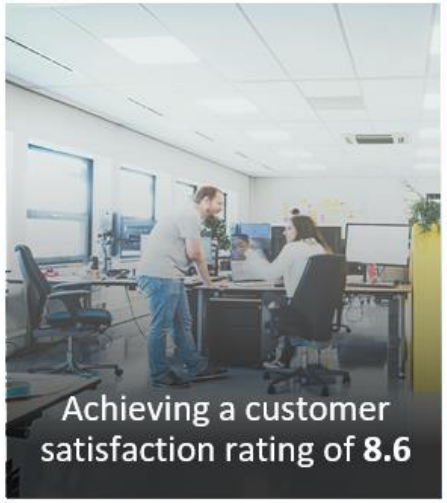
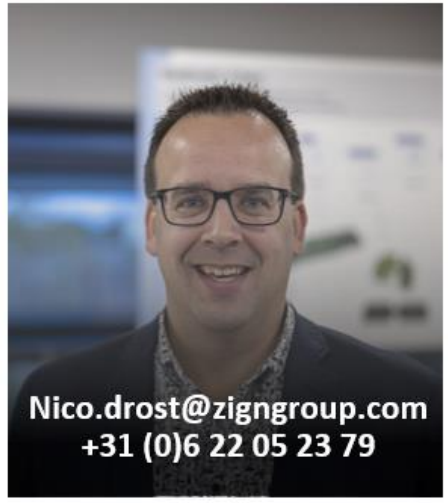
# Let's **work together** to bring your ideas to life!







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