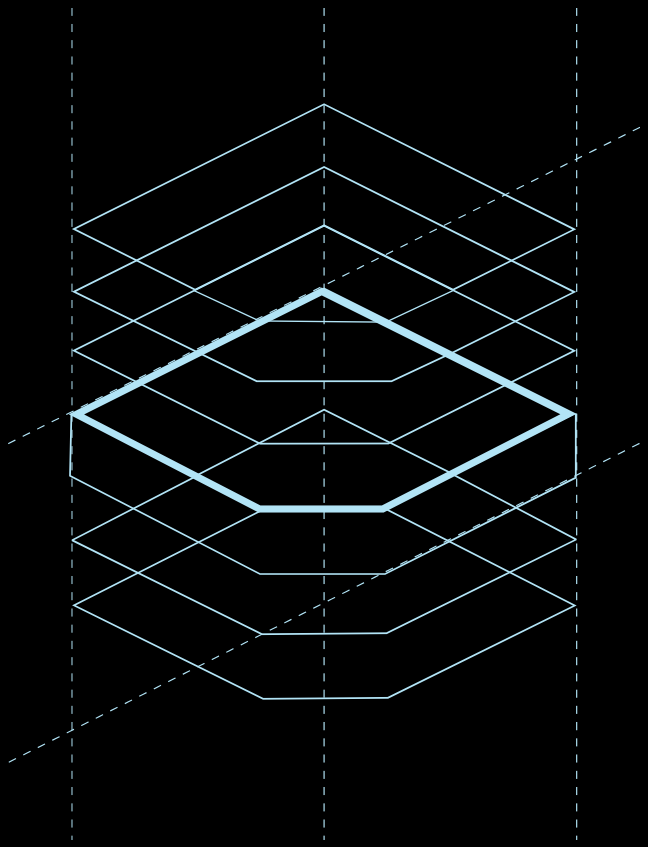
Implementing Risk Throughout the Entire Product Lifecycle

May 25, 2023



Hristina Panovska,
Engineering & Delivery Lead

Miloš Cigoj,
Quality and Compliance Lead

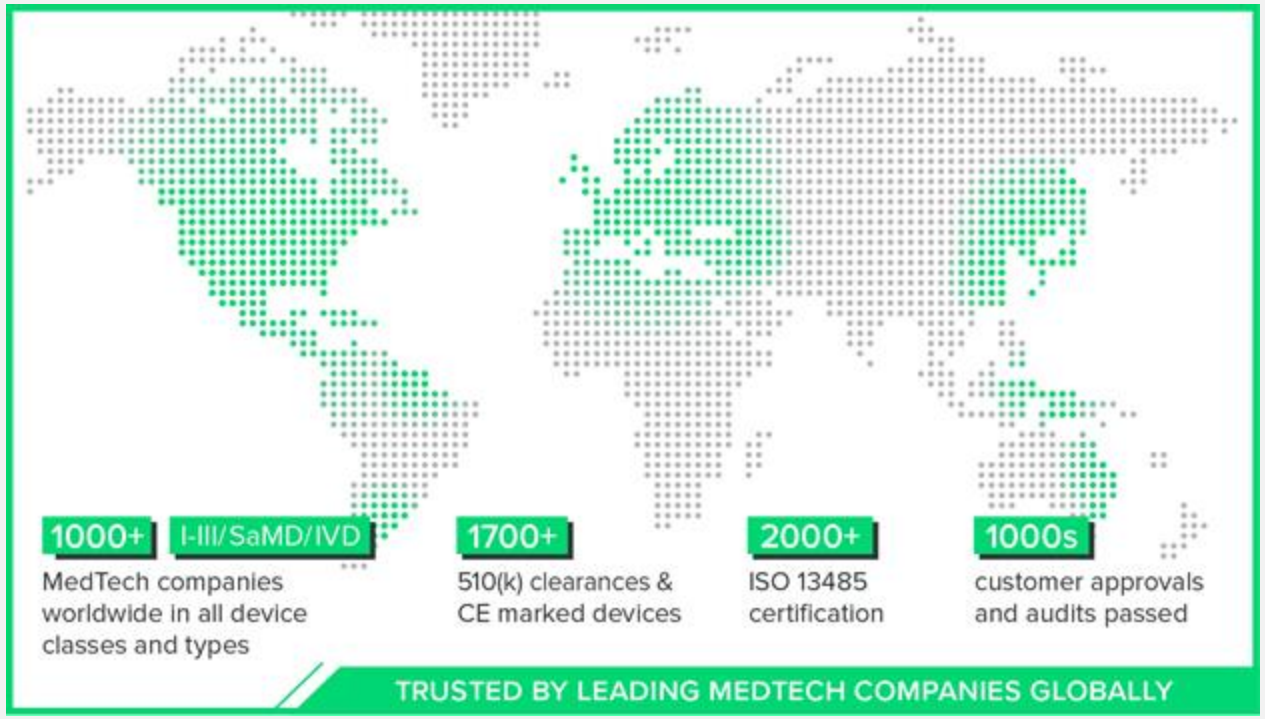
BUILT FOR MEDTECH.
TRUSTED BY MEDTECH.

100+ years industry experience

522k podcast listeners

200k+ look to us for the latest in quality

#1 blog and podcast in the industry



"Best QMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."

★★★★★

"Demystifying QMS and Regulatory Requirements"

★★★★★

"Makes your QMS Simple and Effective"

★★★★★

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With a Growing Global Presence in **10 Countries**

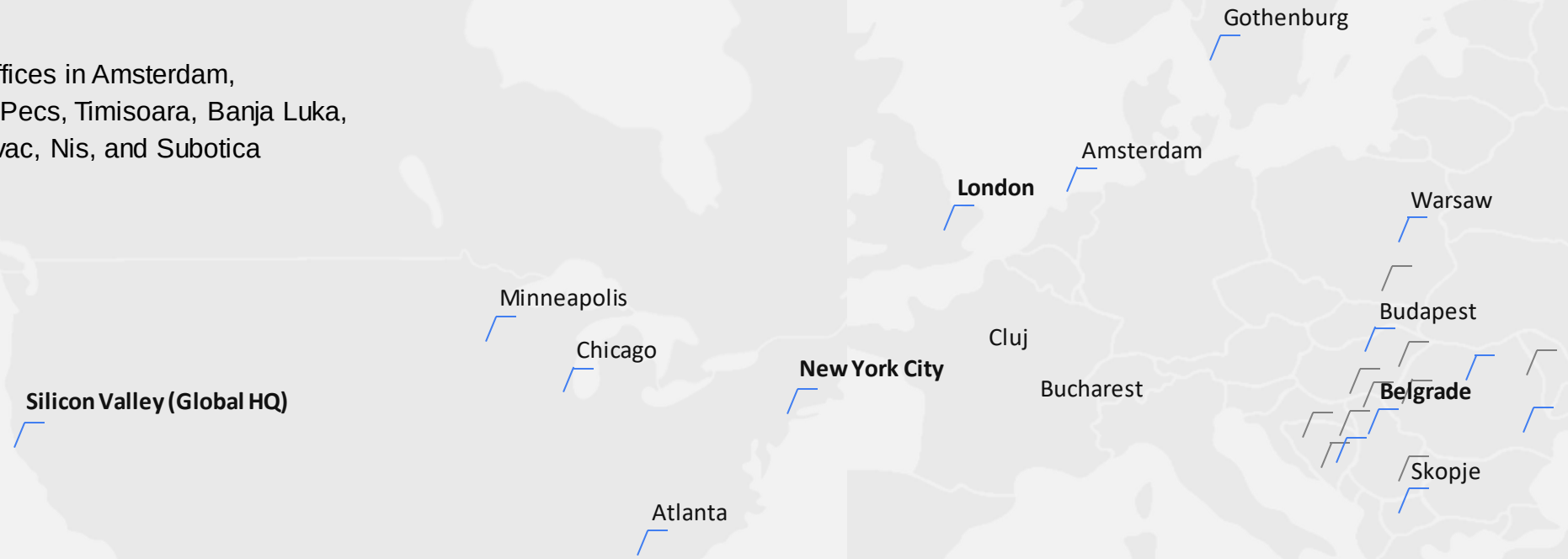
Additional Delivery & Business Offices in Amsterdam, Szeged, Krakow, Debrecen, Iasi, Pecs, Timisoara, Banja Luka, Mostar, Tuzla, Novi Sad, Kragujevac, Nis, and Subotica

FTE Professionals

2,400+

Development Centers & Offices

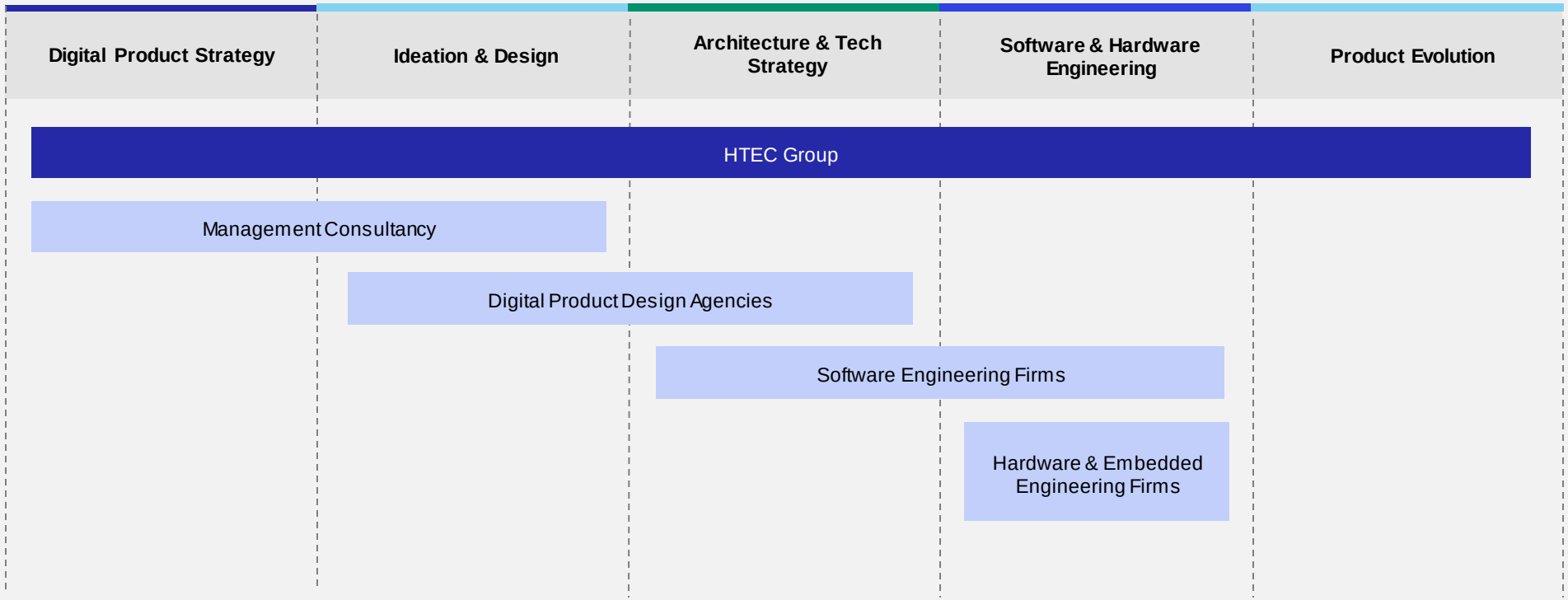
20+



*Opening offices in Latin America through a strategic acquisition is a possibility

Why Organizations Partner With HTEC Group

We are trusted partner who can meet you where you are on your digital journey and help you **achieve your desired goals** by planning a **successful strategy**, but also expertly **design, deliver and evolve a best-in-class digital solution.**



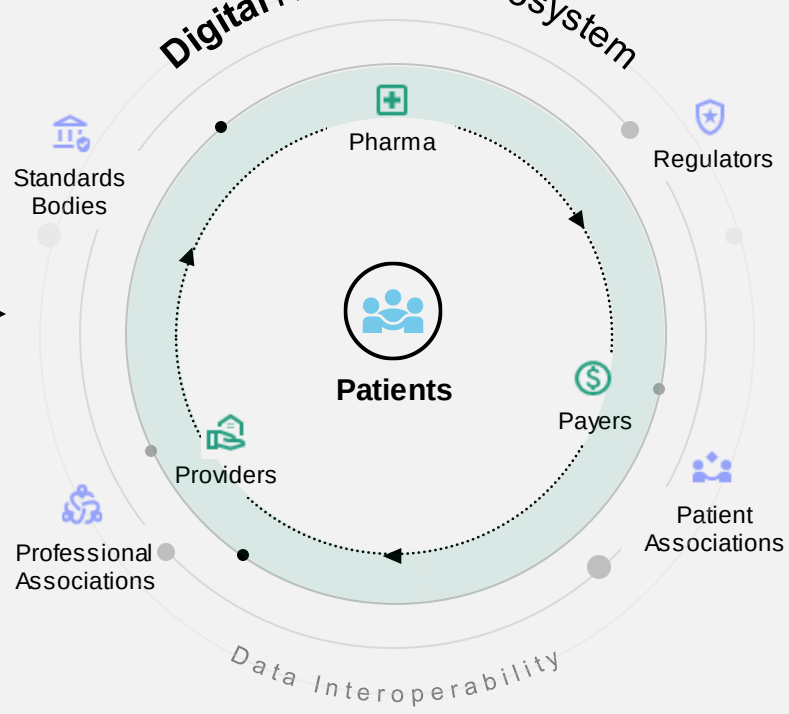
Flexible engagement and commercial models

HTEC Capabilities

Other Vendors Capabilities

Healthcare and Life Science **E2E Solutions**

Digital Devices	Software Solutions	Big Data and AI Products
Hardware Development	Multiplatform Applications	Data Engineering & Analytics
Embedded Development	Cloud Services	Data Science
SaMD (Software as Medical Device)	Signal Processing Algorithms	Machine Learning and AI
• Fast Prototyping • Seamless Dev Flow • Fitting Into Tech Constraints • Tailor Made SDLC • Local Manufacturing • Regulatory Affairs Network	• Healthcare API • Proprietary Signal Processing • Automated Device Management • Real Time Sensing • Multi Platform • Multi Protocol Communication	• Prediction • Improving Healthcare Journey • Multidisciplinary Experts • Domain Driven Data Strategy • AI Augmentation • Governed Data Flow



Quality and Regulatory Affairs Services

Prioritizing Patient Safety

The Role of Risk Management

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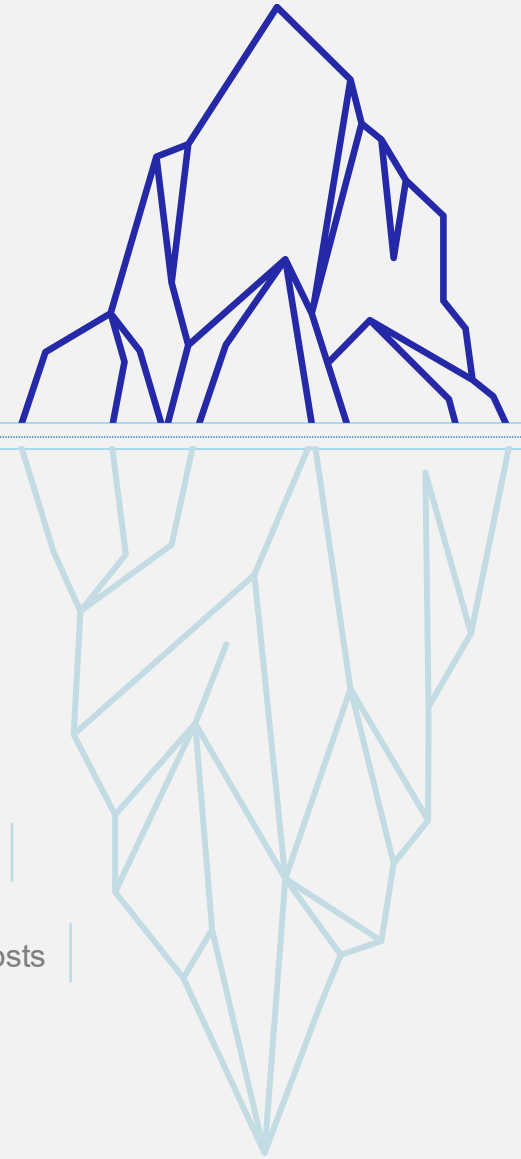
Poor quality is harmful!

Time to market | Revenue | Penalties | Warranty claims | Adverse events | Liquidity

Rework | Missed deadlines | Complaints | Missed regulatory approval | Scrap | Qa&qc costs



Team morale & stress | Complaint investigation costs | Excess verification | Lost sales

Excessive overtime | Loss of future business | Ideal time | Reputation damage

Unused capacity | Improvement program costs | Past due receivables | Rush delivery costs

Recruitment costs | Loss of client goodwill | Loss of market share | Excessive employee turnover

Retrofit costs | Excesive project management costs | Time loss due to adverse events | Expediting costs

Technical documentation revisions | Client loyalty lost | Inability to scale | Planning delays

WHO estimates

1 in 1M

harmed in aviation

WHO estimates

1 in 300

harmed in health care

Unsafe care is in the

Top 10 causes

of death or disability worldwide

15%

of healthcare costs due to unsafe care

42B USD

associated costs globally with medication error

4 in 10

are harmed in primary and outpatient health care

Yearly 5%

of us adults experience diagnostic error

80%

of harm is preventable in primary and outpatient health care

5% - 50%

of all medical errors in primary care are administrative

*(Source: World Health Organization, Patient Safety, 13 September 2019. **who.int/news-room/fact-sheets/detail/patient-safety**, **who.int/news-room/facts-in-pictures/detail/patient-safety**)*

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Quality & Regulatory Affairs + Information Governance

- Security By Design
- Blue & Red Team
- SOC2
- NIST CSF 2.0

- HIPAA & HITRUST
- Privacy Assessment
- GDPR (EU CITIZENS)
- PEPIDA (CANADA)

- FDA Submission Strategy
- Classification
- Device Dossier

- ISO 27001
- ISO 13485 & IEC 62304
- ISO 14971
- HL7 interoperability

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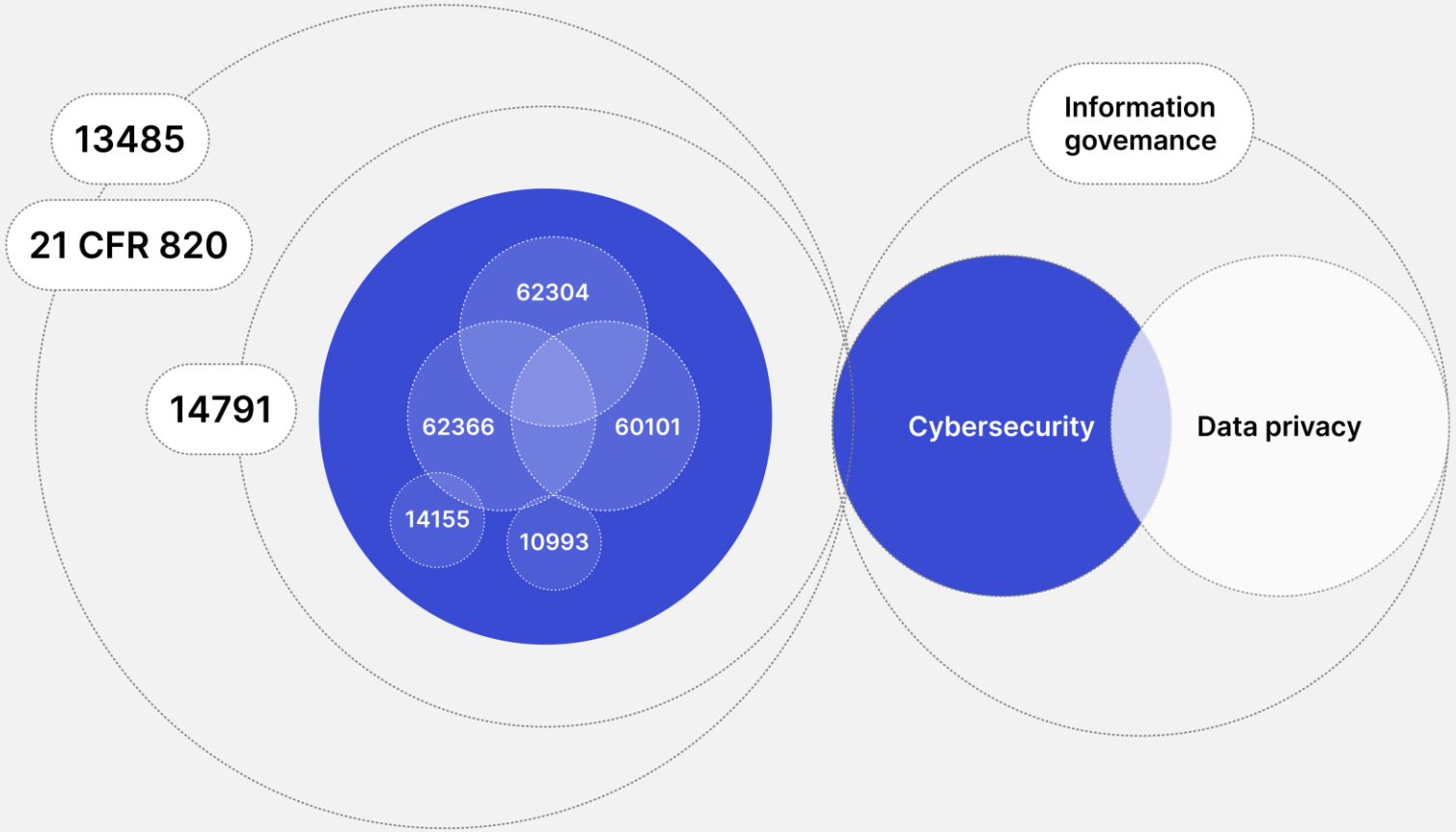
Standards Interaction for Patient Safety



Design for quality

- Quality system **ISO 13485**
- **21 CFR 820**
- Overall Risk Management **ISO 14971**

Test for safety

- **IEC 62304** for SW lifestyle
- **IEC 60601** for electrical safety
- **ISO 10993** for biocompatibility

Test for efficacy

- **ISO 14155** for trial design
- Performance and benefit

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ISO 14971 & Check Greenlight Guru

Risk management for medical devices

The purpose of this infographic and the ISO 14971 standard is to help med device manufacturers establish a risk management process that they can use to:

Identify Hazards

Estimate and evaulate risks

Develop, implement and monitor the effectiveness of risk control measure

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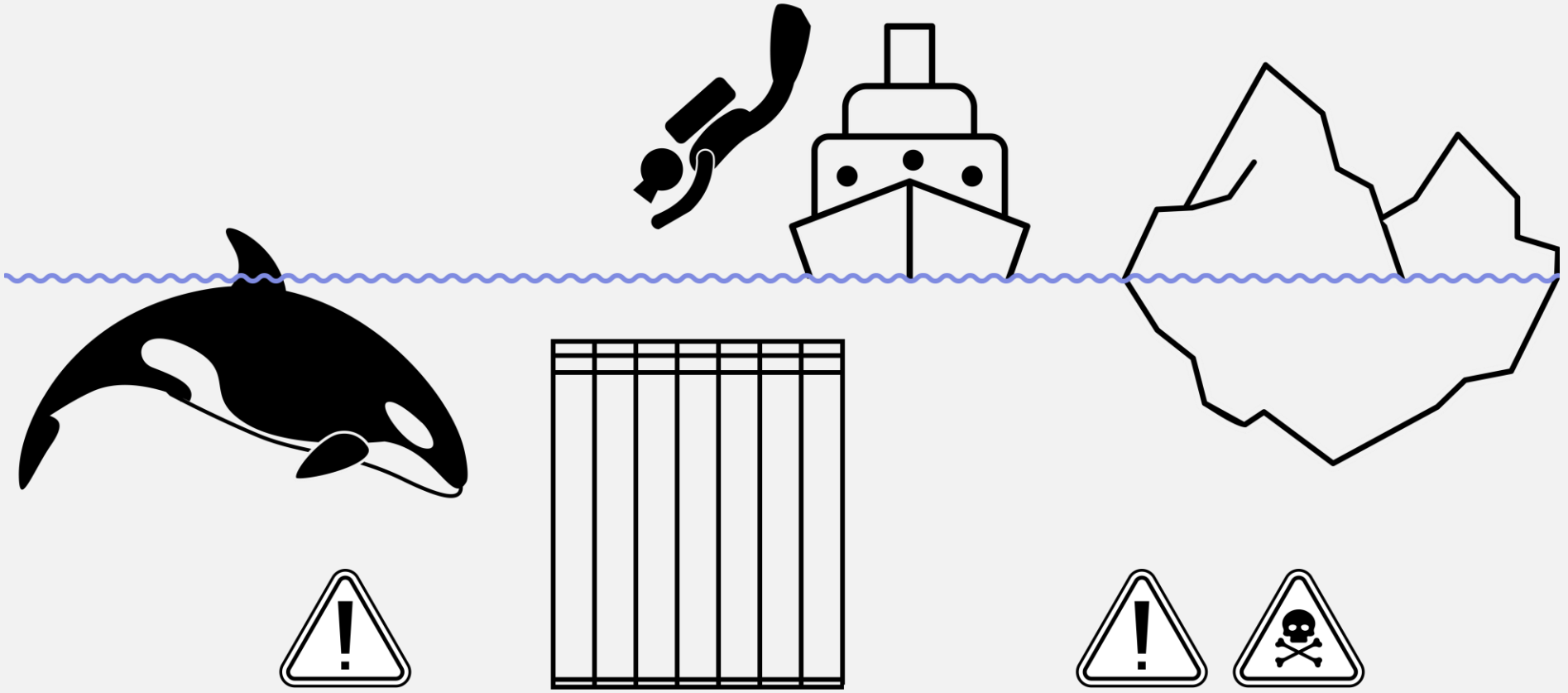
Hazards, Harm, Risks and Controls



Hazard

Something that can potentially cause harm

Risk

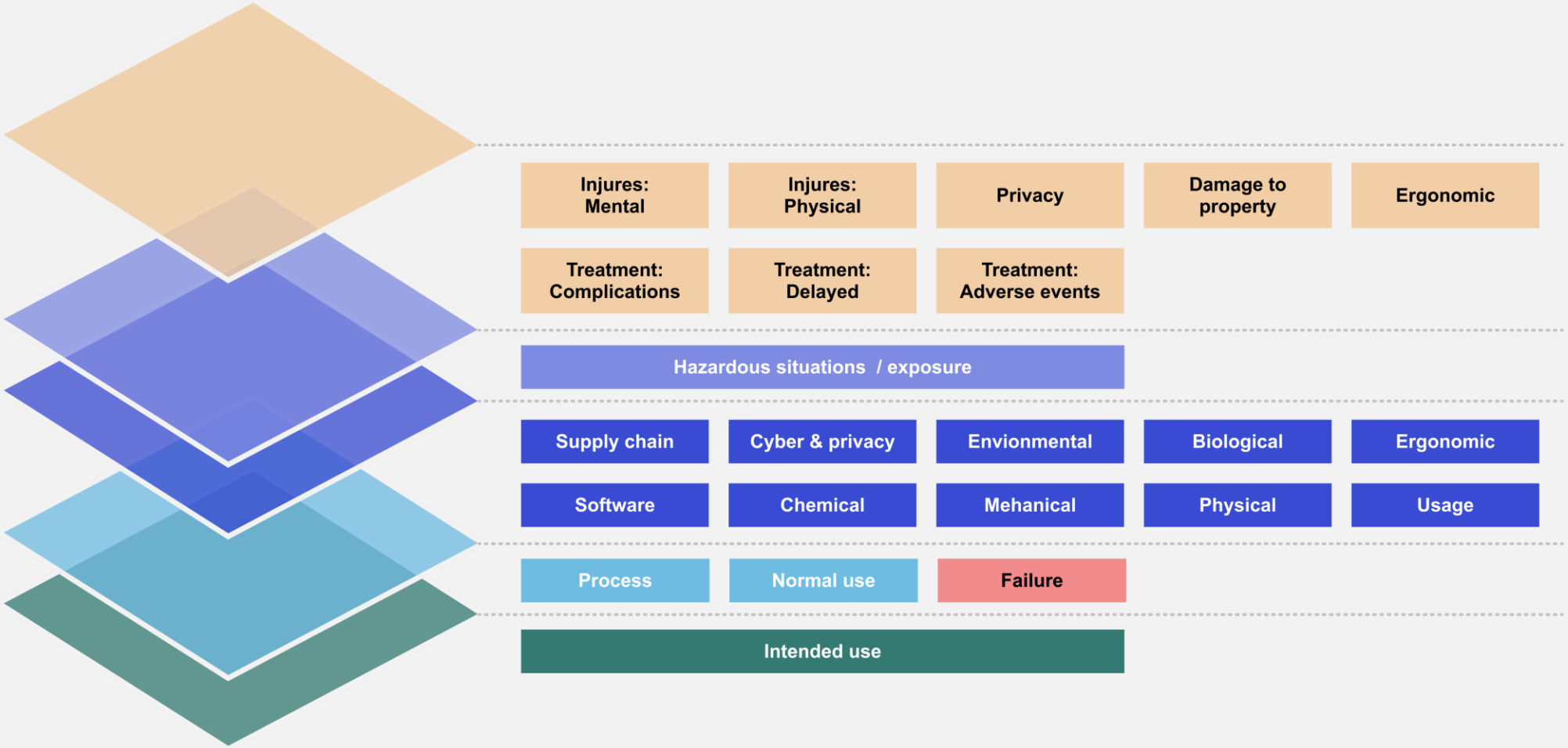
= hazard + exposure

Balance

Risks of using the device

Benefits that risks brings

Decoding the Hazard-Harm Connection



A Journey Through the Product Lifecycle

Ensuring Risk Management at Every Stage

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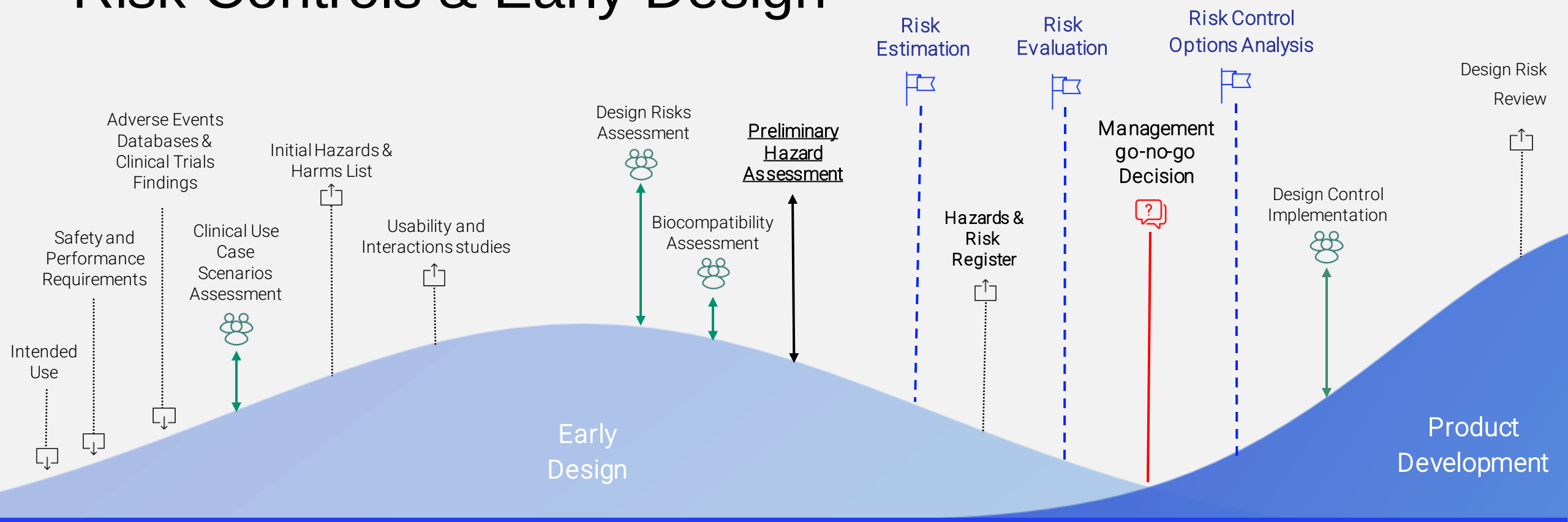
Risk Management & Total Product Life Cycle

Discovery & Ideation → Invention & Prototyping → Development (Preclinical R&D → Clinical Validation → Regulatory Approval) → Device Production → Product Launch → Post Market

Risk Analysis → Risk Evaluation → Risk Control → Residual Risk Evaluation → Risk Mgmt. Review → Production and Post-Production Data

inputs outputs activity controls

Risk Controls & Early Design



Discovery & Ideation → Invention & Prototyping → Development / Preclinical R&D

Risk Analysis | Risk Evaluation | Risk Control

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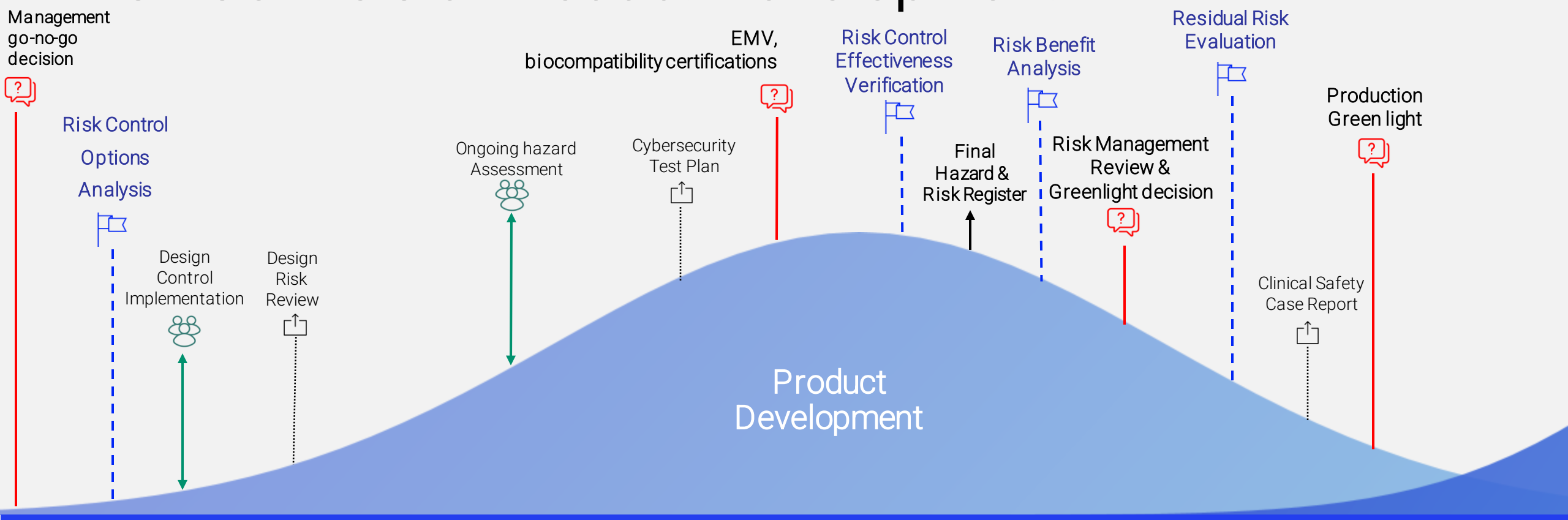
Risk Controls & Product Development



Design and Development

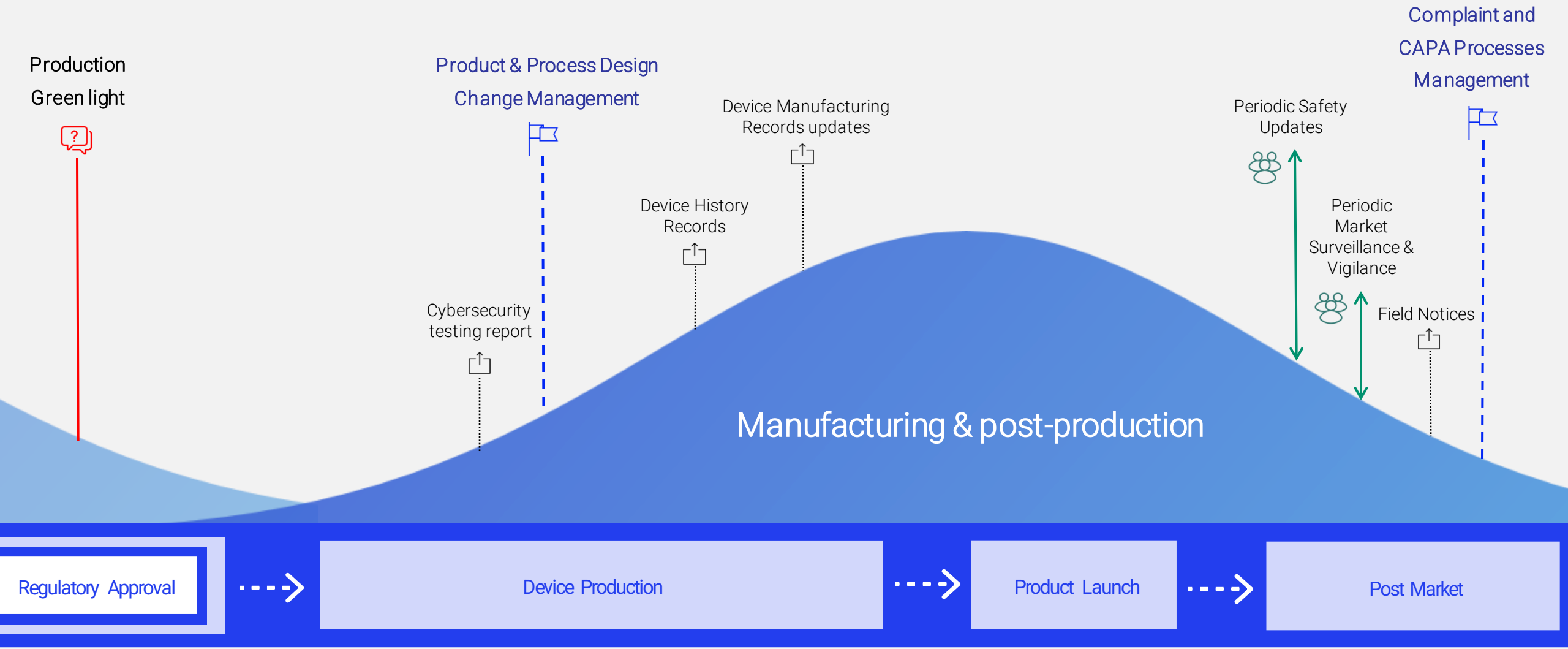
Design | Verification | Development | Final Validation | User Testing | DMR → Clinical Validation → Regulatory Approval

Risk Control

Residual Risk Evaluation → Risk Mgmt. Review → Production and Post-Production Data

inputs outputs activity controls

Risk Controls & Manufacturing and post-production



Regulatory Approval → Device Production → Product Launch → Post Market

Production and Post-Production Data

Essential Recommendations for Success

The sooner the better

Sponsorship and team commitment

Educate and assess

Cross-functional team

Clear responsibilities

Critical thinking

Team continuity

Stick to the Risk Management Plan

Manage evidence

E2E traceability

Review & Sign-off

(don't forget about Cybersecurity)

Don't settle !

Empowering your digital tomorrow

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