BSI Insight Series:
Startup Edition
Webinar #1

Roadmap to Market Access:
Understanding Global Device Regulations

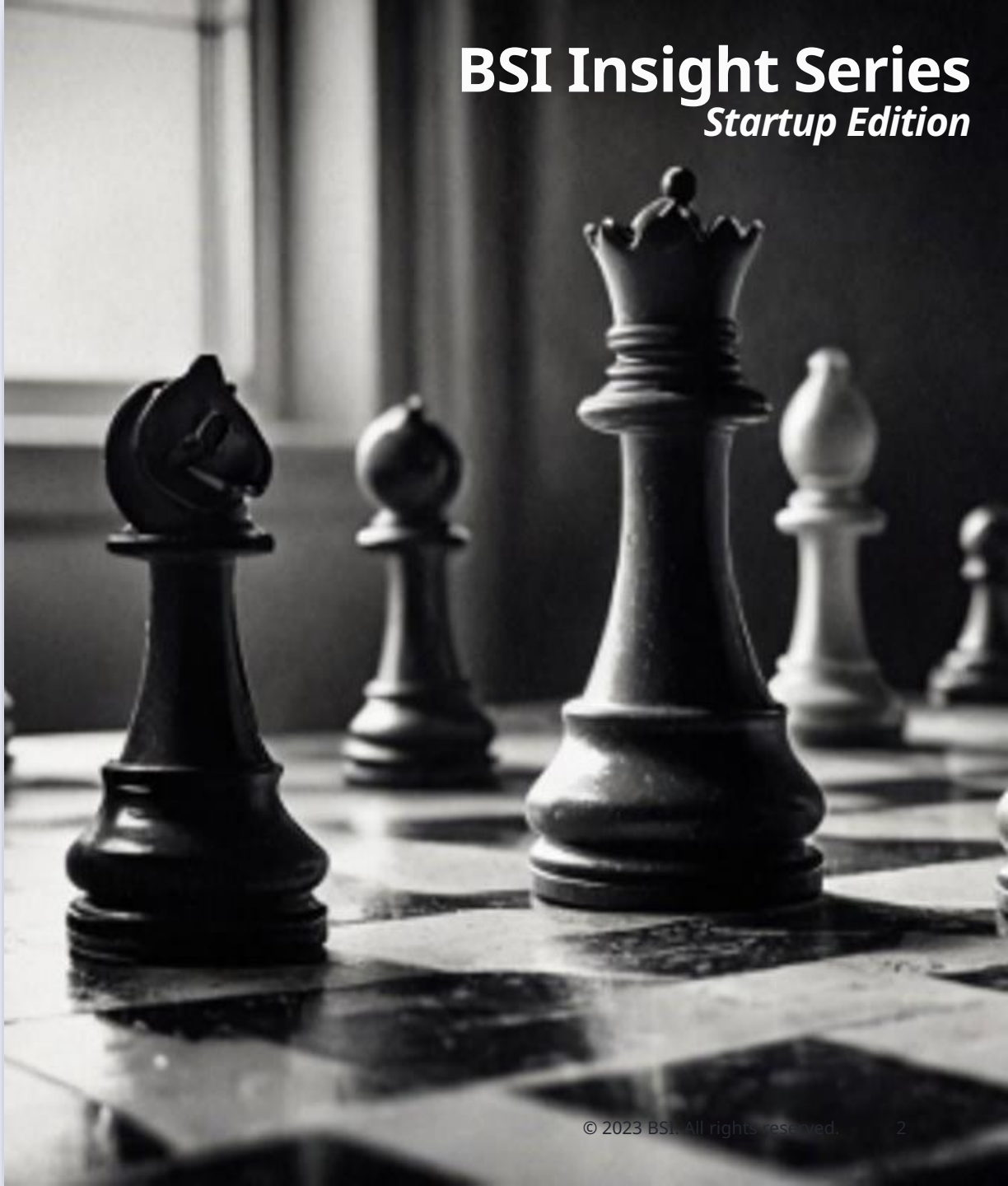
November 11, 2025

With us today...

Kevin Madden
Head of Professional Development

Jason Butcher
Sr. Technical Tech Specialist
Vascular Devices

Vishal Thakker
Head of UK Approved Body



Poll Question

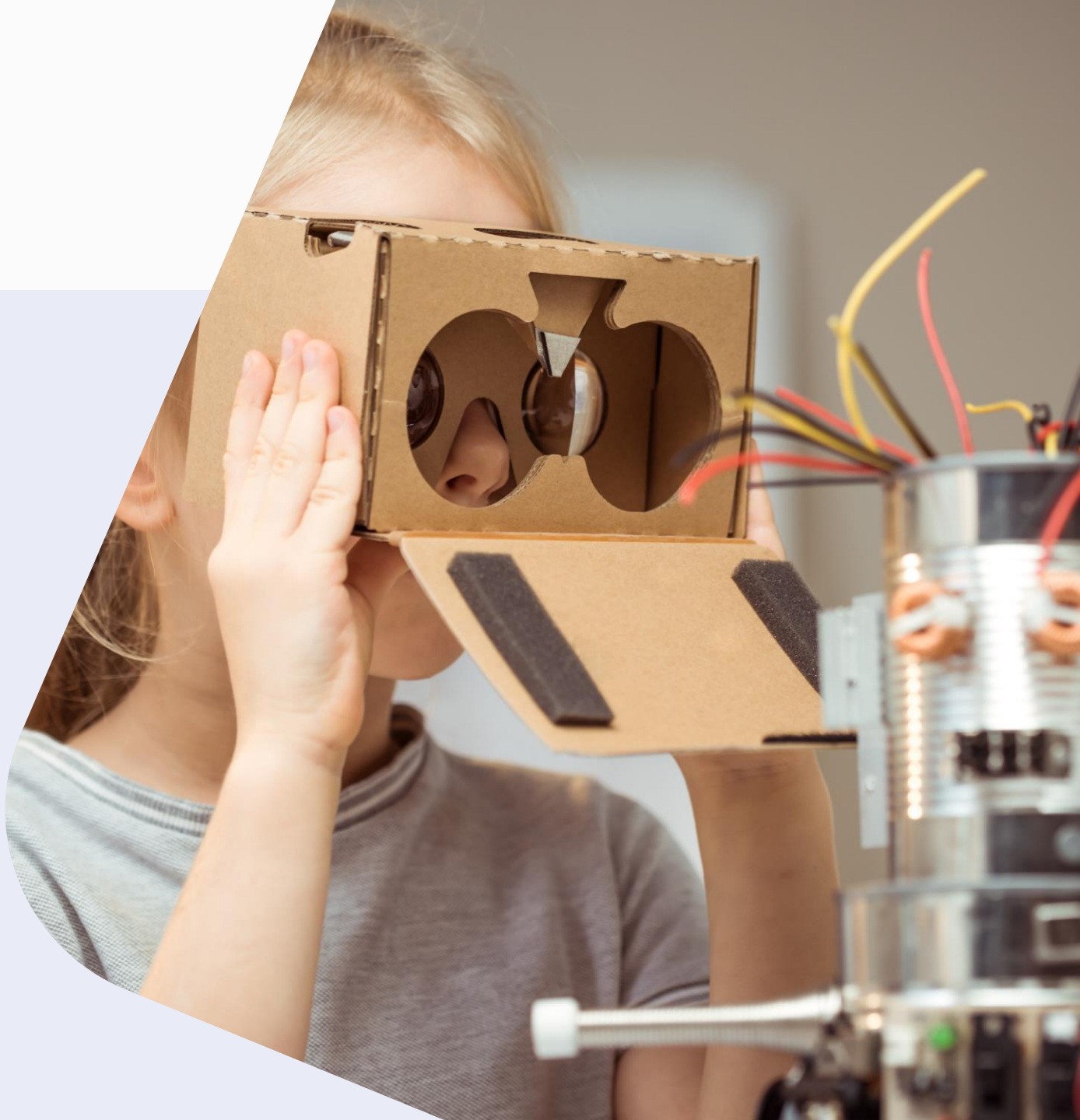
What is your level of knowledge of Regulatory requirements in EU and UK?

a) I have a **High-Level** of understanding

b) I have **Some Level** of understanding

c) I have a **Limited Level** of understanding

d) I have **Little** to No understanding



BSI Insight Series:
Startup Edition

Six webinars to help you ***align*** Regulatory Strategy with Startup Growth Stages:

Webinar Series (Every 2nd Tuesday of the Month):
Nov 11: Roadmap to Market Access: Understanding Global Device Regulations

Dec 9: Cracking the Code: MDR, IVDR and UKCA Classification and Indications for Use

Jan 13: How to Use Risk Mapping to Set Up Your Project for Success

Feb 10: Demystifying Design Controls and Clinical Planning

March 10: Building Safer Devices with Human Factors and Usability Engineering

Apr 14: From Prototype to Production: Manufacturing Pathways Explained

To register for the future Insight Series webinars: click here

Unique Reality of MedTech Startups

- **Design Controls from Day One**
  MedTech startups *must document* design, risk, and traceability *early*. *This is unlike consumer tech, which can iterate freely.*

- **Quality Management (ISO 13485)**
  “Move fast and break things” balanced against *compliant QMS is required* before market entry.

- **Evidence Requirements**
  For MedTech, *scientific data (bench, in-silico, human studies) is essential*, while most startups launch without a formal validation.

- **Regulatory Engagement**
  MedTech founders must plan for *audits, reviews, and submissions*, while others may skip third-party assessments.

- **Longer Timelines**
  Safety testing and regulatory reviews extend time-to-market, thus, requiring *smart capital and investor alignment*

Why Regulation Matters for Startups:
Clear Regulatory Strategy Matters

Investor Readiness & Confidence
Demonstrates *scale readiness* & *Increases valuation*

Access to Non-Dilutive Funding
Enables *eligibility for grants* (e.g. NIH) without giving up equity

Avoids Costly Rework
Early alignment with Regulatory Requirements *prevents expensive redesign* and delays.

Accelerates Time-to-Market
Faster approvals mean *earlier revenue generation* and reduced burn rate; faster global access.

Supports Partnerships
The hospitals, distributors, and acquirers will *expect regulatory maturity* before engagement.

Protects Patients & Brand
Ensures safety, trust, and long-term success; reduces perceived risk.

ISO 13485 (Quality Standard)

- **ISO 13485, International Standard for Quality Management Systems (QMS) in Medical Devices**: Ensures Medical devices are produced consistently and meet customer and regulatory requirements.
- Aligns with global regulatory expectations (FDA, EU MDR, MDSAP).
- Build credibility with your startup, supports investor confidence, and often required for CE/UKCA marking.

MDSAP

MDSAP: Medical Device Single Audit Program.

- A single audit process ***accepted by five major regulators*** (United States, Australia, Brazil, Canada, Japan).
- MDSAP streamlines ***Global Compliance*** and reduces Audit Duplication.
- This can be strategic for startups targeting multiple international markets; aligns with ISO 13485.

EU MDR & EU IVDR:

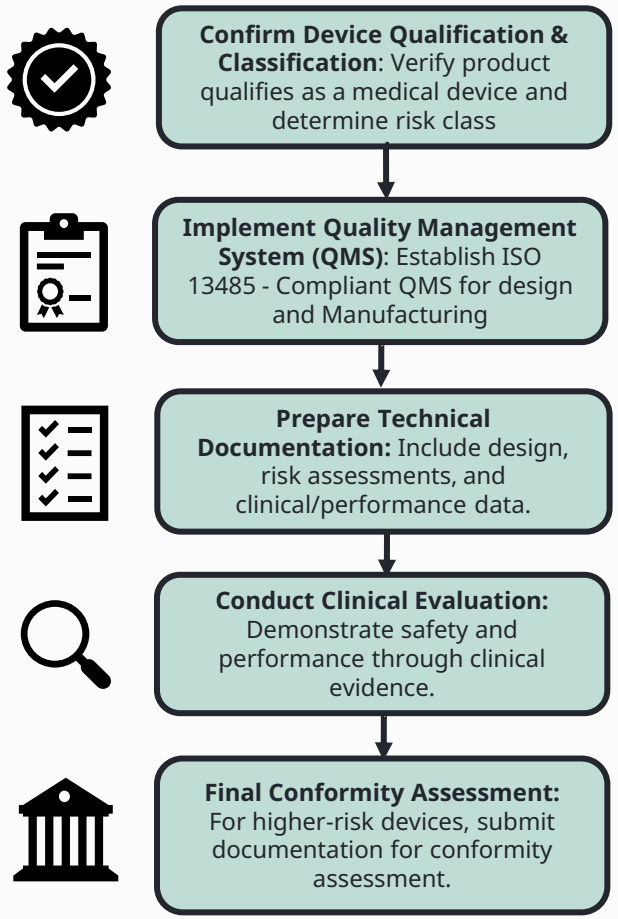
- **EU MDR**: Regulation (EU) 2017/745 governing medical devices in the EU
    - Sets requirements for safety, performance, clinical evidence, and post-market surveillance
    - Requires submission to an EU Notified body for conformity assessment and certification.
- **EU IVDR**: Regulation (EU) 2017/746 for In Vitro Diagnostic devices.
    - Important as it introduces risk-based classification, mandatory clinical evidence, and Notified Body oversight.
    - Critical for diagnostic startups; compliance is mandatory for EU Sales.

UK Conformity Assessment

UK's post-Brexit product conformity mark replacing CE:

- Required for placing devices on the GB Market; governed by UK MDR 2002.
- Impact to Startups where mandatory for UK sales, dual CE/UKCA strategy allows for flexibility.

Align Investment Phase to Regulatory Maturity



Startup Seed Funding Phase	General Startup Stages	General Steps to Regulatory Certification	Regulatory Perspective on Maturity
Pre-Seed	Idea, concept & IP Strategy	**Confirm Device Qualification:** Verify product qualifies as a medical device and determine risk classification. **First Structured Dialogue with Regulatory Body** to cover core essentials: indications for use alignment.	***Early regulatory awareness is essential*** to confirming a medical device, defining its intended purpose, risk classification, and applicable MDR/IVDR requirements.
Seed	Developed prototype, testing, regulatory pathway	**Implement Quality Management System (QMS):** Establish ISO 13485-Compliant QMS for design and Manufacturing. **Obtain ISO Certification** for Design Scope; Impact on **$Company's Valuation**.	Begin to initiate contact with Regulatory Body, ***start building an ISO 13485–aligned QMS,*** and plan V&V testing per harmonized standards.
Series A	Early clinical development, Fund Trials, Submission Prep	**Prepare Technical Documentation:** Include design, risk assessment, and clinical/performance Data. **Extend Certification Scope for Manufacturing.**	Formal engagement with Regulatory Body is acheived. Submit MDR-compliant technical documentation with ***clinical evidence, risk management, and operational QMS*** .
Series B	Pivotal trials & Scale Marketing	**Conduct Clinical Evaluation:** Demonstrate Safety & Performance through Clinical Evidence. **Obtain CE Mark.**	***Company becomes a certified manufacturer*** . Maintain technical documentation, undergo surveillance audits, and implement PMS and PMCF activities.
Series C	Commercialization and scale up	**Final Conformity Assessment:** For higher-risk devices, submit documentation for conformity Assessment. **Obtain MDSAP as you go Global.**	Regulatory function becomes a strategic pillar. ***Manage global submissions*** (FDA, MHRA, TGA) while sustaining MDR compliance and post-market obligations.

Poll Question

With Respect to your Company's Startup Phase, what stage is your company?

a) Pre-Seed
b) Seed
c) Series A
d) Series B or C
e) N/A, none of the above

Building Regulatory Strategy into Startup Success

Regulatory alignment fuels growth
Planning early for global standards builds investor trust and speeds market entry.

Compliance grows with the company
From concept to launch, regulatory focus must evolve & mature with product and funding.

Quality and compliance are strategic
Strong QMS (ISO 13485) and early Regulatory Body engagement enable global scale.

Start with regulation
Regulatory readiness drives innovation, credibility, and patient safety.

Thank you!

Q&A Session Begins

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Have questions? Let's talk!
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Understand your regulatory pathway—strategy matters!
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