BSI Insight Series:

Startup Edition

Webinar #5: *Building Safer Devices with Human Factors and Usability Engineering*

March 10, 2026

Agenda

- Welcome & Introductions
- Why Usability Engineering Matters
- EN 62366-1 Overview
- Example Device Walkthrough
- Formative vs. Summative
- Steps for Human Factors Testing
- Key Takeaways & Summary
- Q&A

With us today...

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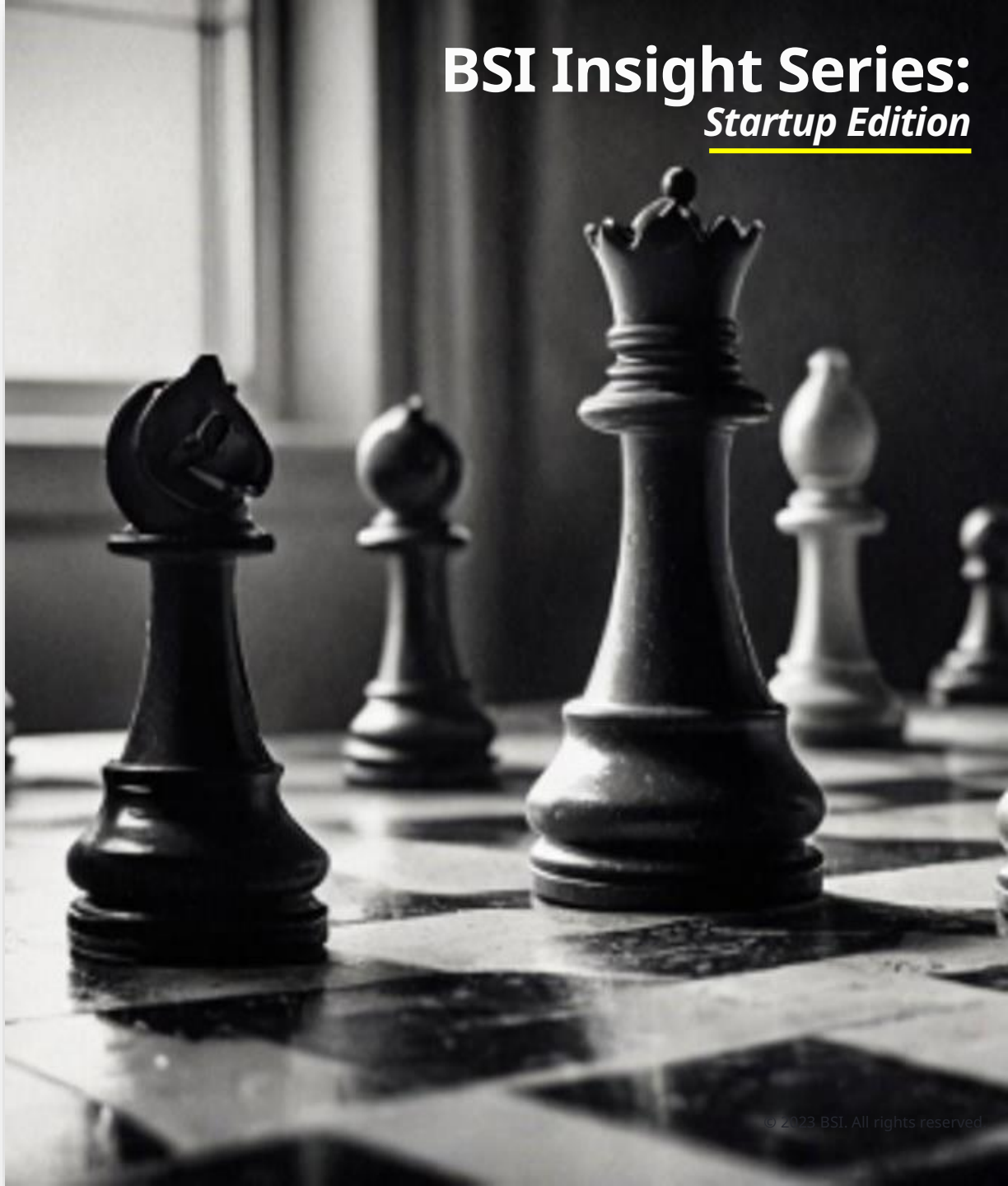

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Our mission is to build venture-backable companies and to connect founders with resources needed to build, grow, & scale their companies in the Digital Delta.

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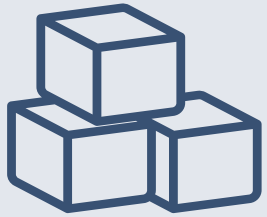

BUILD COMMUNITY

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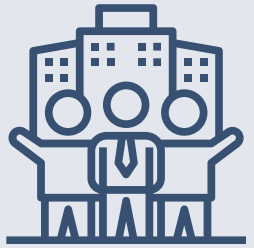

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ZeroTo510 MedTech Accelerator - Nationally Recognized

- 13-week Intensive Curriculum w/ Demo Day

Alumni Stats

- 53 alumni companies
  - Known for capital efficiency
  - Lifespan - 2x national average

Since 2015

- 50% of founders raise $500K+ (2.4× national avg)
- 37.5% of women founders raise $500K+ (8× national avg)
- 41% of minority founders raise $500K+ (~7× national avg)
- $100M+ raised across alumni
- 75% of companies have diverse founding teams

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Why Usability Engineering Matters Early

- Devices developed without usability engineering are non-intuitive, difficult to learn and difficult to use.
- Medical device are becoming more complicated, which increases risk of use error.
- Often used by less skilled users, including patients.
- Devices are often used in situations involving high stress, user fatigue, or medical devices that are rarely used.

MDR Annex I, General Safety and Performance Requirement 5

In eliminating or reducing **risks related to use error**, the manufacturer shall:

(a) Reduce as far as possible the **risks related to the ergonomic features** of the device and the **environment** in which the devices is intended to be used (design and patient safety), and

(b) Give consideration to the technical knowledge, experience, education, **training and use environment**, where applicable, and the medical and physical conditions of **intended users** (design for lay, professional, disable or other users).

Focus Shift: From 'Device – Centered' Design to 'User – Centered' Design

MAUDE: 30.8% use error (Mishali et. al, 2025).

This means, 1 in 4 adverse event errors are NOT rooted in the technology itself, but in the way humans interact with it.

"Is the device designed well?" ✗
"Is the device designed well for the intended user(**S**)?" ✓

- Engineers look at the device
- Human Factors (Usability) looks at the user

- **IEC 62366-1** (Normative Part – focus on SAFETY)
- **IEC TR 62366-2** (Technical report – provides guidance to IEC 62336-1) Guidance Only.

A medical device manufacturer submitting to EU MDR

✓ **Use EN 62366-1** (or the updated EN IEC 62366-1), because Europe expects use of EN-designated standards.

Referring to the global standard or submitting to FDA

✓ **Use IEC 62366-1**, because it is the internationally recognized version and FDA-recognized

Why Usability Remains a Challenge for Most Manufacturers

Human factors and usability engineering overlaps with many areas of device development:

- User needs and design requirements.
- Intended use and intended users
- Risk management
- Labeling and IFU requirements
- Software and user interface design
- Packaging design
- Design verification and validation
- Clinical evaluation
- Post market surveillance

Credit is often not taken for usability design and risk mitigation work.

A systematic method to capture usability engineering is not used.

The harmonized standard for usability, EN 62366-1, is complex and difficult to implement.

EN 62366-1:2015 Principals

The manufacturer shall establish, document, implement and maintain a **usability engineering process** as defined in clause 5 to **provide safety to the patient, user and others**.

Should cover **transport, storage, installation, operation, maintenance, repair and disposal**.

Risk controls as it relates to **user interface**:

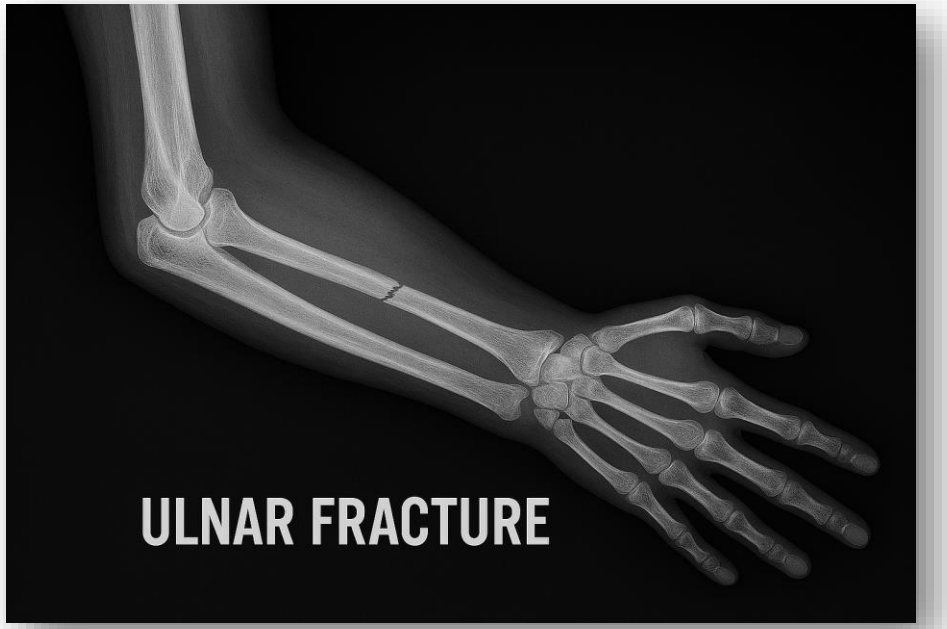
- **Inherent safety by design**
- **Protective measures** in the medical device itself or in the manufacturing process
- ***Information for safety***

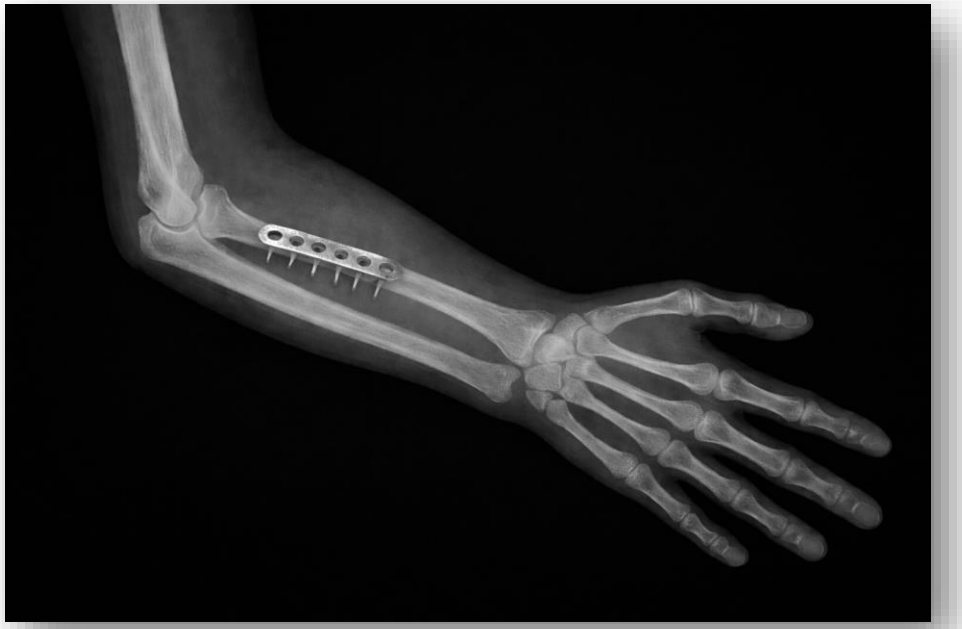
If information for safety is used as a risk control measure, the manufacturer must ensure that the information is perceivable by, understandable to and support the correct use of medical devices.

Usability Engineering for an Example Device

Continuing from the Previous example from Webinar #4 BSI Insight Series: 'Design Controls'

Illustrative Example Only: A 3-D printed Plate with Novel Geometry and Absorbable Material.





Who is the patient group?

Who is the user?

How is it installed?

What devices are compatible?

Section 5.1

Use Specification

THE USE SPECIFICATION SHOULD INCLUDE :	ULNAR FRACTURE PLATE EXAMPLE:
Intended medical indication:	The 3D-printed ulnar fracture plate is intended for internal fixation of fractures, osteotomies, non-unions, and malunions of the ulna in skeletally mature patients.
Intended patient population:	• Skeletally mature patients (≥ 18 years). • Skeletally immature patients (≥ 4 years). • Patients with traumatic, pathological or corrective ulnar fractures. Exclusions: • Active infection at implant site. • Severe bone loss beyond device fixation capability.
Intended part of the body or type of tissue applied to or interacted with:	Ulnar bone and surrounding soft tissue.

Section 5.1

Use Specification

THE USE SPECIFICATION SHOULD INCLUDE :	ULNAR FRACTURE PLATE EXAMPLE:
Intended user profile	• Orthopaedic surgeons, trauma surgeons and surgeons trained in upper extremity fixation techniques. • Surgical assistants and operating room nurses. • Sterile processing personnel (for reusable instruments)
Use environment	Primary Environment: Hospital operating room or ambulatory surgical center Environmental Conditions: Sterile surgical field. Fluoroscopic imaging in use. Presence of blood and body fluids. Time-sensitive surgical conditions. Use with gloved hands. Storage Environment: Controlled warehouse or hospital storage.
Operating principle	Plate provides stabilization and compression of the fracture interface when attached with compatible screws.

Section 5.3

Identify Known or Foreseeable Hazards and Hazardous Situations

Hazards or hazardous situations caused by use errors:

- Incorrect plate orientation or side of body.
- Selection of incorrect plate size.
- Incorrect selection of screw size and type (locking vs. non-locking)
- Improper screw trajectory leading to cortical breach.
- Excessive screw tightening leading to plate or bone damage.
- Failure to recognize plate misalignment under fluoroscopy (limited visibility due to use of plastic)

Section 5.4

Identify and Describe Hazard-Related Use Scenarios

HAZARD	HAZARD-RELATED USE SCENARIO DESCRIPTION (TASK)	HARM	SEVERITY	USER INTERFACE RISK CONTROL MEASURE
Incorrect plate orientation	Physician attempts to locate plate on bone in incorrect orientation.	Incorrect plate orientation results in non-union of fracture.	4	Laser marking of plate to indicate proximal end.
Incorrect screw selection (locking vs. non-locking)	Physician selects incorrect screw type for hole in plate.	Plate loosening causes non-union of bone.	4	Screw head is obvious to experienced users (threaded vs smooth).
Excessive torque when inserting screw	Screw breaks during insertion	Damage to bone during removal of screw.	3	Torque limiting screwdriver

Section 5.5

Select The Hazard-Related Use Scenarios for Summative Evaluation

Selection of hazard-related use scenarios:

- All scenarios (simple device or procedure)
- Subset selected based on severity of potential harm.
- Probability of harm does not need to be considered because it is difficult to estimate, especially for novel devices.

The selection scheme and rational should be documented in the usability engineering file.

- **Formative Evaluation** – Performed on prototype devices to refine the design. “Looks Like”, does not even need to “Function Like”.
- **Summative Evaluation** – Performed on Final *Locked Design*, Protocols are more complex at this stage

10 Essential Steps for Human Factors Testing Set Up

1. **Confirm Readiness**: ***Conduct formative studies***, include IFU, labelling, and correct intended user groups. Base formative work on updated usability into risk assessment.

2. **Update User Risk Analysis**: Identify critical tasks linked to harm or incorrect performance. ***Ensure traceability***. Ensure summative protocol evaluates the critical tasks.

3. **Define User Groups & Recruit Participants**: Ensure users match real-world demographic and experience and ***avoid biased participants*** (FDA guidance states n=15; UKCA n=15 is good, MDR n= not specified, simply must be justified*).

4. **Set up Test Environment**: Ensure it ***realistically reflects*** intended use scenarios and conditions.

5. **Create the HF Test Protocol:** ***Predefine success/error criteria***. Align task scrips with user risk analyses. Ensure risk traceability is captured in documentation.

**EN 62366-1 standard allows for a qualitative research; don't necessarily need a statistical justification. Europe, at least n=5, or more.*

10 Essential Steps for Human Factors Testing Set Up

6. **Prepare Materials:** Use ***final IFU, labelling, and training materials***. Prepare recording equipment and support materials for evaluation.

7. **Pilot test**: Run a protocol with a small number of '***pre-test***' participants and verify clarity of instructions, task flow, and environment set up.

8. **Execute HF Testing**: Observe ***without intervening*** (unless for safety), document failures, close calls, use errors, and root causes.

9. **Analyze Data:** Link findings back to risk controls. ***Identify systematic patterns***; this is key to confirming *mitigation effectiveness*.

10. **Prepare Final HF Report**: Include all required elements and ***conclude risk-control verification*** and safe performance in alignment with ***EN IEC 62366-1***.

Key Takeaways & Summary

- Shift to *user-centered design* and introduced key principles of EN 62366-1.
- Start Usability Early; it will drive design requirements and reduce errors.
- Strengthen the use-error definitions and the "linking" between usability and risk assessment.
- Effective data gathering at the Formative stage leads to a Strong Final Summative Evaluation.
- Outlined 10 essential steps for Human Factors Testing Set Up.

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Startup Edition

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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

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- IVDR Classification White Paper
- Roadmap for Small-Medium Enterprise and Startups White Paper
- (A Roadmap for SMEs and Startups | BSI)

Questions?

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BSI Values our Startup Clients. *We are proud of our **client retention rate** of **96%**, as it truly reflects our proven framework, one that is known for robust due diligence and communication that can help startups succeed with regulatory clarity, from concept and design to global market access.*

Thank you for joining us today!

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