BSI Insight Series:

Startup Edition

Webinar #4: *Demystifying Design Controls and Clinical Planning*

February 10, 2026

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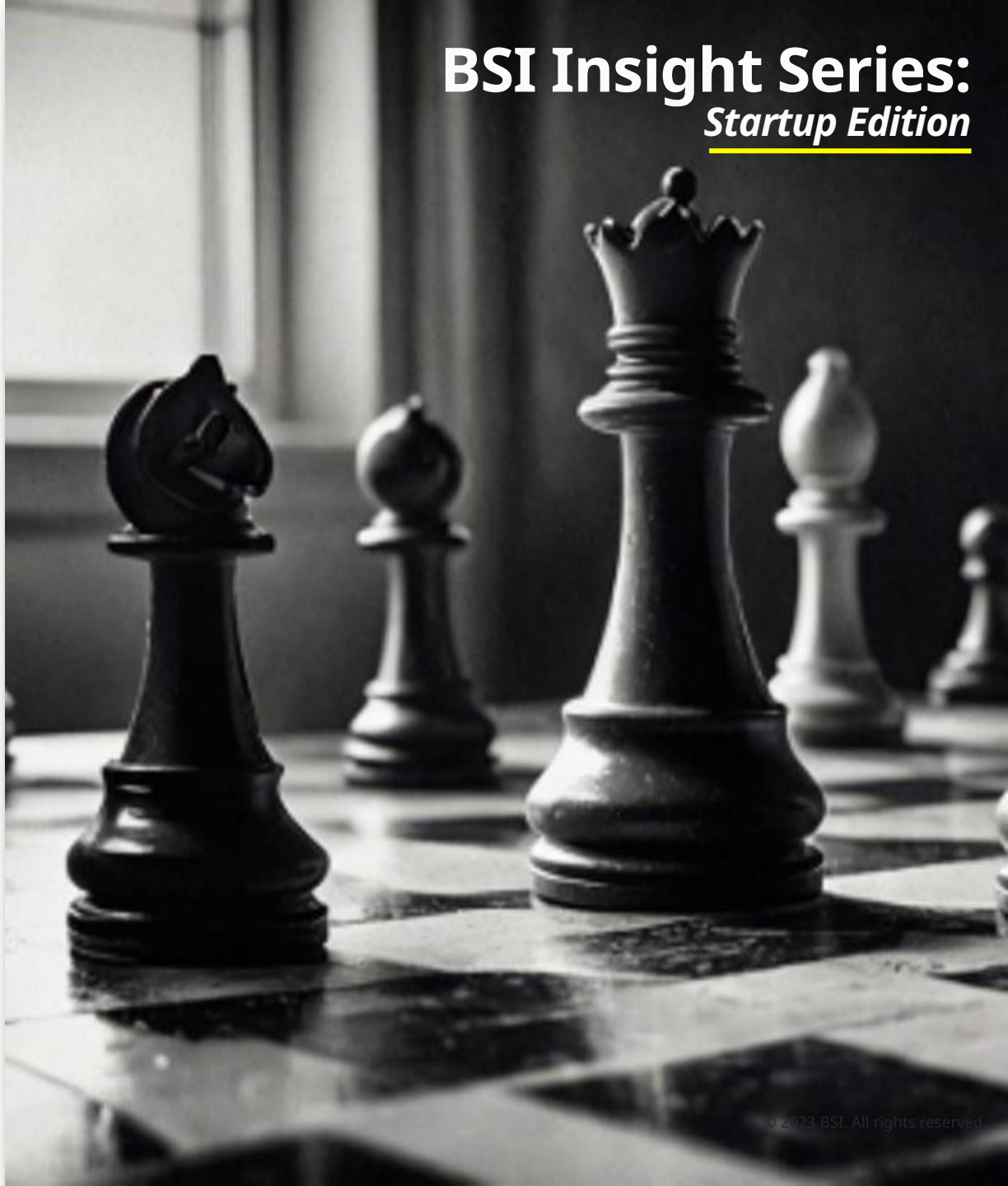
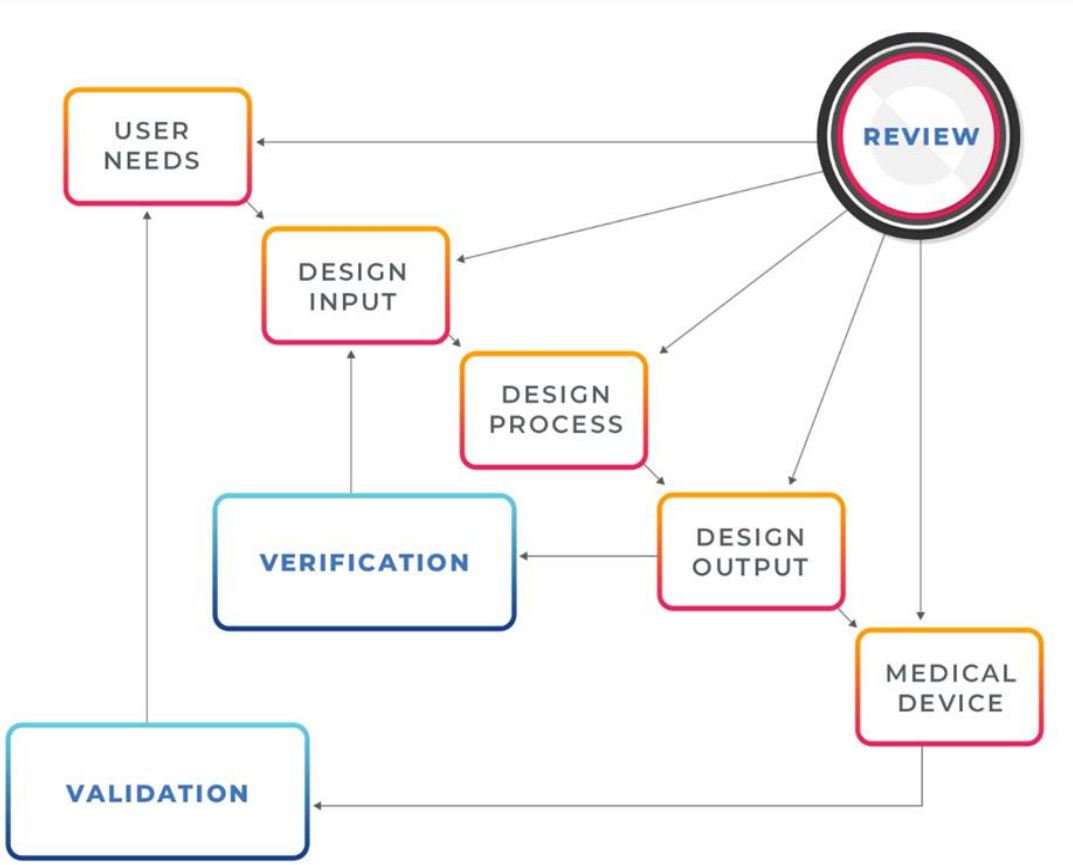


Design Control - Overview

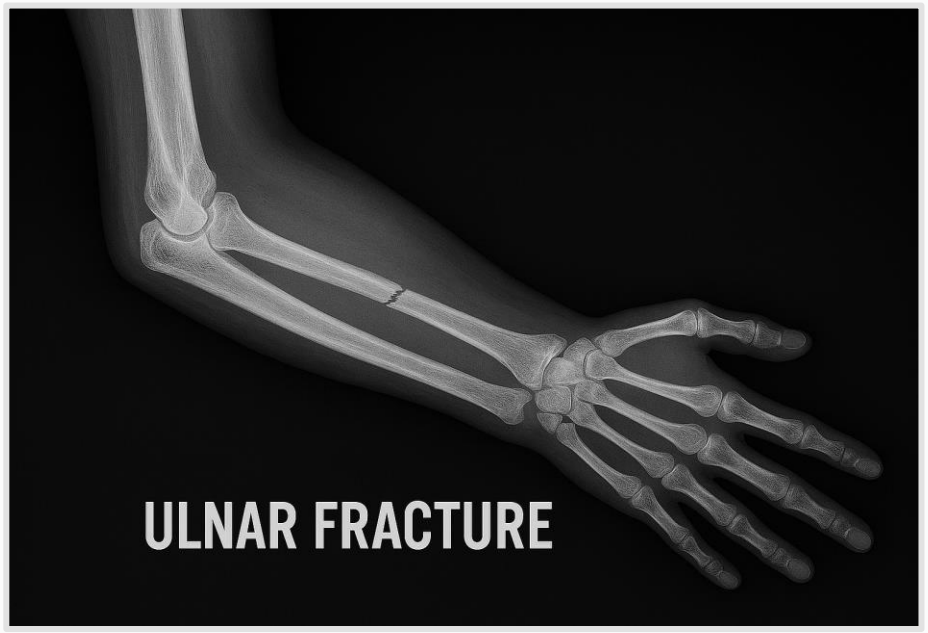
- **User Needs** – Capture the Voice of Customer
- **Design Inputs** – Builds on User Needs, Intended Purpose
- **Design Outputs** – Design specifications, Labeling, Manufacturing Methods; Describe how the device will meet requirements
- **Design Verification** – Ensures Design Outputs meet Design Inputs; meeting design specifications
- **Design Validation**: Ensures device function in a clinical setting; conforms to defined user needs and intended use(s).

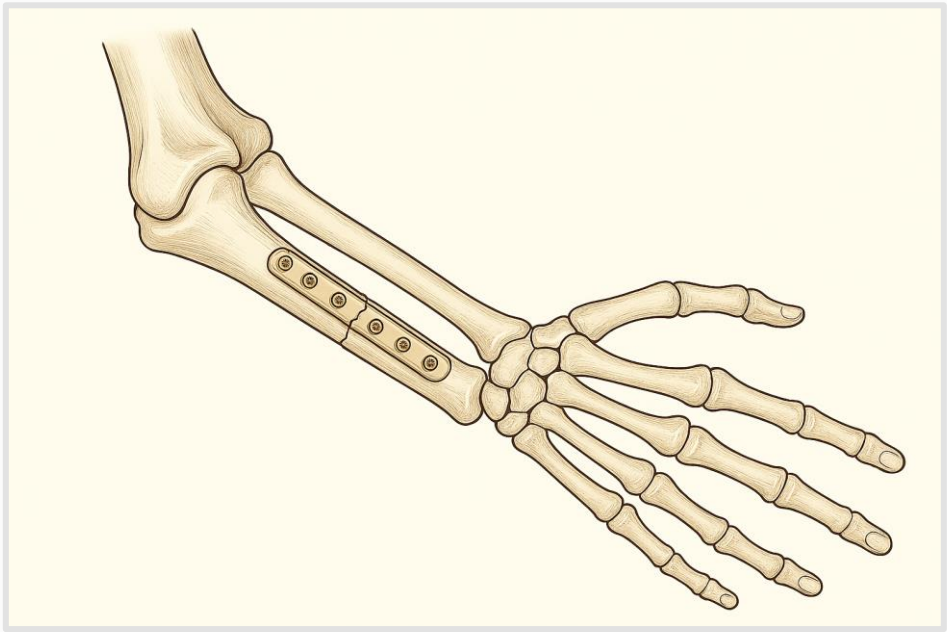
- *Create traceability between requirements, risk testing and clinical Evidence.*
- *Document changes throughout the lifecycle of the product*



Implementing Design Controls which effectively meet the ***user's*** need.

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





Who is the patient group?

Who is the user?

How long does it need to function?

Non-union rate <5%

Design Matrix: User Needs

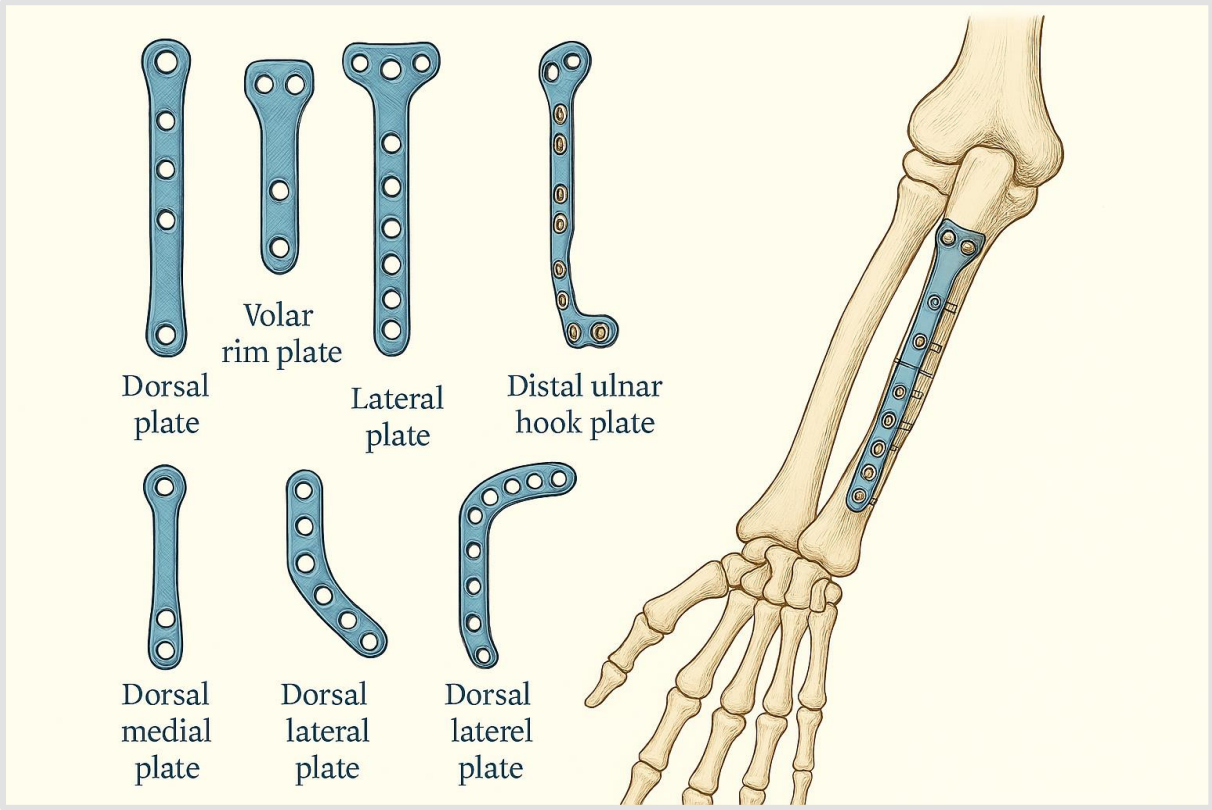
USER NEED
1. Treat osteoporotic patients with a simple or compound ulnar fracture
2. To be used by orthopedic surgeons & support staff
3. Must support healing for at least 6 weeks
4. Does not require removal after healing - must be absorbed over time (> 2 years)
~~*Must be 3D printable~~

User needs describe what the user requires from a medical device to be able to use it safely and effectively as intended.

- Who will use the device (clinicians, nurses and/or the patient).
- Under what conditions the device will be used.
- What the device should do to accomplish the job.
- Recommended to not include items not needed by the user or patient.
- **3D printing of the implant is interesting but not needed by the user. This is a design output.*
- *State of the Art – What is this? How important is this to consider at this stage? (Clinical vs. Technical)*

Discussion: Design Inputs (Requirements)

- How big do they need to be?
- Do I need specific sizes?
- Are there material requirements?
- Improved alignment
- Faster surgical procedure, less blood loss
- Healing time <6 weeks

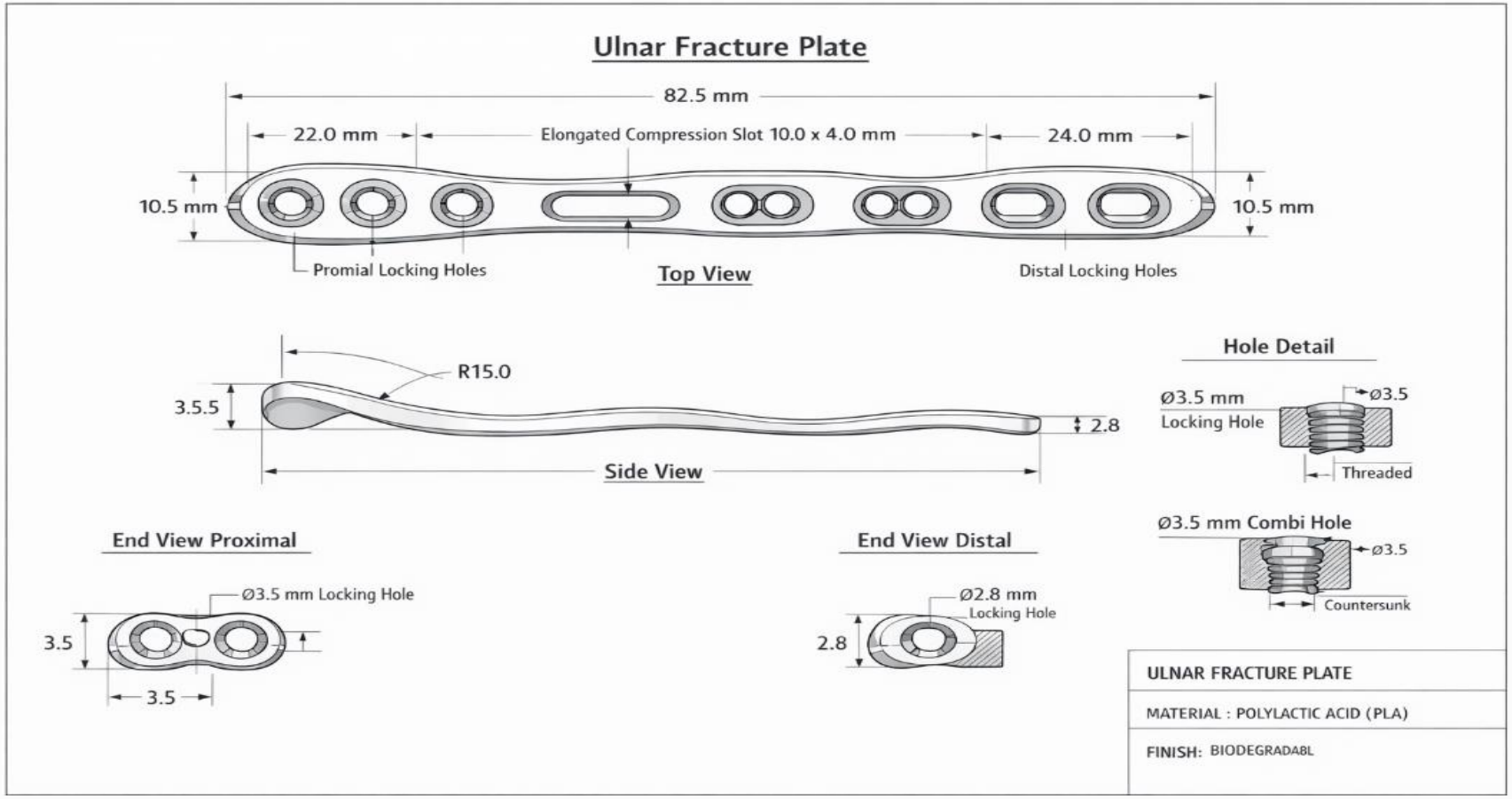


Design Matrix: Design Inputs (Requirements)

USER NEED	DESIGN INPUT (REQUIREMENT)
1. Treat osteoporotic patients with a simple or compound ulnar fracture	1a. Must be compatible with 4mm ϕ cancellous screws
	1b. Must have 10 sizes in 3mm length increments
2. To be used by orthopedic surgeons & support staff	2a. Surgical instruments to be used by orthopedic surgeons, must consist of drill, tap, trails and drill guides
	2b. Instruments to be prepared, cleaned and disassembled by support staff
3. Must support healing for at least 6 weeks	3. Must maintain 90% of mechanical strength up to 6 weeks
4. Does not require removal after healing - must be absorbed over time (2 years)	4a. Long term implantable, must be biocompatible and non-corrosive
	4b. Complete mass resorption at 24 months with no visibility on radiograph.

Discussion: Insights into Design Output

- Technical Drawings
- Design Specifications
- Materials Specifications

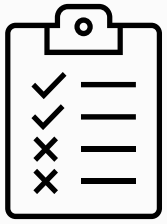


Design Matrix Example: Design Output

DESIGN INPUT (REQUIREMENT)	DESIGN OUTPUT (DESIGN SOLUTION)
1a. Must be compatible with 4mm radius cancellous screws	Technical drawing ABC123 Compatibility matrix COM34
1b. Must have 10 sizes in 3mm length increments	Technical drawings ABC123a-j
2a. Surgical instruments to be used by orthopedic surgeons, must consist of drill, tap, trails, drill guides	Instrument system “Ulnate” to be used. Drawing file CDE124
2b. Instruments to be prepared, cleaned and disassembled by support staff	Cleaning and disassembly instructions IFU 67
3. Must maintain 90% of mechanical strength up to 6 weeks	Martials specification PLA1 MWT >100kg/mol, viscosity 1000 Pas
4a. Long term implantable, must be biocompatible and non-corrosive	Martials specification PLA1, biological control plan BIO12, cleanliness process SCRUB3, aseptic processing AP17
4b. Complete mass resorption at 24 months with no visibility on radiograph.	Materials specification PLA1

Verification vs. Validation under MDR (EU 2017/745)

- Under the EU MDR, manufacturers must demonstrate that their device is **safe**, **effective**, and **performs as intended**. Verification and validation are core parts of this evidence.



Flexural strength of the plate is > 20 MPa

Device has a non-union rate <5%

Verification
Purpose: *Confirm design outputs meet the design inputs and comply with specifications.*

Examples:
- Verifying device strength:

"A device is X Strong"
- Confirming compatibility with accessories:

"A device is compatible with accessories."

Validation
Purpose: *Demonstrate device meets user needs, intended purpose, and clinical performance under real or simulated conditions. Ensure the manufacturing process is consistent and reproducible.*

Examples:
- Usability studies
- Clinical Evaluation
- Process Validation (sterilization, packaging)
- Design Validation.

Design Matrix Example: Verification and Validation

DESIGN INPUT (REQUIREMENT)	DESIGN OUTPUT (DESIGN SOLUTION)	VERIFICATION / VALIDATION METHOD	VERIFICATION / VALIDATION RESULTS	OUTPUT MEETS INPUT?
1a. Must be compatible with 4mm radius cancellous screws	Technical drawing ABC123, compatibility matrix COM34	Design tolerance stack V1203, usability assessment with sawbones and cadaver U876	4mm screws are compatible with plates, usability testing confirms compatibility	Yes
1b. Must have 10 sizes in 3mm length increments	Technical drawings ABC123a-j	Drawing review V1324, usability assessment with sawbones and cadaver U876	Plate sizes are appropriate to nominal, large and small patient sizes and are adequate to stabilize bone.	Yes
4a. Long term implantable, must be biocompatible and non-corrosive	Material specification MS0021	Degradation study V9877, *in vivo* study V8952, CER002	Complete resorption at 24 months in in vivo study. CER002 shows no radiological evidence of plate at 24 months.	Yes
4b. Complete mass resorption at 24 months with no visibility on radiograph.	Material specification MS0021	Degradation study V9877, *in vivo* study V8952, radiograph study after 24 months simulated implantation V9923, CER002	Complete resorption at 24 months in in vivo study. CER002 shows no radiological evidence of plate at 24 months.	Yes

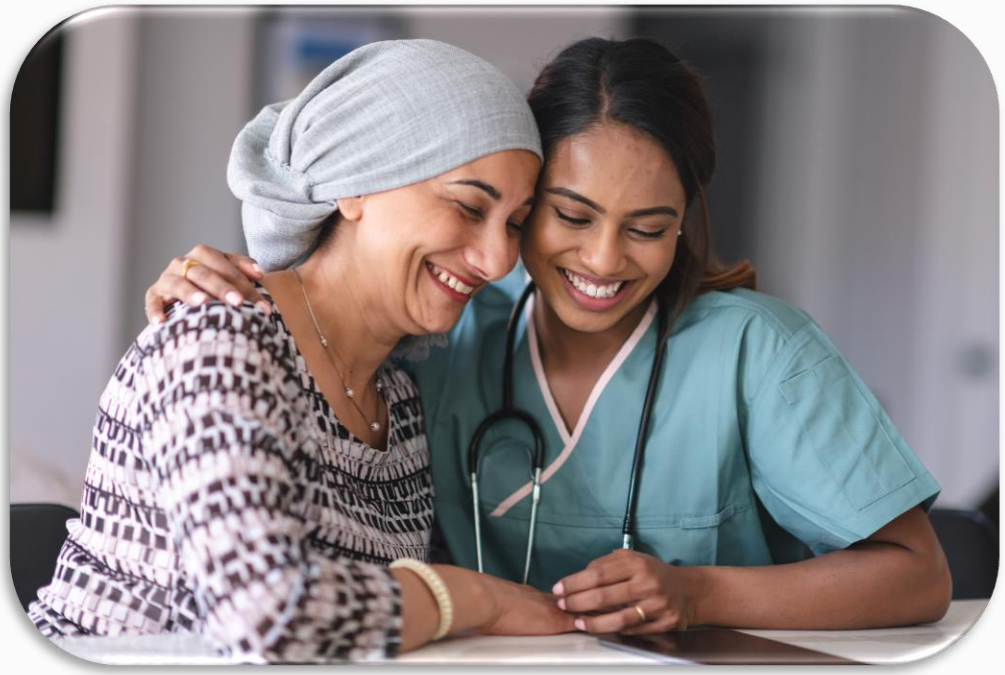
Understanding Pre-Clinical vs Clinical Data

Requirement	Pre-Clinical or Clinical?	Why?
Sterility of the device	Pre-clinical	Can be demonstrated with benchtop testing. Expensive, impractical or unethical to demonstrate with clinical studies.
Mechanical strength of the device	Pre-clinical	
Biocompatibility	Pre-clinical	
Materials Characterization	Pre-clinical	Corrosive testing
Wear Testing (Fatigue)	Pre-clinical	Fatigue Cyclic loading testing
Surgical approach and implantation	Pre-clinical animal study + clinical data	Pre-clinical animal studies may be needed for novel implants, instruments or materials. Clinical data needed to fully demonstrate safety and performance.
Does not cause soft tissue irritation		
Clinical success rates in fracture healing	Clinical data	Not able to be demonstrated with pre-clinical data.
Adverse event rates		

Incorporating Clinical Evaluation Into Design Controls

1. Begin CE at design input stage
2. Integrate State of the Art and clinical benchmarks
3. Connect CE tightly to RMF updates
4. Create a clinical Development Plan early
5. Link V&V to clinical evidence expectations
6. Ensure intended purpose is clinically justified
7. Finalize PMCF plan at design freeze
8. Include CE review at each milestone

Clinical Planning: Clinical Route to Conformity

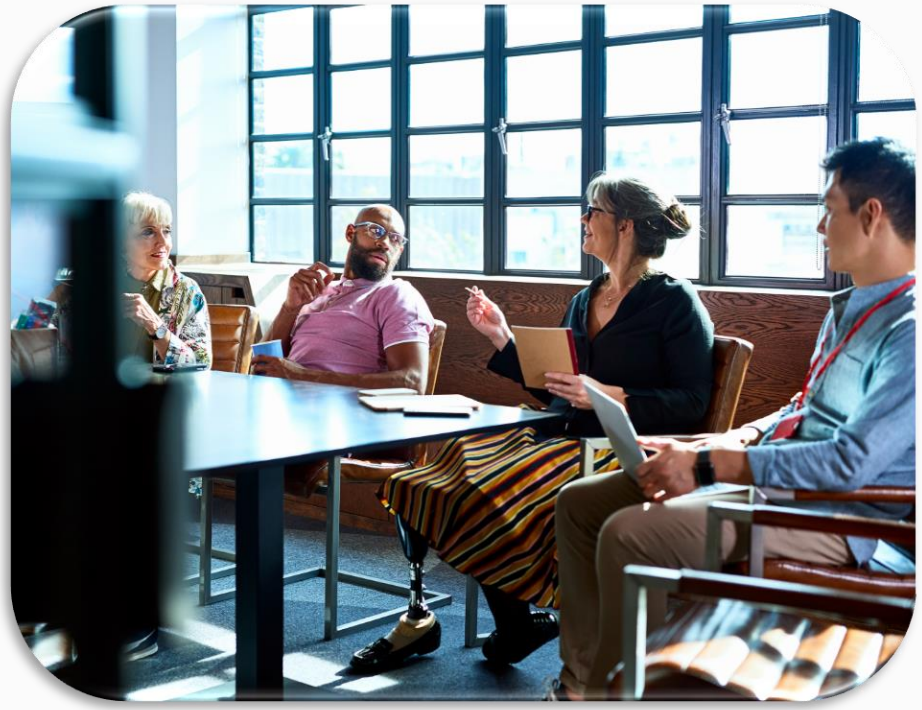


- Identify your ***Clinical Route to Conformity***
  - Consider Device Classification (MDR Article 52)
  - Determine if clinical investigation is required (MDR Article 61)
  - Determine if Equivalency is feasible (must have full data access)
  - If no equivalence, then clinical investigation is needed
- Map Route to Clinical Evidence
  - If Clinical Investigation Required - Annex XV + ISO 14155
  - If Clinical Investigation is not required (Article 61 exemptions), justify the sufficiency of testing and claims.

Clinical Planning: Clinical Route to Conformity

- Build Clinical Planning Documents
  - Develop CEP & CIP – from your clinical route to conformity
  - Align end points, intended purpose, and what you need for evidence
- Documentation and Design Controls
  - Design inputs must match your clinical route to conformity
  - CI: end points are validated
  - Equivalency: inputs match the equivalent device
  - Level of evidence in line with SOTA for the device
- *Planning for market is not the same as post-market planning*
- *Post Market Clinical Follow Up (PMC Considerations are Key*

Clinical Evaluation Planning (MDR 2017/745)



Clinical Evaluation Plan (CEP):

- CEP is mandatory for all medical devices.
- MDR Annex XIV, Part A – Annex XIV Part A gives the minimum content required in CEP (Article 61(3)

CEP under EU MDR:

- Explain what clinical data is needed
- Define how it will be collected, appraised, and analysed
- Provide a plan for generating missing data, including clinical investigations or PMCFs

Notified Body Review:

- Reviewers will go line by line to ensure requirements are met
- **Yes**, NBs expect CDP regardless of the status of your device

Effective Design Controls Matter

Build Smart, Fail Less, Approve Faster

- Turn a big ideas into a ***feasible & deliverable*** products informed by clinical, VOC, and state-of-the-art insights.
- Prevent redesigns and reduce risk through *early evidence-based decisions*.
- Demonstrate safety, effectiveness, and *regulatory readiness*.
- *Strengthen documentation and traceability* throughout development.
- Streamline development to speed approvals and ***stay compliant to regulations***.

Q2 2026: Breakthrough Devices with BSI

MDCG 2025-9: New guidance document, published December 2025

- Definition of a breakthrough device or IVD:
  - High degree of novelty.
  - Significant positive clinical impact.
  - Unmet medical need where there is an absence or insufficiency of alternative options.
- Designation of breakthrough devices is the sole responsibility of the EMA Expert Panel.
- Devices with a high degree of novelty may be associated with limited scientific knowledge or data from similar devices.

Webinar: How to Streamline Your MDR or IVDR Review

Conformity Assessment for Breakthrough Devices with BSI (available Q2 2026):

- BSI does **not** designate breakthrough devices or influence the EMA Expert Panel.
- Structured Dialogue to interpret MDCG and MDR/IVDR requirements.
- Benefits:
  - Priority scheduling of audits and initial MDR or IVDR reviews.
  - Technical and Clinical reviews delivered as Dedicated Interactive reviews but quoted at the standard rate.
  - Certificate may be issued with conditions where confirmatory data is needed.
  - Ability for BSI to discuss review directly with EMA Expert Panel.

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Startup Edition

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

Feb 10: Demystifying Design Controls and Clinical Planning

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BSI White papers - Medical Device White Papers

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

Questions?

While BSI is globally known and trusted by Fortune 100 MedTech companies, did you know that **86%** of our client base is **small- to medium-sized enterprises?**

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!

Feb 10, 2026: *Webinar #4 - Demystifying Design Controls and Clinical Planning*