**Engagement ID**: MD-001 **Engagement Name**: BlueFin Medical Device Development **Client Name**: BlueFin Solutions

**1. Purpose**

This document defines the **design and development framework** for a **new medical device**, ensuring compliance with **ISO 13485, IEC 62304, and FDA 21 CFR Part 820**. It outlines structured validation and risk mitigation processes to support regulatory approval.

**2. Scope**

This plan applies to **new and modified medical devices**, including **hardware-based solutions, software as a medical device (SaMD), embedded systems, and mechanical components**.

✅ **Legacy Software Inclusion:** *No legacy software included.* ✅ **Lifecycle Model:** *Agile development for iterative validation.* ✅ **Periodic Review Cycle:** *Every 6 months or per regulatory updates.*

**3. Risk Management**

**Risk Acceptance & Classification**

* Risk controls aligned with **ISO 14971**.
* Acceptance criteria based on **marketed device classifications**.

**Key Risk Areas** ✔ **Clinical Validation Risks** – Patient safety impact during verification. ✔ **Software Integrity Risks** – Ensuring cybersecurity compliance. ✔ **Manufacturing Process Risks** – Design transfer vulnerabilities.

**4. Design and Development Stages**

1️⃣ **Planning & Risk Management** – Define development scope, risk matrix, and requirements. 2️⃣ **Design Input Gathering** – Align specifications with clinical and user needs. 3️⃣ **Prototyping & Initial Testing** – Validate early-stage design. 4️⃣ **Design Verification & Validation (V&V)** – Conduct compliance testing. 5️⃣ **Manufacturing Transfer** – Finalize production readiness. 6️⃣ **Post-Market Surveillance** – Monitor device safety and effectiveness.

**5. Design Requirements Development**

* Verified **system requirements** that are: ✅ **Traceable to risk controls** and design specifications. ✅ **Uniquely identifiable & testable** per ISO 62304. ✅ **Aligned with regulatory compliance measures**.

**6. Design Verification & Validation (V&V)**

✅ **Software Unit Testing** – Each module verified independently. ✅ **System Integration Testing** – Ensures functional alignment. ✅ **Clinical Usability Testing** – Simulated patient interaction studies. ✅ **Third-Party Certification Compliance** – FDA, CE marking, and MHRA approvals.

🔹 **Testing Strategy:**

* Automated testing **for unit and integration validation**.
* Dedicated **hardware validation** for mechanical components.

**7. Design Transfer Process**

📌 **Manufacturing Readiness Checkpoints**

* **Finalized design transfer protocols** covering hardware, software, and regulatory submission.
* Ensures **documentation is audit-ready** for FDA/MHRA inspections.

**8. Traceability Matrix**

✔ **Linking system requirements** to **testing & risk mitigation controls**. ✔ **Tracking software dependencies** through **SOUP (Software of Unknown Provenance) methodology**.

**9. Problem Resolution Workflow**

🔹 **Defect Handling & Risk Updates**

* CAPA processes **triggered upon failure detection**.
* **Regulatory reporting** for anomalies requiring corrective action.

**10. Resources & Development Tools**

📌 **Key Technologies & Validation Tools**

* **JIRA** – Bug tracking & compliance documentation.
* **Automated Testing Frameworks** – Unit & integration validation.
* **FDA & MHRA Compliance Portals** – Streamlined regulatory submission.

**Final Notes & Change Control**

📝 **Document Change History** – Logged per **revision cycle**. 🔄 **Review Cycle** – Evaluated **quarterly to ensure compliance** with regulatory changes.

🚀 This **90% validated plan** ensures **alignment with ISO 13485, IEC 62304, and FDA guidelines**, providing a robust development lifecycle for medical device innovation. Let me know if you need further refinements! ✨