



ISO 13485 Manufacturing for a Boston-Based Startup

Accelerating production of a wearable scoliosis sensor from concept to pilot manufacturing in just 3 months

OVERVIEW

Digital Health Solutions partnered with a Boston-based medical device startup to establish ISO 13485-compliant manufacturing for a wearable sensor. Our team oversaw every stage of manufacturing readiness from designing and qualifying production equipment to creating the assembly process and validating it through IQ, OQ, and PQ. We developed systems for device history recordkeeping, integrated testing fixtures, and ensured all documentation met FDA requirements. Leveraging our certified facility and deep regulatory expertise, we delivered a pilot manufacturing run of 300 devices and positioned the client for scalable production of up to 5,000 units annually.

CHALLENGES

- **Rapid scale-up requirements** – Expand manufacturing to support 5,000 sensors/year within 3 months.
- **Regulatory compliance** – Meet FDA manufacturing regulations, including documentation, cybersecurity, and quality control.
- **Complex technology integration** – Coordinate hardware, firmware, mobile app, and cloud backend systems.
- **First-time manufacturing** – Client engineering team lacked prior medical device manufacturing experience.

IMPACT

- **On-time delivery** – Achieved full manufacturing readiness in 3 months, enabling a successful market launch.
- **Pilot production** – Completed a pilot batch of 300 fully compliant sensors.
- **Regulatory readiness** – Delivered all documentation and processes to meet FDA and FCC requirements.
- **Quality assurance** – Validated manufacturing processes with IQ/OQ/PQ for consistent, reliable output.

APPROACH

- **Comprehensive systems engineering** – Created all manufacturing requirements and designed the workflow, tools, and systems to meet ISO 13485 standards.
- **Advanced software development** – Built a cloud solution for automated device history records and traceability, for firmware, mobile app, and cloud components.
- **Automated testing fixtures** – Developed programming and Bluetooth test fixtures to configure, verify, and track devices before packaging.

About Digital Health Solutions

DHS, located near Boston, MA, provides key engineering, testing, documentation & regulatory services for Medical Device, Diagnostics, Healthcare and Life Science industries. Our expertise & services include:

- **End-to-end Product Development**
- **Firmware/Software Engineering (AI/ML)**
- **Systems Engineering**
- **Quality & Regulatory Guidance**
- **Cybersecurity**
- **ISO 13485 Contract Manufacturing**
- **Verification and Validation Testing/Documentation**

Accelerating MedTech Innovation

Let's build something together.

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