Regulatory Services

Our Approach

At BeanStock Ventures we rely heavily on our collective expertise of quality, systems, architecture, software and verification and validation to ensure your product and process is both technically sound and compliant.

When approaching a regulatory/quality project, our focus is on patient safety and privacy, product usability and reliability, using an Agile approach to Software Regulatory Requirements.

Together, our team of certified experts have delivered on numerous 510k and PMA submissions, letter to file and global international filings (China, Japan, EU, Canada) for multiple fortune 500 companies.

Our certifications include CLIA, RABQSA Certified ISO 9001, SAFe® Program Consultant (SPC), ASQ CSQE & CQA.

BEANSTOCK VENTURES

BeanStock Ventures recognizes that each project has unique needs and requires specialized skills.

Key Areas of Expertise

Premarket Submissions for Medical Devices with Embedded Software

General Principals of Software Validation

Software as a Medical Device (SaMD)

Clinical Decision Support Software

Cybersecurity in Medical Devices

Medical Device Data Systems

EU Medical Device Regulation IEC/ISO 62304, 62366, 13485, 14071

Regulatory/Quality Services

SOAR™ Training for your software online/onboarding agile regulatory needs

Technical and compliance assessments and audits

Standard procedures, processes, templates and tools

Design history/technical file creation and/or remediation

Risk management and hazard analysis

Software tool validation

Cyber-security

Usability

Special Considerations

CLIA, LDTs, IVD, HIPAA, CCPA, GDPR, 21 CFR - Part 820, GAMP5, home use devices, transport, critical care

Domains

Next generation sequencing, assays, diagnostics, artificial intelligence, ventilation, machine learning, medical dispensing, wearables, cloud applications, wireless, lab automation

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> Thank you, BeanStock Ventures, for being a key and valued contributor to the success of our recent 510K submission. The collaboration with our regulatory, quality partners and product development team could not have gone better. BeanStock Ventures deep understanding of the medical device industry and regulatory landscape helped deliver a professional, thorough software process and thereby a finished product for submission. Your careful oversight and guidance aligns with our corporate objectives and allowing us to achieve our key milestones. We look forward to working together on our future software quality and regulatory needs."
>
> **Paul DiPerna - CEO, Modular Medical and Founder of Tandem Diabetes**

Our Track Record

Diagnostics, disease detection and trend analysis, artificial intelligence

Ventilation, home health, critical care

Medication dispensing systems

Hemoglobin and immunoassay analyzers

Project Showcase

National Cardiac is the developer of a cloud-based wearable cardiac monitoring device. The organization held strong competence in regulatory requirements for an electro-mechanical device but needed the software expertise to bring the product to fruition.

BeanStock Ventures collaborated with the regulatory and quality team to provide a full software development process and complete design history file for NCI's 510k submission in less than 6 months. As a result, the product was cleared and additional funding was secured.

Safety Classification

Device Classification
- ✓ I
- ✓ II
- ✓ III

US FDA Medical Device Software Level of Concern
- ✓ minor
- ✓ moderate
- ✓ major

IEC 62304 Software Safety Class
- ✓ A
- ✓ B
- ✓ C

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