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How to Clear a Software Medical Device with the FDA

WHITEPAPER

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This whitepaper discusses the standards and requirements needed for a successful FDA submission and clearance for a software medical device, and also defines pre-market v.s. post-market activities, submission timelines, CFR, XGMP, QMS, and DHF.

It provides resources for businesses that help to ensure regulatory compliance and prevent unnecessary costs and delays.

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How to Clear a Software Medical Device with the FDA

Written by the experts at BeanStock Ventures

Pre-market and Post-market

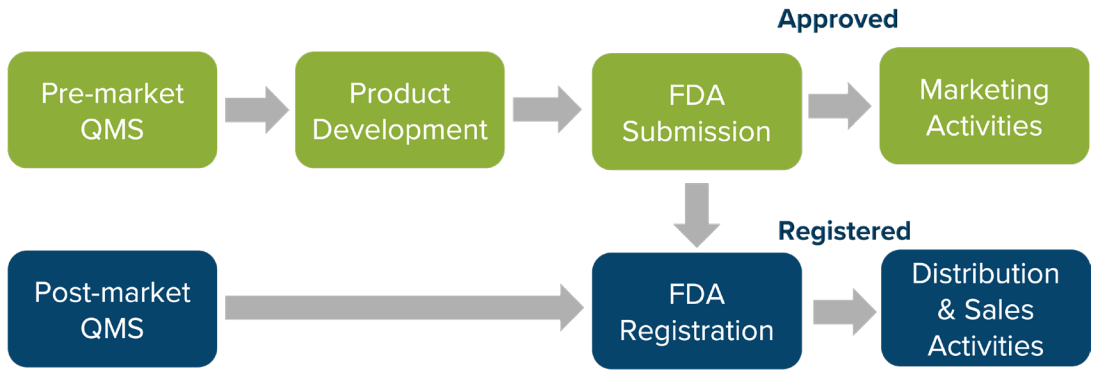
What you need to do as a business to get your device to market can be simplified into two phases: Pre-market and post-market.

Pre-market and post-market activities can be done in parallel to expedite time to market.

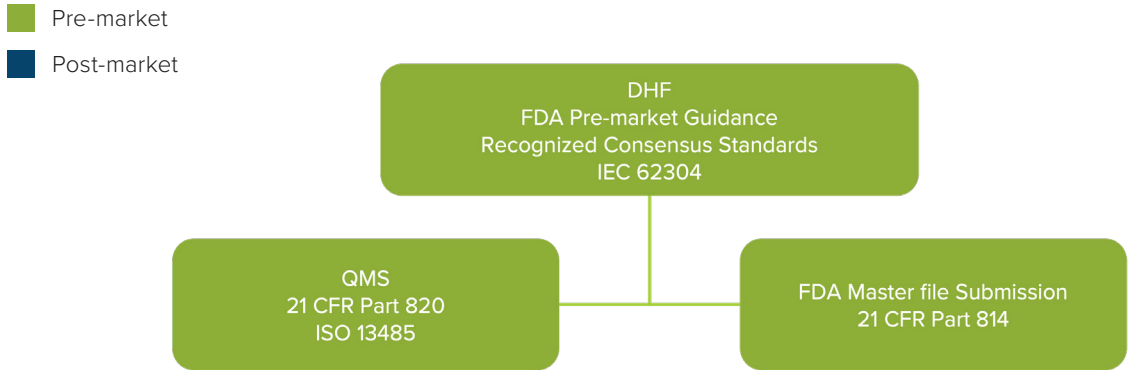
For start-ups that have limited funding and want to reduce market risks, we propose you focus on the requirements needed to obtain FDA clearance or pre-market approval.

This approach will reduce risks to your business and help you secure investment. For the purposes of this white paper, we will be focusing on pre-market activities.

What's Really Needed to Clear a Software Medical Device with the FDA?



Regulatory Overview – Getting to a Submission



Pre-market Approval Requirements

Pre-market approval requirements

The **Code of Federal Regulations (CFR)** is the FDA's legal authority to regulate both medical devices and electronic radiation-emitting products, specifically in CFR Title 21, Chapter I, Subchapter H, Part 814[1].

For pre-market approval you will need to design, develop, and maintain your product following **Current Good Manufacturing Practices (CGMP)**, including documenting your design and associated changes along the way.

Developing a **Quality Management System (QMS)** that meets the ISO 13485 standard is beneficial as an essential characteristic to any successful medical device manufacturer[2].

Developing and maintaining a **Design History File (DHF)** that meets the IEC 62304 standard provides specifications and technical input required for clearing your software medical device.

Effort vs. Time vs. Cost

Designing and developing a software medical device is a long-term commitment and the regulations are complex. According to a survey conducted by Boston Consulting Group and the UCLA Biodesign Innovation Hub, the median regulatory costs for clearance were $3.1M and the median approval wait time was 31 months[3]. Regulatory investments are substantial, and if regulatory compliance is not viewed as a priority early in development, businesses are at risk for additional regulatory costs and delayed time to market.

TYPICAL MEDICAL DEVICE COST

Designing and developing a software medical device is not a small feat. In the same survey conducted by Boston Consulting Group and the UCLA Biodesign Innovation Hub, the development cost of a medical device leading up to regulatory submission ranges from $2-5 million[3]. It is important to understand the investment needed to clear, market, register, commercialize, and maintain your device throughout the product lifecycle.

"Non-routine quality events—such as major observations, recalls, warning letters, and consent decrees, along with associated warranties and lawsuits—cost the industry between $2.5 billion and $5 billion per year on average." (The Business Case for Medical Device Quality, 2013)[4]

HOW TO MINIMIZE SUBMISSION COSTS

Failed FDA submissions are costly, but there are resources available to ensure regulatory compliance and prevent unnecessary costs and delays. Preparing your device submission should be started at least 18 months prior to the planned submission date. BeanStock Ventures provides software development and regulatory compliance products and services to minimize complexity, reduce cost, and reduce time to market for innovative medical devices.

DIY Software Regulatory Kits (DHF Support): BeanStock Ventures offers a do-it-yourself regulatory kit to streamline your FDA submission.

This kit includes associated design templates for your DHF creation and training that provides you with guidance and best practices to help you complete your SiMD/SaMD regulatory technical submission.

Included in the DIY Software Regulatory Kit is a 12-month subscription to Software Online Agile Regulatory (SOAR®) Training–fundamentals training for today's software engineer. Developed by experts with 20+ years of experience in medical device, the easily digestible courses teach you how to get your innovative medical device to market faster. In SOAR®, medical device software engineers are taught to efficiently integrate Agile into the regulatory landscape, establish regulatory background and review requirements, and meet aggressive product launches and increase ease in passing internal and external audits and inspections.

These courses are on-demand training program that has been designed to enable software engineers to satisfy regulations while maintaining their agility.

The DIY Software Regulatory Kit helps businesses save over $200k and 18 months in FDA preparation. The kit is low cost access, contains high quality DHF templates, on-demand training, and monthly support from industry experts. All content in the DIY Regulatory Kits are continuously updated, ensuring that your team remains informed and compliant. Enroll today for a free starter version of this regulatory kit:

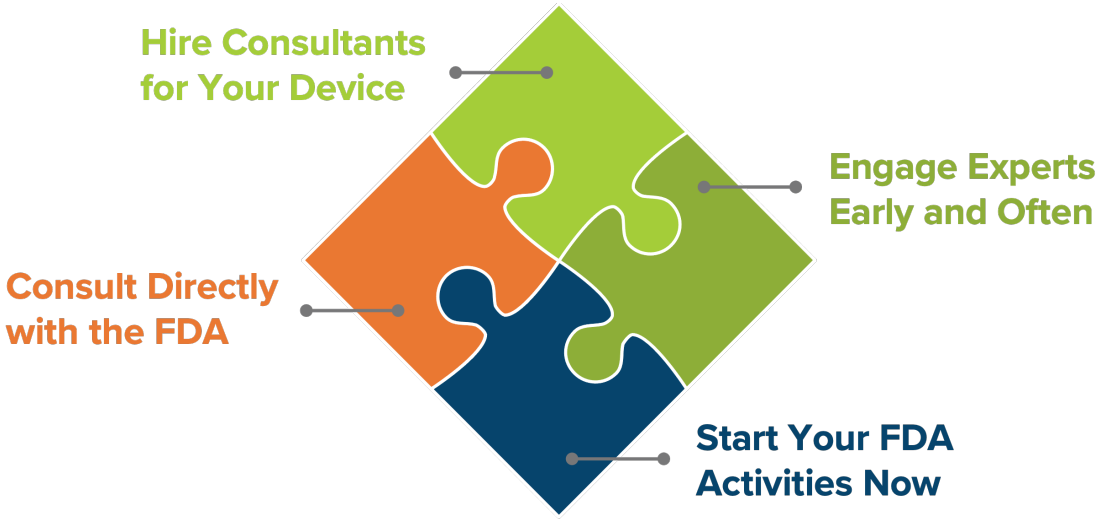
https://grassrootsdx.beanstockventures.com/diy-software-regulatory-kit

3P510(k) Third Party Review Program:
Many medical device developers are unaware of the FDA's 510(k) Third Party Review Program–3P510(k). This is an alternative to the traditional 510(k) review process and allows a select FDA-accredited organization to review your submission on behalf of the FDA. While the average review time directly with the FDA is 31 months, 3P510(k) speed up your review process to as quick as 47 days*.

BeanStock Ventures is 1 of only 9 globally FDA-accredited review organizations. Learn more about the FDA's 3P510(k) program and get your product to market faster:

https://beanstockventures.com/3p510k/

FDA Third Party Review Program



Pieces of a Successful FDA Submission

Choosing the Best Consultants to Help Clear Your Medical Device

REGULATORY VS. CLINICAL KNOWLEDGE

Ensure your consultants have the regulatory knowledge to support your product, and not just clinical knowledge. Regulatory knowledge in fields like software, pharmaceutical, electro-mechanical, and consumables are all equally important.

TECHNICAL VS. CLINICAL KNOWLEDGE

Ensure your consultants have direct or comparable technical knowledge to support your product. Technical knowledge in software, cybersecurity, and AI/ML are equally important.

DOMAIN KNOWLEDGE

Ensure your consultants understand your domain, such as cardiology, oncology, opthalmology, neurology, or radiology.

VALIDATION

Hire qualified consultants by validating their years of experience, employment history, client references, and relevant certifications.

DIVERSITY

Consider hiring professional consultants in multiple disciplines like regulatory, quality, and technical to cover the wide range of complexity of your medical device.

DEFINITIONS

AI: Artificial Intelligence

CGMP (Current Good Manufacuring Practice): Requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

DHF (Design History File): A repository of all documents related to your medical device design.

IEC 62304: An FDA Recognized Consensus Standard which defines the life cycle requirements for medical device software. The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes. Applies to the development and maintenance of medical device software when software is itself a medical device or when software is an embedded or integral part of the final medical device.

ISO 13485: An international regulatory standard that specifies the requirements for Quality Management Systems (QMS) in the medical device industry.

ML: Machine Learning

QMS (Quality Management System): A set of policies, processes, procedures, and resources implemented within an organization to ensure that its products or services consistently meet or exceed customer expectations and comply with applicable regulations and standards.

REFERENCES

[1] 21 CFR Part 814 -- Premarket Approval of Medical Devices. (n.d.). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-814

[2] 21 CFR Part 820 -- Quality System Regulation. (n.d.). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820

[3] Hammerand, J. (2022, March 21). How much time and money does it take for FDA 510(k) clearance versus De Novo classification? - Medical Design and Outsourcing. Medical Design & Outsourcing. Retrieved June 9, 2023, from https://www.medicaldesignandoutsourcing.com/fda-510k-clearance-de-novo-classification-cost-time-new-medical-product/

[4] The Business Case for Medical Device Quality. (2013). [EBook]. McKinsey & Company. https://mck.co/3P70Rz9

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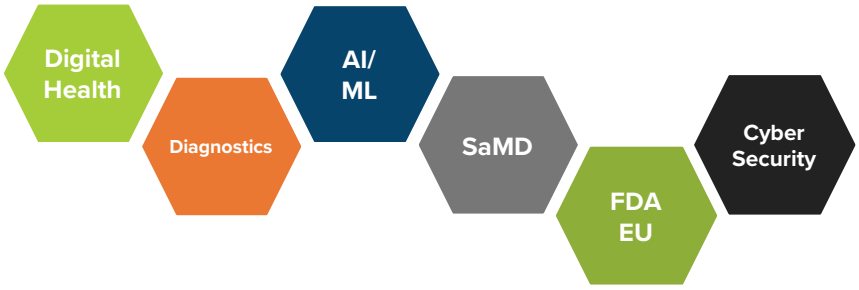
Enabling Digital Health



- Schedule a meeting with BeanStock Ventures
  - Software Product Development
  - Regulatory Compliance

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- See if you qualify for a 3P510k Third Party Review

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