Rook Quality Systems
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QuickVault

MedTech Regulatory Submissions Made Easy

Presented By: Kyle Rose, Axel Strombergsson, and Jeff Hau

Session Agenda

1. Introductions
2. Regulatory Submissions: US & EU
3. FDA Pre-submissions: What, Why, When & How
4. QuickVault: A Modern Tool for Submission Success
5. Q&A

Jeff Hau

Senior Director, Product Management at Veeva Systems

- → 17+ Years in Software Product Management
- → Software Engineering at University of Waterloo
- → Part of Two Successful Startups (One IPO, One Acquisition)
- → Product Innovation at Amazon prior to Veeva Systems
- → Loves to Build Product that Delight Customers and Deliver Value

Axel Strombergsson

Vice President, QuickVault at Veeva Systems

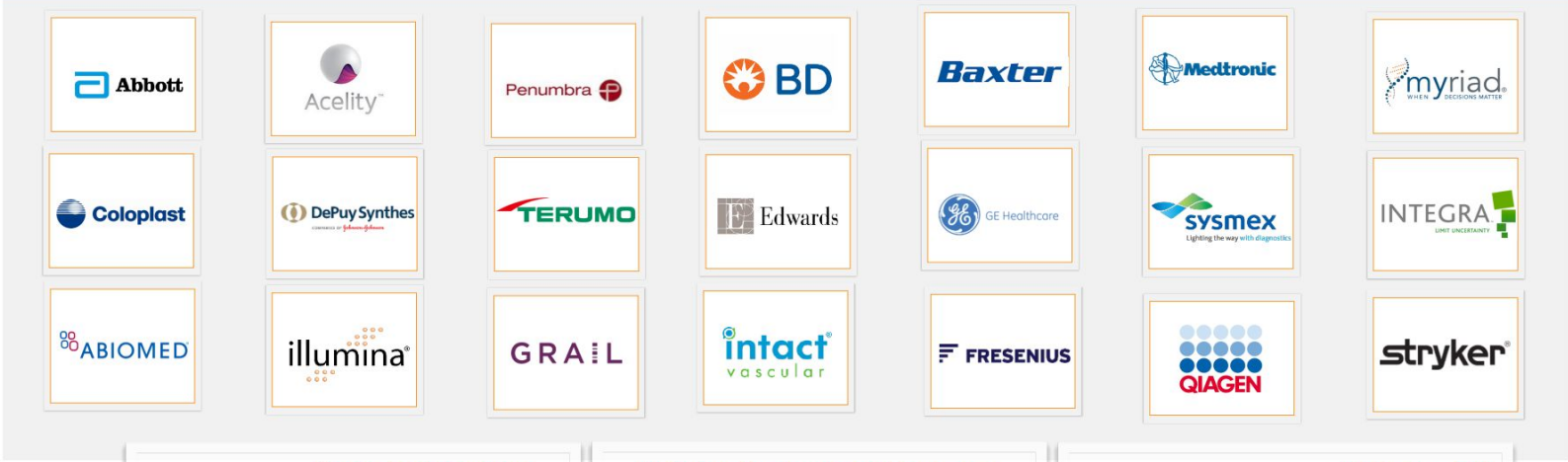
- → In the MedTech Industry for 20+ Years
- → Master's Degree in Mechanical Engineering, R&D
- → Later Focused on Device Commercialization and Operations
- → Direct Hands-on Involvement in 6 Startups
- → Vanderbilt University, Technology Transfer Office
- → Over 10 Years as a Startup Mentor

Veeva

Veeva is the global leader in cloud software for the life sciences industry

Founded 2007 • 1,400+ customers • 7,000+ employees • $3B+ revenue

140+ MedTech customers. **19 of Top 20** largest companies already using Veeva



Forbes #8 Fastest Growing Public Tech Company

Building for the Long Term as a Public Benefit Corporation

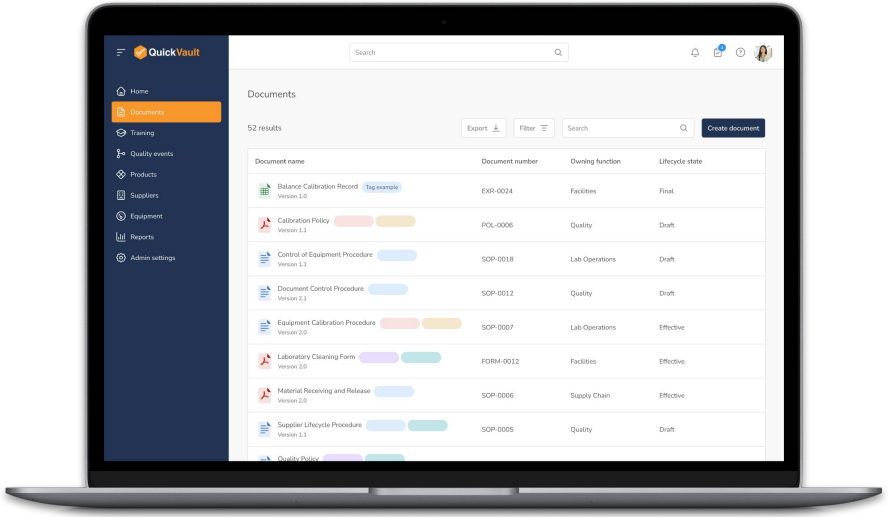
FORTUNE #2 Future 50 Company

QuickVault

The Device-to-Market Platform℠

Design › Submission › Production

- → Documents and Data
- → Quality Events (NCRs, CAPAs, Complaints)
- → Training Management
- → Design and Development (Design Controls)
- → Risk Management
- → Supplier Management
- → Regulatory Submissions*
- → Equipment Management**



*Coming Q2, 2025
*Coming Q3, 2025

Rook Quality Systems
MAKE EVERY MOVE COUNT

QuickVault

QuickVault

Easy OnBoarding ▪ Easy Compliance ▪ Easy-to-Use Solution

Ready-Day-One

Quick Start - Zero implementation costs. Zero maintenance costs.

Fully Validated

Always fully validated. No additional customer effort required.

Pre-Configured & Compliant

21 CFR 820, ISO 13485, MDR, IVDR, 21 CFR Part 11

Includes Library of Resources

Complete MedTech documentation package, SOP, eLearning, assessments, guides, & more!

Continuous Improvement

Appreciating asset - new functionality constantly being added at no additional cost.

Budget Friendly

Flexible subscriptions. Select Annual or Monthly payment plans

Purpose-Built for MedTech Success!

Kyle Rose

CEO & Founder, Rook Quality Systems

- → Quality and Regulatory consultant advising medical device companies around the world for over 12 years.
- → NIH lead for multiple programs including RADx supporting over 100 COVID diagnostic devices
- → Advisor to multiple Fortune 500 on all aspects of Quality and Regulatory for medical devices, software, and diagnostics
- → Dedicated Mentor to multiple Medical Device Incubators, Hospital Systems, Accelerators, and Universities

Georgia Tech
Wallace H. Coulter Department of Biomedical Engineering
Emory University
NIH National Institutes of Health
Turning Discovery Into Health
MC MASSCHALLENGE
UCSF University of California San Francisco
Stanford University
TMC INNOVATION

Rook Quality Systems
MAKE EVERY MOVE COUNT

Quality, Compliance, and Regulatory Support for MedTech

- Founded in 2012
- Global Consulting Team
- 35+ Consultants
- 13 Certified Auditors

Field Medical
PhotoniCare
ZiphyCare
XANDAR KARDIAN
CIRCADIA
PENUMA®
IMPLANT FOR MEN
neosoma
HURA IMAGING
Sotera® WIRELESS
safeBVM
Big Health
CLYRA Medical Technologies Inc
dianx INNOVATIONS
yunu

Regulatory Submissions: US & EU

What is a 510(k) Submission?

→ The 510(k) process is a premarket submission to the FDA to demonstrate the device is safe and effective.

- Uses a predicate method to demonstrate that the device under review is substantially equivalent to the predicate device.

→ Required for **most Class II** and some **Class I** devices.

Content Of A 510(k)

- → **Administrative Information** (Cover letter, contact details, FDA Form 3514)
- → **Device Description** (Intended use, technological characteristics)
- → **Predicate Device Comparison** (Side-by-side comparison of key features)
- → **Performance Testing** (Bench, animal, and/or clinical testing as required)
- → **Sterilization & Biocompatibility (if applicable)**
- → **Software Documentation (if applicable)**
- → **Labeling & Instructions for Use (IFU)**
- → **Summary of Safety & Effectiveness**
- → **eCopy & eSTAR Compliance (electronic submission format required)**

Submission Process for a 510(k)

→ **Identify Predicate Device**

- Must have **similar intended use and technological characteristics**.

→ **Determine Appropriate 510(k) Pathway**

- **Traditional 510(k):** Standard pathway for most devices.
- **Special 510(k):** For modifications to an existing **cleared** device (faster review).
- **Abbreviated 510(k):** Uses FDA-recognized consensus standards for faster review.

→ **Prepare the 510(k) Submission**

- Includes detailed device description, test results, and comparison to predicate.

Submission Process for a 510(k)

→ **Submit via FDA eSTAR Portal**

- As of October 1, 2023, **eSTAR is required** for all 510(k) submissions.

→ **FDA Review Process (90 days)**

- **Acceptance Review (15 days):** FDA checks if the submission is complete.
- **Substantive Review (60 days):** FDA evaluates the data and may request additional info.
- **Additional Information (AI) Request (180 days):** Response to any questions from the FDA during review
- **Final Decision (90 days total):**
  - Substantially Equivalent (SE): Device is cleared for marketing.
  - Not Substantially Equivalent (NSE): The device must go through De Novo or PMA.

Best Practices for Submitting a 510(k)

- → Start the FDA 510(k) planning as early as possible
- → Research predicate devices for everything they did including testing, instructions for use, packaging, device claims, and any post market feedback or complaints.
- → Software documentation is more thorough than hardware devices so if you device contains software you need to ensure the initial design requirements and decisions are documented.
- → Cybersecurity and AI regulations are getting more difficult and the current guidances are often out of date on what the FDA is currently accepting
- → Over-the-counter and at home devices and/or software will require usability. Ensure you have this planned, documented, and tested prior to your submission.
- → With reduced FDA staff the use of justification or other negotiation regarding your device is less likely to succeed.

What is a De Novo Classification Request

→ The **De Novo process** provides a pathway to classify **novel medical devices** that have **no prior predicate** but present **low to moderate risk** (Class I or II).

→ It is an alternative to **automatic Class III classification**, which would otherwise require a **Premarket Approval (PMA)**.

→ Once granted, the De Novo classification creates a **new device type** that can serve as a **predicate** for future 510(k) submissions.

Key Content of a De Novo Submission

- → **Administrative Information** (Applicant details, device name, etc.)
- → **Device Description** (Intended use, technological characteristics)
- → **Classification Summary** (Justification for Class I or II classification)
- → **Benefit-Risk Assessment** (Safety and effectiveness data)
- → **Performance Testing** (Bench, animal, and/or clinical data)
- → **Labeling & Instructions for Use**
- → **Comparison to Similar Devices** (If applicable)
- → **Proposed Special Controls** (If requesting Class II classification)

Overview of the De Novo Submission Process

→ **Pre-Submission (Optional but Recommended)**

- Engage with the FDA for feedback on the regulatory pathway and study requirements.

→ **De Novo Request Submission**

- Submitted after either:
  - **A 510(k) submission receives a Not Substantially Equivalent (NSE) determination.**
  - **The applicant determines no predicate exists (Direct De Novo).**

→ **FDA Review (Up to 150 days)**

- The FDA evaluates the device's risk profile, safety, and effectiveness.

→ **De Novo Decision**

- **Approval:** Device is granted Class I or II status, enabling future 510(k)s.
- **Denial:** The device remains Class III, requiring a PMA for marketing.

Best Practices for Submitting a De Novo Request

- → Plant to meet with the FDA to determine the device classification, testing required, and claims.
- → Prior to meeting with the FDA you need to seek regulatory guidance to have a strategic plan to address all of the questions above and propose the path that best suits your product and testing plans.
- → Clinical endpoints should be defined and discussed with the FDA prior to starting a clinical study.
- → It may take more than one pre-submission meeting to clarify the path and testing.
- → Breakthrough designations offers a good path for increased communication and is a good option if you are also seeking De Novo.
- → Use the De Novo classification as a competitive barrier. If you are the first to market you can define the tests and requirements of your potential competitors and use this to your competitive advantage.
- → De Novo submissions and PMAs typically take multiple years so it's important to ensure your Design Files are current and testing aligns with latest revisions throughout the process.

What is a PMA Submission?

- → **PMA = Pre-Market Approval**
- → PMA process is the FDA's most stringent regulatory pathway for medical devices.
- → Required for **Class III devices,** which present high risk and are life-supporting, life-sustaining, or of substantial importance in preventing impairment of human health.
- → PMA approval is based on scientific evidence demonstrating the device's safety and effectiveness.
- → Unlike 510(k) or De Novo, a PMA requires **extensive clinical data and manufacturing controls.**

Key Content of a PMA Submission

- → **Administrative Information** (Applicant details, device name, indications for use)
- → **Device Description & Principles of Operation**
- → **Non-Clinical Testing** (Bench, biocompatibility, electrical safety, software, sterilization, etc.)
- → **Clinical Study Data** (Human studies demonstrating safety & effectiveness)
- → **Manufacturing Information** (Quality control, design controls, risk management)
- → **Labeling & Instructions for Use**
- → **Post-Market Surveillance Plan** (If required)
- → **Summary of Safety & Effectiveness Data (SSED)**

Overview of the PMA Submission Process

→ **Pre-Submission (Optional but Recommended)**

- Engage with the FDA for guidance on study design, testing requirements, and data expectations.

→ **PMA Submission**

- Includes comprehensive clinical, non-clinical, and manufacturing data.

→ **FDA Acceptance Review (45 days)**

- Determines if the submission is complete for substantive review.

→ **Substantive Review (180 days)**

- Includes potential Advisory Panel review for high-risk or novel devices.

→ **FDA Decision**

- **Approval:** Device can be marketed in the U.S.
- **Approvable Letter:** Minor deficiencies must be addressed before approval.
- **Not Approvable Letter:** Major deficiencies require significant changes.
- **Denial:** The device does not meet safety and effectiveness standards.

What is a CE Mark Submission?

- **The CE Mark indicates that a medical device meets the regulatory requirements of the European Union (EU) and can be legally marketed in EU and EEA countries.**
- Medical devices are regulated under the EU Medical Device Regulation (MDR 2017/745) or In Vitro Diagnostic Regulation (IVDR 2017/746).
- The CE Mark is not an FDA approval — it signifies compliance with EU safety, performance, and quality standards.
- Requires an EU Authorized Representative for companies outside the EU.

Key Content for a CE Mark Submission

- → **Device Description & Intended Use**
- → **Classification Justification** (Per MDR/IVDR rules)
- → **Technical Documentation (TD) / Design Dossier**
  - Risk management (ISO 14971 compliance)
  - Biocompatibility, electrical safety, sterilization, software validation
- → **Clinical Evaluation Report (CER)**
  - Literature review and/or clinical investigations
- → **Quality Management System (QMS) Documentation**
  - ISO 13485 certification required for Class IIa, IIb, and III
- → **Post-Market Surveillance (PMS) Plan**
- → **Labeling & Instructions for Use (IFU)**
- → **Declaration of Conformity (DoC) & Notified Body Certificate (if applicable)**

CE Mark Submission Process

→ **Device Classification (Class I, IIa, IIb, III)**

- Classification determines the regulatory pathway.
- Higher-risk devices require **Notified Body (NB) review.**

→ **Conformity Assessment**

- **Class I (low-risk):** Self-certification via a Declaration of Conformity (DoC).
- **Class IIa, IIb, III (higher-risk):** NB review of technical documentation.

→ **Technical Documentation & Clinical Evaluation**

- Compliance with General Safety & Performance Requirements (GSPR).
- Clinical evidence required for higher-risk devices.

CE Mark Submission Process

→ **Notified Body Review & Certification**

- NB audits the manufacturer's Quality Management System (QMS) (ISO 13485 compliance).
- NB issues a CE Certificate for Class IIa, IIb, and III devices.

→ **Declaration of Conformity & CE Marking –** Manufacturer issues a Declaration of Conformity (DoC) and affixes the CE Mark.

→ **Registration & Post-Market Surveillance** – Register the device in EUDAMED and Implement PMS, vigilance, and Periodic Safety Update Reports (PSURs).

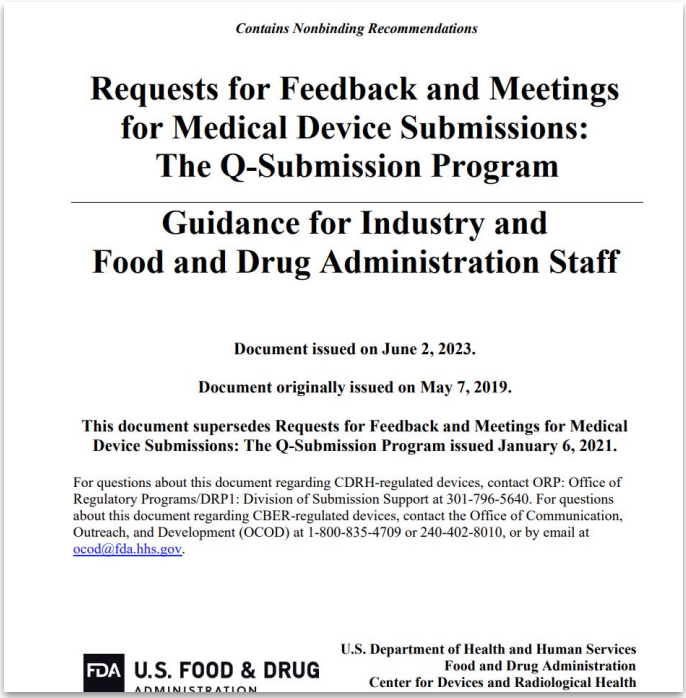
Best Practices for Submitting a CE Mark

- → Identify a notified body that has codes for your product type and specializes in your type of technology if possible
- → Prepare for both onsite quality audits as well as offsite technical review of the Technical File and Clinical Evaluation Report.
- → The EU MDR requires additional pre-market and post-market clinical documentation so this process and practice should be built into your QMS and business plans.
- → Clinical Evaluation Reports and Post-Market Follow Ups require significant resources both for development and communication during technical review.
- → EU classification requirements, guidances, and harmonized standards outline the testing requirements for each type of product. As these get updated you must proactively ensure your device complies and evaluate additional testing to the new standard.

FDA Pre-submissions: What, Why, When & How

FDA MedTech Pre-submission: What is it?

- → Written request for feedback from FDA
- → Used to guide development and/or application preparation
- → Feedback received in 75-90 days
- → and lastly: it's free!



Contains Nonbinding Recommendations

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 2, 2023.

Document originally issued on May 7, 2019.

This document supersedes Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program issued January 6, 2021.

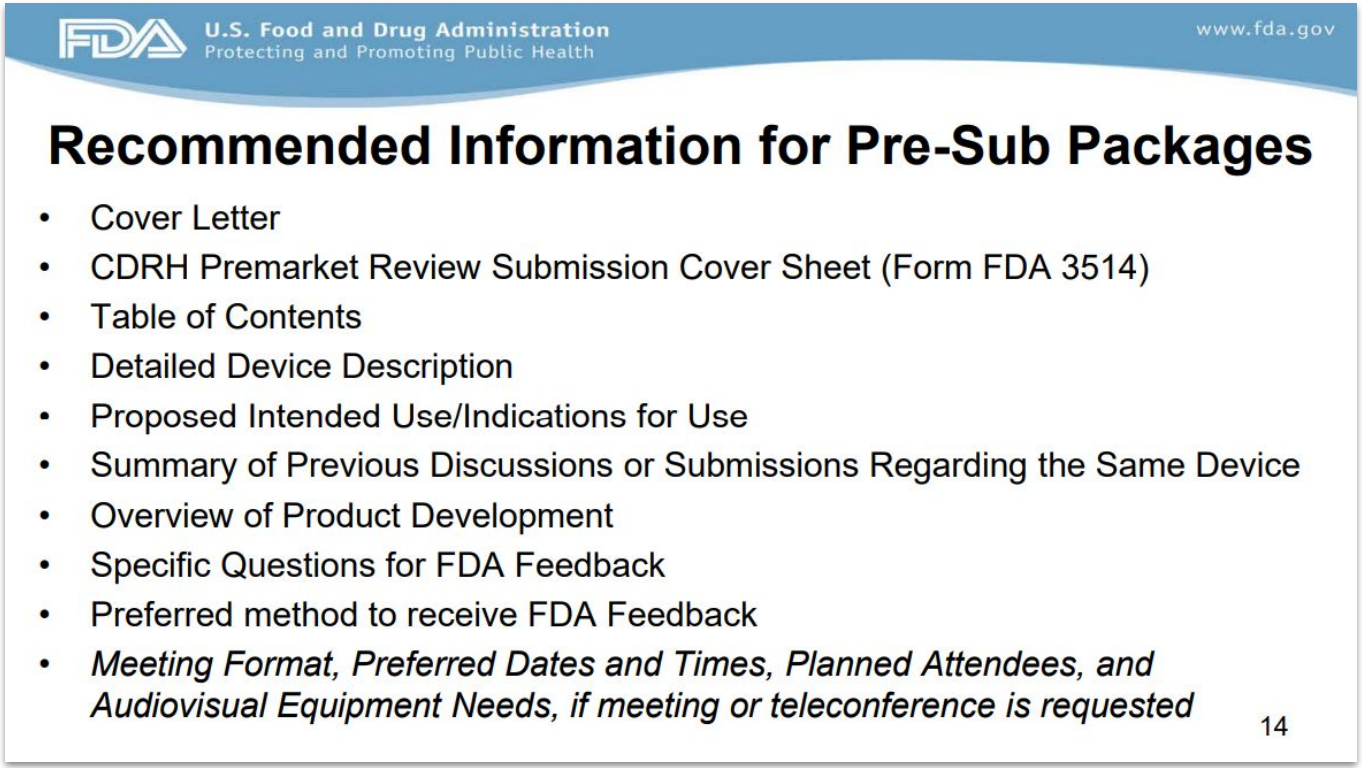
For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs/DRP1: Division of Submission Support at 301-796-5640. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

https://www.fda.gov/media/114034/download

FDA MedTech Pre-submission: What does it contain?



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FDA MedTech Pre-submission: Why does FDA want it?

- → Make the review process on faster
- → Learn about your device - many new devices are novel
- → Provide feedback to manufacturer's early in the process
- → Provide guidance on required DV&V testing to ensure safe and effective devices

The program is entirely voluntary on the part of the submitter. However, early interaction with FDA on planned non-clinical and clinical studies and careful consideration of FDA's feedback may improve the quality of subsequent submissions, shorten total review times, and facilitate the development process for new devices. FDA believes that interactions provided within Pre-Subs are likely to contribute to a more efficient and transparent review process for FDA and the submitter. Our staff develops feedback for Pre-Subs by considering multiple scientific and regulatory approaches consistent with least burdensome requirements and principles[7], to streamline regulatory processes. FDA has found that feedback is most effective when requested prior to execution of planned testing. Issues raised by FDA in a Pre-Sub do not obligate

https://www.fda.gov/media/114034/download

FDA MedTech Pre-submission: Why should you do it?

- → Significantly de-risks your regulatory strategy
- → The “handshake” with the FDA
- → Get to the market faster - less risk of rejection
- → Clear pathway for DV&V, including any clinical testing
- → Fundraising: de-risking for investors

FDA MedTech Pre-submission: When should you do it?

are likely to contribute to a more efficient and transparent review process for FDA and the submitter. Our staff develops feedback for Pre-Subs by considering multiple scientific and regulatory approaches consistent with least burdensome requirements and principles[7], to streamline regulatory processes. FDA has found that feedback is most effective when requested prior to execution of planned testing. Issues raised by FDA in a Pre-Sub do not obligate

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FDA MedTech Pre-submission: When should you do it?

When you have:

- → A solid understanding of the design and how your device will be operating
- → Decided on intended use and indications for use
- → An assessment of device class
- → An assessment of pathway to market (510k, De Novo, PMA etc.) and any predicates
- → An approach to how you will be testing your device (DV&V)

FDA MedTech Pre-submission: How to do it?

- → Ensure you have someone very experienced by your side - Rook support
- → The words you are using are crucial - can be a risk if you say the wrong thing
- → Don’t ask open-ended questions - provide your thinking and let FDA respond
- → Provide information to easily understand your device - the FDA may never have seen it before

FDA MedTech Pre-submission: In summary

- → Don’t see this just “optional” - make sure you do it
- → Drastically de-risk your path to market
- → Provide confidence in your device testing plan
- → Promote marketing submission success (510k etc.)
- → Fundraising: de-risked for investors

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QuickVault: A Modern Tool for Submission Success

Q/A

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