

# QUICK GUIDE: FDA PRE-SUBMISSION PROCESS

## Abstract

The pre-submission process is a valuable opportunity for medical device developers to engage with the FDA early in the product development cycle. This process allows for feedback on development plans, testing protocols, and clinical trial designs, helping streamline regulatory approval. While non-binding, the FDA's guidance can reduce unnecessary studies and increase the likelihood of successful submissions.

Authors: Srilekha Deka, MD, PhD; Jaspreet Seth, PhD  
sdeka@scriptmolecular.com; jaspreetseth@qura.solutions



## Quick Guide to FDA Pre-Submission Process

### Introduction

When you're developing a molecular diagnostic product, the journey begins with a concept. Turning that idea into a marketable diagnostic product involves several coordinated steps, and it's crucial to work within the guidelines set by regulatory agencies like the FDA. One of the key steps early in this process is engaging with the FDA through a well-planned pre-submission. This step is vital because it allows you to request feedback from the FDA on your product development and regulatory submission strategy.

### Why Pre-Submission Matters

The pre-submission process is an opportunity to initiate direct communications with the FDA. It allows you to discuss your device's development plans, testing protocols, and clinical trial designs. Through this interaction, you can receive valuable guidance on regulatory requirements, the type of data you'll need to submit, and any potential issues with your proposed device. This early alignment can streamline the design and execution of the necessary studies and increase the likelihood of successful regulatory approval.

### Classification of Medical Devices

Before diving into the pre-submission, it's important to understand how the FDA classifies medical devices, including in vitro diagnostic (IVD) products. Devices are categorized based on their intended use and the level of risk they pose to patients:

- **Class I:** Low-risk devices, subject to the least regulatory control.
- **Class II:** Moderate-risk devices, requiring more regulatory oversight.
- **Class III:** High-risk devices, subject to the most stringent regulatory controls.

For combination products (those that include drugs, devices, and/or biologics), a different regulatory pathway is required, based on the primary mode of action of the product.

### The Pre-Submission Process

The pre-submission process involves submitting a formal written request to the FDA, seeking feedback on your product development plans. Here's how it works:

#### 1. Prepare Your Pre-Submission Package:

- Start with a cover letter explaining the purpose of your request.
- Include a description of the medical device, its intended use, and a summary of your product development plan.
- If you've communicated with the FDA about this device before, include a summary of those discussions.

## **2. Submit to the FDA:**

- Once submitted, the FDA may respond with written feedback or arrange a teleconference to discuss your submission in detail.
- The feedback provided can guide you in refining your development strategy, ensuring your study designs and protocols align with FDA expectations.

## **3. Use the Feedback:**

- Although the FDA's feedback during this process is non-binding, it's incredibly valuable. It can help you identify and address potential issues early, saving time and resources in the long run.

## **4. Advantages of Pre-Submission:**

- For novel devices or those with complex development plans, the pre-submission process can be particularly helpful.
- It allows the FDA to become familiar with your technology, helping to define the key information needed for approval.
- Engaging with the FDA early can reduce unnecessary studies and focus your efforts on what is essential for the regulatory review process.

## **Summary**

The pre-submission process is a voluntary but highly beneficial step in the development of medical devices. By aligning with the FDA early, you can streamline your product development, reduce costs, and increase the likelihood of regulatory approval. Remember, the recommendations made by the FDA during this process are not binding, but they provide a solid foundation to guide your development efforts and future submissions.

This document is designed to help you navigate the pre-submission process with confidence, ensuring that your product development aligns with FDA expectations and sets you on the path to successful regulatory submission.

## **Our Expertise**

### **Enabling you Transition RUO Products to FDA Approved**

At QuRA Solutions, we specialize in providing comprehensive solutions for companies looking to transition their research-use-only (RUO) products to FDA-approved products. Our team of experts brings together decades of experience in regulatory affairs, quality management, and strategic marketing, ensuring a seamless journey from concept to market. Discover how our expertise can drive your product's success.

### **Our Team**

Jaspreet Seth, PhD, Srileka Deka, PhD, MD, Krishnan Allampallam, PhD, MBA

### **Our Services**

#### **Regulatory Strategy and Submission**

We guide you through the complex regulatory landscape, ensuring your product meets all necessary requirements for FDA approval.

#### **Quality Management Systems**

Implementation and management of robust quality systems, including ISO 13485 and cGMP compliance, CAPA processes, and internal audits.

#### **Product Development and Validation**

From initial concept to final product, we assist in developing, validating, and documenting your product to meet regulatory and market standards.

#### **Clinical and Regulatory Compliance**

We provide comprehensive support for clinical trials, regulatory submissions, and interactions with Institutional Review Boards and Scientific Review Committees.

#### **Market Entry and Commercialization**

Our strategic marketing expertise ensures a successful market entry, leveraging global marketing strategies and go-to-market plans tailored to your product.

### **Why Choose Us?**

Combining decades of experience in regulatory affairs, quality management, and strategic marketing, our team offers unparalleled expertise and support. We understand the challenges of transitioning RUO products to FDA-approved products and are dedicated to guiding you through every step of the process, ensuring your success in the market.

Partner with us to transform your innovative ideas into market-ready products. Contact us today to learn more about how we can support your journey from research to regulatory approval

### **Contact information**

Script Molecular, 4198 Rennellwood Way, Pleasanton, CA 94566

Email: [sdeka@scriptmolecular.com](mailto:sdeka@scriptmolecular.com)

QuRA Solutions 9808 Juniper Hill Road, Rockville, Maryland 20850, US

Email: [jaspreetseth@qura.solutions](mailto:jaspreetseth@qura.solutions) Phone: (240) 793 3660