OFFICE OF REGULATORY SERVICES

REGULATORY STRATEGY: WE PROVIDE EXPERTISE AND INSIGHT TO HELP YOU INITIATE THE RIGHT PATH FOR YOUR MEDICAL DEVICE.

Strategy Plans and Business Development to identify objectives in the research, development, and marketing of a medical device. We help you understand what steps to take in order to move your medical device to market–How does the regulatory process work? What challenges might arise? What are the best practices when submitting an application? How can you best navigate the process?

Determine U.S. Food & Drug Administration (FDA) Oversight for your medical device. With deep knowledge of the various offices and divisions within the agency, we can help you determine a high-level strategy for moving your device to the U.S. marketplace.

Identify Pathways for your medical device. If you are working with the FDA for the first time–whether you are new to the medical device world or new to the U.S. regulatory process–we can help determine the appropriate pathway for your device or drug-device combination product (e.g., Pre-Market Approval, 510K, DeNovo, or Humanitarian Device Exemption).

Contacting the FDA. We take the guesswork out of whom to contact at the FDA, helping you establish contact with the right people to answer your questions and facilitate the process.

EARLY FEASIBILITY STUDIES & RISK ANALYSIS: LET US ASSESS THE EARLY FEASIBILITY OF INITIATING A DEVICE STUDY IN THE U.S. AND HELP DE-RISK YOUR PRODUCT TO ACCELERATE IT ALONG THE PATHWAY.

Risk Assessment for novel technologies and the identification of challenges as well as potential paths forward in bringing a medical device to market. We assess the uncertainty you may face when moving from idea to reality via a clinical study and help to identify solutions to mitigate those risks and facilitate regulatory engagement.

Evaluation of FDA Strategies and Proposed Submissions. We will evaluate your strategy for submitting to the FDA, as well as your submission, while considering the type of device technology and your stage or status in the submission process.

Substantive Review of Submissions. Let us review what you have submitted to the FDA, to help you anticipate regulatory feedback and potential challenges.

Summary of Challenges and Recommended Solutions. In addition to identifying potential challenges with bringing your ideas to reality, we propose solutions that enable a path forward. We can identify potential solutions and provide you with trusted partners along the way.

"Early engagement with the FDA can help gain a better understanding of the regulatory landscape and requirements to get your medical product to the marketplace and, ultimately, to patients.

The best first step is to include initiating contact with the FDA early. If you think it's too early to contact the FDA, that's the best time to contact the agency."

–Dr. Carlos Peña, Jacobs Institute Chief Regulatory Officer

PREPARING SUBMISSIONS FOR THE FDA: WE CAN EASE THE BURDEN OF THE REGULATORY SUBMISSION PROCESS AND PUT YOU ON A SOLID PATH.

Review, edit, and assist in preparing your documents to streamline the FDA application process and increase the probability of success in reaching the U.S. marketplace.

FDA Documentation Preparation and Submission to FDA and supporting agency engagement over the total product life cycle of the medical device. We can focus your engagement with the FDA, whether we assist in pre-submission or in helping prepare your final submission.

Outline Submission. We can help build an outline for your submission and assist with the development of your regulatory strategy.

Submit to FDA. If you haven't submitted to the FDA before, we can help every step of the way, introduce you to the process, identify the appropriate contacts, and support your idea to reality.

IN-HOUSE EXPERTISE:

The Office of Regulatory Services is led by our Chief Regulatory Officer, **Dr. Carlos Peña, former Director of the Office of Neurological and Physical Medicine Devices, at the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration (FDA).** Before his FDA Director role, Carlos served as Assistant Director of Emerging Technologies in the White House Office of Science & Technology Policy (OSTP) in the Executive Office of the President. He looks forward to sharing his expertise and helping advance life-saving neuro and physical medicine technologies to get them to patients sooner.

Please let us know if you are interested in engaging with the JI on any of the above listed services by contacting: ORS@jacobsinstitute.org.

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