KHI
KIDNEY HEALTH INITIATIVE

A Guide to Regulatory Resources for the Product Developer

Recognizing the need for continuous innovative advancements in the treatment of kidney diseases, the Kidney Health Initiative (KHI) was created in September 2012. KHI is a public-private partnership between the American Society for Nephrology (ASN) and the U.S. Food and Drug Administration (FDA) focused on promoting development of safe and effective therapies for kidney disease. KHI leadership established an initiative on Developing a Roadmap for Innovative Approaches to Renal Replacement Therapy (RRT) to foster a new, multidisciplinary approach to advancing solutions that can improve the lives of millions of kidney patients with end stage renal disease (ESRD).

In October 2018, KHI issued the **Technology Roadmap for Innovative Approaches to Renal Replacement Therapy** which outlines the desired future state of improved patient quality of life that innovative RRT solutions aim to achieve. The Roadmap also laid out the technical and market challenges that must be overcome, the overarching solution strategies, and the high-priority research activities with the greatest potential to focus the efforts of the industry and drive the field forward.

Efforts to guide a clearer pathway to product development and commercialization should facilitate more widespread availability, adoption, and patient access to innovative RRT solutions. The roadmap included supporting activities to facilitate the coordinated effort between regulators and the nephrology community in order to streamline product development throughout its life cycle.

The goal of this resource guide is to increase the awareness and understanding of:

- FDA Centers and the products they review; and
- communication mechanisms that enable developers to obtain advice from the FDA; and
- available programs intended to facilitate development and review of eligible RRT products.

The information below is simplified and intended to provide a basis for engaging with FDA for further discussions. It should not be used to make a final decision about the regulatory status, classification and/or pathway.

For additional information, please refer to:

- FDA Website
- Laws that are enforced by the FDA
- Code of Federal Regulations

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RRT
ROADMAP

Is my proposed product regulated by FDA? If yes, which FDA Center will review it?	Where to Start with the FDA
If my proposed product is a medical device, how will it be classified?	Overview of Device Regulation How to Study and Market your Medical Device
If my proposed product is a combination product (e.g., drug-device, biologic-device), which FDA Center will be assigned primary jurisdiction for pre-market review and regulation?	Combination Product Definition and Combination Product Types Frequently Asked Questions about Combination Products

	Devices	Biologics	Drugs
Links to contact FDA Centers	CDRH	CBER	CDER
How can I discuss the proposed product's development plan with the FDA?	Pre-Submission Program	INTERACT (CBER) Pre-IND Meeting	Pre-IND Meeting
Information for investigational clinical trials	Investigational Device Exemption (IDE) Process	Information on Submitting an Investigational New Drug Application (CBER)	Investigational New Drug (IND) Application
Information for marketing authorization	Premarket Notification-510(k) Premarket Approval Application (PMA) De Novo Designation Process Humanitarian Device Exemption (HDE)	Biologics License Application (BLA) Process Therapeutic Biologics Applications (BLA)	New Drug Application (NDA) Guidance for New Drug Applications
What programs are available for to facilitate development and expedite review?	Breakthrough Devices Program	Expedited Programs for Serious Conditions – Drugs and Biologics Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review Expedited Programs for Regenerative Medicine Therapies for Serious Conditions	Expedited Programs for Serious Conditions – Drugs and Biologics Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review What Happens Post-Designation?