



U.S. Agent for Foreign Companies



Corporate Office
400 Fifth Avenue, Suite #115, Waltham, MA 02451
Tel. 781.672.4200
Email: info@globalregulatorypartners.com
Website: www.globalregulatorypartners.com

GLOBAL
REGULATORY PARTNERS

Why do you need a U.S. Agent?

The FDA requires any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device imported into the United States to identify and appoint a United States agent (U.S. agent) for that establishment.

The U.S. agent must either reside in the U.S. or maintain a place of business in the U.S., cannot use a post office box as an address or an answering service. He must be available to answer the phone or have an employee available to answer the phone during normal business hours.

The information about a foreign establishment's U.S. agent is submitted electronically using the FURLS system and is part of the establishment registration process.



Global Regulatory Partners is licensed to be your US Agent and can handle all of the FDA responsibilities and compliance activities on your behalf in the U.S. Market.

What are the Responsibilities of a U.S. Agent?

1. Assist FDA in communications with the foreign manufacturer/establishment.
2. Respond to questions concerning the foreign establishment's devices that are imported or offered for import into the United States.
3. Assist FDA in scheduling inspections of the foreign establishment.
4. Be FDA main contact point, when the Agency needs to send information or documents to foreign company.

FDA Establishment Registration

FDA requires the following categories of foreign establishments to register with FDA prior doing business in the US:

- Primary Manufacturers
- Contract Manufacturers and Remanufacturers
- Contract Sterilizers
- Specification Developers/Reprocessors of single use devices.

Need help with Establishment Registration and Medical Device Listing?

Global Regulatory Partners helps medical devices companies register their establishment and list their medical devices with FDA. To learn more about the process, check out our white paper on this subject or Contact Us today!

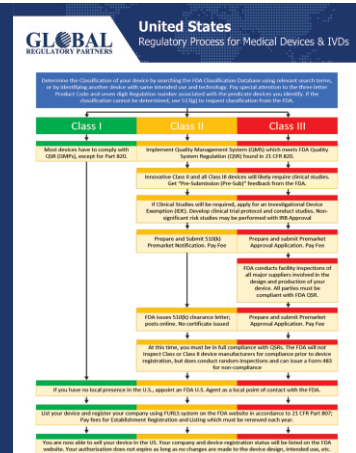


Need help with medical device & IVD registration in the US?

Global Regulatory Partners helps medical devices companies register their products with the FDA and access U.S. market by providing the following services:

- Medical Device Classification
- Pre-Submission meetings with the FDA
- Medical Device Registration
- FDA 21 CFR Part 820 - Quality Management System

For detailed information, check out our white paper on Medical Device Registration Process in US today!



Corporate Office

400 Fifth Avenue, Suite #115, Waltham, MA 02451
Tel. 781.672.4200
Email: info@globalregulatorypartners.com
Website: www.globalregulatorypartners.com