

# Mastering FDA Compliance:

A Freight Forwarder's Guide To  
Hassle-Free Medical Device  
Imports



# Avoid Costly Delays and FDA Holds

Did you know that FDA import detentions increased by 22% last year, costing businesses millions in delays, storage fees, and lost revenue?

For medical device importers, even a minor compliance misstep—such as incorrect documentation or an improper product classification—can cause weeks of delays, additional inspections, or even rejected shipments.

The key to avoiding these costly disruptions? Partnering with a freight forwarder that specializes in FDA compliance and regulatory logistics.

At Dedola Global Logistics (DGL), we ensure your shipments meet all FDA requirements before they ever reach U.S. shores—so you can focus on delivering products on time, avoiding fines, and keeping your supply chain running smoothly.



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# How Freight Forwarders Ensure Compliance & Prevent Delays

## 1. Ensure FDA Compliance Before Shipment

Proactive compliance management prevents costly surprises at the border. Before a shipment leaves the origin country, DGL verifies:

- **FDA Facility Registration** – Confirming that all manufacturers and suppliers are properly registered and up to date.
- **Product Compliance** – Ensuring devices meet FDA regulations for labeling, packaging, and classification.
- **Accurate Product Classification** – Assigning the correct FDA Product Code and HTS Code to prevent import issues.



### How This Helps

Identifying and correcting compliance gaps before shipment reduces clearance delays and regulatory holds.

## 2. Manage Required Documentation

Proper documentation is essential for seamless customs clearance. DGL ensures:

### Complete & Accurate Paperwork – Including:

- **Commercial Invoice (detailed product descriptions)**
- **Packing List (quantities and packaging details)**
- **FDA-Specific Compliance Documents (if required)**

Prior Notice Submission (if applicable) – Filed accurately and on time to prevent automatic shipment holds.



### How This Helps

Ensuring complete and correct documentation eliminates one of the most common causes of shipment delays.



### 3. Coordinate with U.S. Customs & FDA

Once a shipment arrives, close coordination with regulatory agencies ensures smooth entry. DGL:

- **Monitors for Potential FDA Holds or Examinations** – Identifies risks early and takes steps to mitigate delays.
- **Facilitates Customs Clearance** – Works directly with Customs and Border Protection (CBP) to ensure compliance.
- **Provides Immediate Response to FDA Inquiries** – Quickly resolves requests for additional documentation or inspections.



#### How This Helps

Active management of FDA and CBP interactions reduces clearance times and prevents costly storage fees.

### 4. Provide Real-Time Shipment Visibility

Transparency is key when importing FDA-regulated products. DGL offers:

- **Live Shipment Tracking** – Full visibility into clearance status.
- **Immediate Alerts for Customs Holds** – Enabling quick action to prevent extended delays.
- **Proactive Issue Resolution** – Providing alternative solutions when shipments face detentions



#### How This Helps

Real-time updates allow importers to stay ahead of potential disruptions and regulatory challenges.

# Real-world example:

## How a medical device importer reduced FDA holds by 85%

A medical device importer was experiencing repeated FDA holds due to improper product classification and inconsistent documentation. These delays led to increased costs, missed delivery deadlines, and strained relationships with distributors.



### How Dedola helped?

- ✓ Conducted a pre-shipment compliance audit to ensure FDA facility registration was up to date.
- ✓ Reclassified products with the correct FDA Product Code and HTS Code, reducing regulatory red flags.
- ✓ Implemented real-time tracking and proactive customs coordination, resolving potential issues before they caused delays.

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## The result?

FDA clearance time improved by

**85%**

**0** rejected shipments in the next 12 months

The importer saved

**thousands**

in storage fees and late penalties

# What to Look for in a Freight Forwarder for FDA-Regulated Imports

Not all freight forwarders have the expertise to navigate FDA compliance. Importers should look for a logistics partner with:

- **FDA Compliance Knowledge** – Experience in handling FDA-regulated medical device imports.
- **Regulatory Pre-Screening** – Ensures documentation and compliance requirements are met before shipping.
- **Customs & FDA Coordination** – Works directly with CBP and FDA to minimize delays.
- **Real-Time Tracking & Reporting** – Provides full shipment visibility and immediate updates.
- **Proactive Problem-Solving** – Quickly resolves compliance issues to keep supply chains moving.

## Why Choose Dedola?

Unlike general freight forwarders, DGL specializes in FDA compliance and offers tailored solutions for medical device importers, ensuring smooth, compliant, and efficient shipments.

## Secure FDA-Compliant Imports with the Right Logistics Partner

Importing FDA-regulated goods requires precision, planning, and the right logistics partner. A freight forwarder with deep regulatory expertise doesn't just move cargo - they ensure compliance, minimize risks, and prevent costly delays.

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# Talk to an expert

## US Headquarters

[sales@dedola.com](mailto:sales@dedola.com)

Local:

**+1 562-594-8988**

Toll Free Sales #:

**800-516-0399**

6101 Ball Rd, Suite 308  
Cypress, California 90630

## China Headquarters

[dglshanghai@dedola.com](mailto:dglshanghai@dedola.com)

Local:

**011-86-21-6253 8526**

Rm 1403 A, Xin Cheng Mansion 167  
JiangNing Road, Jingan District  
Shanghai 200041