



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**.

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.

A photograph of a long, illuminated yellow sign with black text that reads 'U.S. Customs and Border Protection'. To the right of the text is a small icon of a person at a computer and a white circle with a black arrow pointing right. The sign is mounted on a dark wall.

U.S. Customs and Border Protection

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 DGL 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.



The result?

- FDA clearance time improved by 85%
- Zero rejected shipments in the next 12 months
- The importer saved thousands in storage fees and late penalties

With the right freight forwarder, avoiding costly delays and ensuring compliance is possible.

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 DGL?

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**.



