



Regulatory
services



LUMBAR HEALTHTECH PVT LTD

GLOBAL REGULATORY CONSULTING SERVICES

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Presented By
LUMBAR HEALTHTECH



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Company Profile

Introduction — Lumbar Healthtech Pvt Ltd

Lumbar Healthtech Pvt Ltd is a regulatory consulting firm based in Perumbakkam, Chennai, India, providing regulatory support for medical device manufacturers seeking market authorization in global markets.

The company assists clients in obtaining regulatory approvals from authorities such as the **Central Drugs Standard Control Organization (CDSCO)** in India, the **U.S. Food and Drug Administration (US FDA)** in the United States, CE compliance under the **European Medical Device Regulation (MDR)**, and Brazil's **Agência Nacional de Vigilância Sanitária (ANVISA)**.

Lumbar Healthtech provides services including regulatory strategy, device classification, technical documentation preparation, regulatory submissions, and compliance support, helping companies achieve efficient market entry while meeting international regulatory standards.

Overview of Regulatory Consulting Services

Regulatory consulting services assist medical device manufacturers in obtaining regulatory approvals and ensuring compliance with international regulations. These services include device classification, regulatory strategy, preparation of technical documentation, and submission to regulatory authorities.

Consultants support regulatory processes for agencies such as the **Central Drugs Standard Control Organization (CDSCO)** in India, the **U.S. Food and Drug Administration (US FDA)** in the United States, CE Marking under the **European Medical Device Regulation (MDR)**, and Brazil's **Agência Nacional de Vigilância Sanitária (ANVISA)**.

These services help companies achieve faster approvals, maintain regulatory compliance, and successfully enter global medical device markets.

Company Focus

Lumbar Healthtech Pvt Ltd provides regulatory consulting services focused on **medical devices, pharmaceuticals (drugs), and cosmetics**.

For **medical devices**, the company supports regulatory approvals and compliance in international markets including the **Central Drugs Standard Control Organization (CDSCO)** in India, the **U.S. Food and Drug Administration (US FDA)** in the United States, CE compliance under the **European Medical Device Regulation (MDR)**, and Brazil's **Agência Nacional de Vigilância Sanitária (ANVISA)**.

For **pharmaceuticals (drugs) and cosmetics**, regulatory consulting services are provided primarily for approvals and compliance with the **Central Drugs Standard Control Organization (CDSCO)** in India.

About Lumbar Healthtech

Lumbar Healthtech Pvt. Ltd. is a professional regulatory consultancy specializing in **medical device and in-vitro diagnostic (IVD) regulatory compliance** in India.

Lumbar Healthtech Pvt. Ltd. was established in March 2021 with the objective of providing professional regulatory consulting services for the medical device and healthcare industry in India.

Since its inception, the company has focused on supporting medical device manufacturers, importers, and distributors in navigating the complex regulatory framework under the Medical Device Rules (MDR) 2017 governed by the Central Drugs Standard Control Organization (CDSCO).

We assist **medical device manufacturers, importers, distributors, and healthcare startups** in obtaining regulatory approvals from Indian authorities and expanding their presence in the healthcare market.

Our expertise covers **CDSCO medical device registration, regulatory documentation preparation, import licensing, and international regulatory consulting.**

With deep knowledge of the **Medical Device Rules (MDR) 2017**, we provide complete support from **regulatory strategy to license approval.**

Vision & Mission

Vision

To become a trusted global regulatory consulting partner that supports medical device, pharmaceutical, and cosmetic companies in achieving regulatory compliance and successful market access across international markets.

Mission

To provide reliable and efficient regulatory consulting services by guiding manufacturers through regulatory requirements, preparing compliant documentation, and supporting approvals with authorities such as the **Central Drugs Standard Control Organization (CDSCO)**, the **U.S. Food and Drug Administration (US FDA)**, CE regulatory frameworks under the **European Medical Device Regulation (MDR)**, and Brazil's **Agência Nacional de Vigilância Sanitária (ANVISA)**, enabling safe and compliant access to global healthcare markets.



Our Regulatory Services

Lumbar Healthtech Pvt Ltd provides comprehensive regulatory consulting services to support product approval and compliance in multiple regulatory markets.

Medical Device Regulatory Services

✓ India – Central Drugs Standard Control Organization (CDSCO)

- Import License Application – MD-14 / MD-15
- Manufacturing License – MD-5 / MD-9
- Loan License
- Test License
- Device Classification
- Regulatory documentation preparation
- Online submission through CDSCO SUGAM portal

✓ Authorized Indian Agent Services

We provide **Authorized Agent representation in India** for foreign manufacturers entering the Indian market.

Services include:

- Authorized Indian Agent support
- Importer coordination
- Regulatory liaison with CDSCO
- Compliance management

✓ Regulatory Documentation Preparation

Preparation of regulatory dossiers including:

- Device Master File (DMF)
- Plant Master File (PMF)
- Free Sale Certificate documentation
- Risk Management Files
- Labeling compliance documentation
- Technical documentation

✓ Global Regulatory Consulting

Support for international regulatory approvals including:

- ANVISA Registration (Brazil)
- INMETRO Certification (Brazil)
- Regulatory strategy for global markets
- Market entry advisory

✓ Medical Device Market Entry Support

For international manufacturers entering India:

- Regulatory pathway assessment & Licensing roadmap
- Device classification under CDSCO & Compliance guidance

Global Regulatory Markets (CDSCO / USFDA / CE / ANVISA)

- ✓ **India – Central Drugs Standard Control Organization (CDSCO)**
 - **Medical device**
 - Import License Application – **MD-14 / MD-15**
 - Manufacturing License – **MD-5 / MD-9**
 - Loan License
 - Test License
 - Device Classification
 - Regulatory documentation preparation
 - Online submission through CDSCO SUGAM portal
 - **Drugs and Cosmetics (India)**
 - Import Registration
 - Manufacturing License
 - Product Approval and Regulatory Compliance under **Central Drugs Standard Control Organization (CDSCO)**.
- ✓ **United States – U.S. Food and Drug Administration (US FDA)**
 - Establishment Registration
 - Device Listing
 - 510(k) Premarket Notification
 - Regulatory Compliance Support
- ✓ **Europe – CE Compliance under European Medical Device Regulation (MDR)**
 - Technical Documentation Preparation
 - Clinical Evaluation Report (CER)
 - Risk Management Documentation
 - CE Marking Regulatory Support
- ✓ **Brazil – Agência Nacional de Vigilância Sanitária (ANVISA)**
 - Device Registration & Notification
 - Brazilian Regulatory Documentation
 - Market Authorization Support

Medical Device Expertise

Lumbar Healthtech Pvt Ltd provides specialized regulatory expertise for medical devices, supporting manufacturers through regulatory approval processes and compliance requirements in global markets.

The company offers professional guidance in device classification, regulatory pathway identification, technical documentation preparation, and regulatory submissions. Lumbar Healthtech assists clients in meeting regulatory requirements of authorities such as the **Central Drugs Standard Control Organization (CDSCO)** in India, the **U.S. Food and Drug Administration (US FDA)** in the United States, CE compliance under the **European Medical Device Regulation (MDR)**, and approvals through **Agência Nacional de Vigilância Sanitária (ANVISA)** in Brazil.

With knowledge of international regulatory frameworks and evolving compliance standards, Lumbar Healthtech supports medical device companies in achieving regulatory approvals efficiently while ensuring product safety and compliance.

Our Process

Lumbar Healthtech Pvt Ltd follows a structured regulatory process to support efficient product approval and compliance.

Regulatory Assessment

Evaluation of product classification and applicable regulatory requirements.

Regulatory Strategy

Identification of the appropriate regulatory pathway for submission to authorities such as the Central Drugs Standard Control Organization (CDSCO), U.S. Food and Drug Administration (US FDA), CE compliance under the European Medical Device Regulation (MDR), and Brazil's Agência Nacional de Vigilância Sanitária (ANVISA).

Documentation Preparation

Preparation of technical documentation and regulatory dossiers.

Submission & Approval Support

Regulatory submission management and communication with regulatory authorities until approval.

Our Clients

Lumbar Healthtech has supported regulatory and compliance processes for various medical device companies and healthcare product suppliers.

Client / Company	Products Supported
Everest Medical Technologies Private Limited	DYNEELAX and Spine Implants/Instruments
	Rigid Endoscope
	Endoscopic Camera
Cube Dental Equipments	Dental Units
D.P. New Life Healthcare Private Limited	Aqua Wipes Originals Baby Wipes, Aqua Wipes Essentials Baby Wipes
Globus Medical (I) Pvt. Ltd	Spine Implants
	Spine Instruments
Thermo Fisher Scientific India Private Limited	Gloves
Hytek Arogyacare Private Limited	Focile Aspiration Needle
South India Surgical Company Limited (SISCO)	Capsule Endoscopy Systems
Surana Enterprises	Patient Education Models
Chengene Private Limited	Flushing Medium
Inno Metrix Healthcare India	Nebulizer
Star Radiance Medical devices	Tracheal Stent
Jayam Marketing	Ostomy Bag
	Suction Jar
IMA-PG India Pvt Ltd	Dummy Syringe
	Ampoules with Water
Vital Science Industry	DBS Card
Hearsound Technology LLP	Audiometer
	Hearing Aid
Geneshine diagnostics LLP	Liquid Based Cytology (Pap Smear Test) – IVD

OUR CLIENTS



Product Categories Supported

Our regulatory experience covers:

- Orthopaedic Implants
- Endoscopy Systems
- Surgical Instruments
- Diagnostic Devices (IVD)
- Respiratory Devices
- Audiology Equipment
- Hospital Consumables
- Medical Education Models
- Interventional Devices

Why Choose Us

We provides reliable regulatory consulting services with a strong understanding of global regulatory requirements. The company supports medical device manufacturers in achieving efficient regulatory approvals and maintaining compliance with international standards.

With expertise in regulatory pathways for authorities such as the **Central Drugs Standard Control Organization (CDSCO)**, **U.S. Food and Drug Administration (US FDA)**, CE compliance under the **European Medical Device Regulation (MDR)**, and Brazil's **Agência Nacional de Vigilância Sanitária (ANVISA)**, Lumbar Healthtech helps clients navigate complex regulatory systems efficiently.

The company focuses on accurate documentation, regulatory strategy, and dedicated client support to ensure timely approvals and successful market entry.

Contact Us

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