# Manni Sharma

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## Objective

Regulatory Affairs Specialist with 6+ years of experience in pharmaceuticals and medical devices, specializing in regulatory submissions, global regulatory intelligence, technical documentation, and market access. Experienced in CDSCO regulations, ISO 13485, ISO 14971, EU MDR, FDA compliance support, quality systems, and business development. Skilled in regulatory strategy, lifecycle management, client consulting, and cross-functional collaboration to ensure global regulatory compliance.

## Work Experience

**Regulatory Affairs Executive**
CEHTRA
May 2026 - Present

- Lead CDSCO regulatory submissions, import registrations, and lifecycle management
- Develop regulatory strategies, classification assessments and market entry pathways
- Prepare STED, GSPR, CER, technical files, labeling, and regulatory dossiers
- Support ISO 13485, ISO 14971and US EPA compliance activities
- Manage eQMS, CAPAs, SOPs, audits, document control, and cross-functional compliance
- Support AIR registrations and regulatory consulting for global clients
- Drive business development through lead generation, LinkedIn outreach, proposals, market research, and promotional content

**Senior Associate - Global Regulatory Intelligence**
Freyr Solutions
Nov 2022 - Dec 2025

- Monitored regulatory updates across India, China, Taiwan, Hong Kong, Macau, and the USA
- Delivered regulatory intelligence and compliance support for multinational clients including Kenvue, GSK, Sanofi, and Takeda Supported labeling compliance, lifecycle management, regulatory impact assessments, and strategic compliance planning

**Medical Writer**
Meril LifeScience
Dec 2021 - Sept 2022

- Prepared scientific manuscripts, white papers, study reports, literature reviews, and regulatory documentation
- Supported cardiovascular and orthopedic medical device projects
- Conducted literature searches and evidence synthesis
- Collaborated with Regulatory Affairs, Clinical Affairs, and Quality teams

**Medical Content Writer**
Bioayurveda
Apr 2021 - Dec 2021

- Developed healthcare, skincare, and pharmaceutical content
- Conducted scientific and market research
- Prepared product descriptions, articles, blogs, press releases, and training materials
- Collaborated with technical experts to ensure scientific accuracy

**Editorial Representative**
Medcrave Publishing Group

Apr 2018 - Sep 2018

- Managed scientific manuscript submissions
- Coordinated with researchers and authors from the USA and UK
- Edited scientific articles and ensured publication quality
- Supported editorial and peer-review workflows

## Education

**Master in Pharmacy**
Delhi Pharmaceutical Science and Research University

- Graduated with a 81%

**Bachelor in Pharmacy**
Ram-eesh Institute of Vocational and Technical Education

- Graduated with a 76.68%

## Achievements

- Supported regulatory submissions and market access for pharmaceutical and medical device products
- Delivered regulatory intelligence for multinational healthcare organizations
- Developed regulatory strategies for international manufacturers entering the Indian market
- Contributed to scientific publications and medical writing projects in collaboration with clinical and regulatory teams
- Authored and published healthcare-related eBooks

## Core Competencies

Regulatory Affairs, CDSCO, US EPA, FDA Compliance, ISO 13485 & ISO 14971, Product Registration & Market Authorization, Technical Documentation (STED, GSPR, CER, Technical Files), Regulatory Intelligence & Quality Management Systems

## Personal Attributes

Strory telling& Content Creation, Published Author, Stage Performer & Storyteller, Travelling, Public Speaker

## Technical Skills & Regulatory Tools

CDSCO SUGAM, Regulatory Intelligence Platforms, Technical Documentation, Medical Writing, eQMS, Literature Review, Adobe Acrobat Pro

## Languages

- English ( Professional Proficiency)
- Hindi (Native)