KHADIJA AFRIN

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PROFESSIONAL SUMMARY

Regulatory Affairs Associate with 3+ years of hands-on experience in medical device regulatory compliance, specializing in CDSCO submissions, import licensing, post-approval change management, and labeling compliance under Medical Device Rules (MDR) 2017. Experienced in regulatory authority liaison and audit-ready documentation for imported medical devices in India.

CORE REGULATORY COMPETENCIES

- Medical Device Regulatory Affairs (India)
- CDSCO Submissions & Follow-ups
- Medical Device Rules (MDR) 2017
- Import License & Import Compliance
- Post-Approval Change Management
- Labeling Compliance (MDR, BIS, Legal Metrology)
- Regulatory Documentation & management

PROFESSIONAL EXPERIENCE

Regulatory Affairs Associate – MED-EL India Pvt. Ltd., New Delhi
March 2023 – Present

- Prepared and submitted regulatory applications to CDSCO for medical device imports under MDR 2017.
- Managed minor and major post-approval changes and coordinated timely approvals.
- Acted as primary liaison with regulatory authorities and responded to CDSCO queries within timelines.
- Supported import compliance and advised on ETA, BIS, and Legal Metrology requirements.
- Coordinated labeling approvals, prepared and reviewed product labels for regulatory compliance.
- Maintained audit-ready regulatory documentation for inspections and internal reviews.

Healthcare Business Analyst – Entero Healthcare Solutions Pvt. Ltd., Faridabad
Nov 2019 – Dec 2020

- Compiled and maintained clinical and non-clinical drug data including safety, toxicity, and usage information for internal analysis and regulatory reference.
- Managed nationwide drug sales data and prepared analytical and performance reports for senior management.
- Conducted data mapping and integration to ensure consistency and accuracy across multiple data sources.

Research associate intern – i2cure Pvt. Ltd., Gurugram
June 2021 – Dec 2021

- Authored three review articles on Molecular Iodine published in peer-reviewed pharmaceutical journals
- Conducted literature review and scientific writing for pharmaceutical research publications

EDUCATION

- M. Pharma (Pharmacognosy & Phytochemistry), DPSRU (2020–2022)
- PG Diploma in Regulatory Affairs, Jamia Hamdard (2019–2020)
- B. Pharma, Jamia Hamdard (2015–2019)

PROJECTS

- M. Pharma Project: Development and characterization of antifungal polyherbal gel for topical infections.

LANGUAGES

English, Hindi