**VIDUSHI BHARAT DHAKAD**

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**EDUCATION**

**Northeastern University, Boston, MA**

*Master of Science in Regulatory Affairs*

Relevant Coursework - Regulatory Compliance and Practice, Pharmaceutical and Medical Device Law, Legal Issues and FDA

**University of Mumbai, Mumbai, India**

*Bachelor of Pharmacy*

**PROFESSIONAL EXPERIENCE**

**Design Quality Assurance Engineer | Boston Scientific,** Marlborough, United States **Jun 2024- Dec 2024**

* **Collaborated with cross-functional teams** in sustaining engineering and new product development (NPD) to ensure compliance with regulatory and quality system requirements.
* **Applied IEC 60601 standards (60601-1 & 60601-1-2)** in design verification, developing standardized DV report templates to streamline compliance documentation.
* Led **the creation and maintenance of Risk Management Files (RMF)** in accordance with ISO 14971, compiling internal guidance documents to strengthen risk-based decision-making.
* Supported **development of software FMEAs**, contributing to risk mitigation strategies for medical device software in alignment **with IEC 62304.**
* Served as **scribe in usability studies**, capturing study outcomes and ensuring traceability of user needs to design and risk documentation (per IEC 62366).
* **Authored technical reports** for medical device components, providing clear documentation to support regulatory submissions and product lifecycle management.

**Regulatory Affairs Consultant | Lighthouse XR,** Boston, United States **Apr 2024- Jun 2024**

* **Developed a regulatory strategy** for a flagship product, Class II medical device
* Conducted risk-benefit assessments, handled data, and navigated FDA submission and regulatory approval processes

**Regulatory Affairs Consultant | Healthy Design,** Vermont, United States **Jan 2024 - Apr 2024**

* Determined classification and regulatory approval pathway for a Lift Assist Device
* Utilized the knowledge obtained from IP and 510(k) database to find a predicate device to act as a base while determining the classification and regulatory protocol

**QA Intern | Khandelwal Labs**, Mumbai, India **Jun 2022 - Aug 2022**

* Contributed to a 10% increase in production efficiency through effective collaboration with the regulatory affairs team
* Conducted rigorous quality control checks, reviewing packaging documentation and inspecting final finished packages, achieving 99% defect-free rate, reduced stock discrepancies by 25%
* Reviewed SOPs, validation protocols and gained hands-on experience in manufacturing of capsules and lyophilised injectables, while ensuring compliance with cGMP

**SKILL BASED PROJECTS**

**IP Strategy & Regulatory Compliance Project**

* Researched and authored a 20-page analysis on high profile IP disputes
* Evaluated FDA patent and exclusivity frameworks, IND/NDA submission requirements, and international regulatory considerations impacting IP ownership and infringement
* Developed stepwise corporate IP protection strategy addressing risk mitigation, regulatory compliance and future safeguards

**Review article- Article Intelligence in the field of Pharmacy**

* Composed a comprehensive review article on the role of Artificial Intelligence (AI) in medicine, categorizing it into **virtual** (e.g., advanced informatics, deep learning, information management) and **physical** (e.g., assistive robots, nanorobots for TDD) domains.
* Highlighted innovative AI applications such as **intelligent drug delivery systems**, showcasing the potential of nanotechnology-integrated robotics in modern pharmacotherapy.

**Publication- Dhakad, V., Panchal, P., & Aushima, A. (2025). Development of a chocolate-based drug delivery system of Niclosamide. *Journal of Pharmaceutical Innovations*, 14(2), 123–130.**

* Led the development of an innovative medicated chocolate formulation incorporating Niclosamide, aiming to improve patient

compliance through palatable drug delivery.

* Compiled, structured, and maintained comprehensive regulatory documentation, including formulation composition, analytical testing protocols, and safety assessment reports in alignment with standard compliance guidelines.

**SKILLS**

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| **Regulatory Affairs & Compliance** | **Medical Device Standards** | **Quality & Risk Management** | **Technical & Instrumentation** |
| 21 CFR Labeling Requirements | IEC 60601 (Safety & EMC) | Quality System Audits | HPLC, LC-MS/MS, ICP-MS |
| IND & NDA Submissions | IEC 62366 (Usability) | Risk Management Files (RMF) | FTIR, ATR, IR Spectroscopy |
| FDA, EMA & ICH (GMP, GLP) | ISO 14971 (Risk Management) | FMEA (Design & Software) | Spectrophotometer, Viscometer |
| ISO 9000 & ISO 13485 | IEC 62304 (Software) | Validation & Verification | Centrifuge |
| Regulatory Documentation |  |  |  |