Ms. Herkar Radhika Kedar

M.Pharm (Regulatory Affairs)

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Career Objective: Regulatory Affairs professional, M.Pharm (Drug Regulatory Affairs) with a strong foundation in Medical Device Regulations and global regulatory requirements. Knowledge of EU MDR 2017/745, US FDA medical device regulations, 21 CFR Part 820, 21 CFR Part 11, ISO 13485, ISO 14971, ISO 14155, and CDSCO Medical Device Rules 2017. Familiar with technical documentation, eCTD, regulatory submissions, design control, clinical evaluation, and post-market surveillance. Passionate about supporting regulatory compliance, product registration, and market access for medical devices while gaining hands-on experience in a dynamic environment.

Education qualifications(University/Pre-University):

Education	Institution (name, place, university /board)	CGPA/Percentage
Master of Pharmacy	Sanjivani College of Pharmaceutical Education and Research, Kopargaon. (Autonomous)	7.67
Bachelor of Pharmacy	D.S.T.S. Mandal's College of Pharmacy, Solapur (Punyashlok Ahilyadevi Holkar, Solapur University)	7.75
HSC	Maharashtra State Board	84%
SSC	Maharashtra State Board	62%

Internship:

QA/RA Intern | Mediscient Devices Pvt. Ltd.

- Assisted in Quality Assurance and Regulatory Affairs activities for medical devices, gaining practical exposure to regulatory and quality requirements.
- Worked with MDR 2017, ISO 13485, and ISO 14971 requirements and supported regulatory documentation.
- Assisted in preparation, review, and maintenance of Device Master File (DMF), technical documentation, and quality records.

- Gained exposure to medical device classification, risk management, regulatory compliance, and documentation practices.
- Supported day-to-day QA/RA documentation and compliance activities under supervision.

Certification:
Medical Devices and Regulatory Affairs

Publications and Conferences:

- Secured 2nd prize in a National conference on Phytoinformatics in Ethnopharmacology Bridging Traditional Knowledge with Computational Drug Discovery, sponsored by Shivaji University, Kolhapur, in March 2026.
- Participant in a National-level Popular Series And Poster Presentation At Sanjivani College Of Pharmaceutical Education And Research, Kopargaon, in Dec 2025.
- Participant in a National conference on AI-driven design and development of new chemical/biological entities and formulations: Approaches, challenges, and road ahead. Organized by the School of Pharmacy, DRIEMS University in December 2025.
- Participant in a one-day National Level Poster presentation on "Inventions & Innovations in Pharmacy" organized by Lokmangal College of Pharmacy, Wadala, North Solapur, India, held on 18 Feb 2025.

Academic Project:

B. Pharmacy: Development and optimization of IN-SITU RAFT-forming gel containing Vachellia nilotica pod extract with a Quality by Design approach (QbD).

Key Contributions

- Applied QbD principles for formulation development.
- Identified Critical Quality Attributes (CQAs).
- Performed formulation optimization using factorial design.
- Performed stability studies.
- Prepared technical reports and documentation.
- Interpreted experimental data using statistical tools.

M. Pharmacy: Working on a review article: Mechanisms of Nanocarrier-Induced Pulmonary Toxicity: Implications for Inhalable Drug Delivery Systems

Key Areas

- Medical device combination products
- Pulmonary drug delivery
- Nanotechnology
- Biocompatibility
- Toxicological risk assessment
- Regulatory challenges

- Safe-by-Design approaches

Skills:

- **Technical Tools:** MS Office (Excel, PowerPoint, Word, eCTD software)
- **Regulatory Submission:** 510 (k), PMA**,** EU MDR 2017/745**,** CTD, eCTD, IND, NDA, ANDA dossier preparation basics, Technical Documentation, DMF, DHF**.**
- **Regulatory Knowledge:** 21 CFR Part 820, 21 CFR Part 11**,** ISO 13485, ISO 14971, ISO 14155, ISO 11608, ICH, USFDA, WHO, EMA, CDSCO, EU Guidelines.
- **Soft Skills:** Time Management, Teamwork, Conflict Resolution, Communication, attention to detail.

Languages:

English, Hindi, Marathi, Kannada

Hobbies

Drawing, Sketching, Story writing

Declaration:

I, Herkar Radhika Kedar, declare that the above facts and information are correct to the best of my knowledge and belief.