

Shraddha Barange

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SUMMARY

Regulatory Affairs Associate (M.S. Regulatory Affairs, '25) skilled in 510(k), SaMD, and NDA support. Drafted & validated eCTD modules, built Veeva Vault/GlobalSubmit workspaces, and coordinated cross-functional inputs that won FDA clearance in 87 days (vs 120) and cut review cycles 40 %. Known for clean templates, data-driven dashboards, and 95 % first-pass reviews.

SKILLS

Regulatory Skills: Quality Assurance, 510(k) submissions, ICH Guidelines, CAPA, GCP, FDA Premarket Submission, Post Market Surveillance, NDA, BLA, IND Applications, 21 CFR 210&211, GVP, cGMP regulation, eCTD, Regulatory Compliance, ISO 13485, Clinical Trial Protocol, Quality Inspection (Audits), Regulatory Writing, Drug and Medical Device Safety, Global Regulatory Strategy

Technical Skills: Microsoft Office Suite, MedDRA, 21 CFRs, Product Labeling, SOP creation, Compliance Management, Research and Literature Review, Medical Writing, Statistical analysis, Document Management, Crafting Documentation (SOPs, ICF reports), DailyMed, Hypothesis testing

EDUCATION

Northeastern University

Master of Science, Regulatory Affairs (GPA: 3.96)

Boston, MA, USA

09/2023 - 06/2025

SCES Indira College of Pharmacy

Bachelor of Pharmacy (GPA: 3.3)

Pune, India

08/2018 – 07/2022

WORK EXPERIENCE

Tecomet, Inc.

04/2025 – 06/2025

Regulatory Affairs Project Associate

Boston, MA

- Analyzed **MAUDE reports**, internal complaint logs and **TrackWise** deviation data to spot safety trends in FSM and KCT devices, then briefed RA leadership on **FDA** and **EU MDR** implications.
- Drafted and validated a **MasterControl**-hosted **post-market surveillance** plan and report in line with **21 CFR 803/820** and **EU MDR Articles 83–86**, boosting audit readiness and laying groundwork for future **510(k)/PMA** submissions.
- Ran **root-cause investigations** using **5 Whys** and **Ishikawa diagrams** in **TrackWise**, then rolled out corrective actions that cut repeat deviations by **30 %** and lifted first-pass review rates to **95 %**.
- Worked closely with **QA**, **R&D**, **clinical** and **engineering** teams to update **SOPs** and **change-control** procedures based on surveillance findings, improving document accuracy and accelerating review cycles.

Keva Health

07/2024 – 08/2024

Regulatory Affairs Project Coordinator Intern

Boston, MA

- Conducted comprehensive **market research** for innovative **remote patient monitoring (RPM)** devices, analyzing competitive landscape of 15 medical technology products to support **New Product Development** processes and inform regulatory pathway selection.
- Updated company **regulatory documentation** and **SOPs** to reflect latest product offerings and **FDA guidance**, enhancing reporting capabilities for **510(k)** and **De Novo** submission readiness.
- Communicated complex health information clearly across different platforms, supporting **regulatory intelligence** processes and translating technical requirements for cross-functional teams including **engineering** and **clinical** stakeholders.
- Maintained **document control** systems and version management protocols, ensuring compliance with **21 CFR Part 820** requirements and supporting regulatory investigation processes.

Purcell Ltd

04/2024 – 06/2024

Regulatory Affairs Intern

Boston, MA

- Gathered and analyzed technical data from **predicate device** databases and **FDA guidance** documents to ensure compliance with global regulatory requirements for **Class II medical devices**, supporting **510(k)** submission preparation.
- Supported cross-functional teams in implementing **document management** processes for product safety documentation, including **risk management** files per **ISO 14971** and design control records per **21 CFR 820.30**.
- Reviewed scientific data for accuracy and completeness using **quality control** protocols, maintaining meticulous attention to detail for **eCTD** module preparation and **regulatory submission** packages.
- Collaborated with subject matter experts in **QA**, **R&D**, and **clinical** teams to collect comprehensive information for regulatory submissions, coordinating input through **MasterControl** workflows and ensuring **audit trail** integrity.

APIs Atlas LLP

11/2022 – 08/2023

Regulatory Data Analyst

India

- Improved **data quality** for pharmaceutical sales reporting by implementing **data cleansing** techniques and validation protocols aligned with **21 CFR Part 11** requirements, supporting regulatory compliance for **NDA** and **ANDA** submissions.
- Led **quality control** and **data validation** processes for chemical product information using **statistical analysis** tools, ensuring data integrity for **regulatory reporting** and **post-market surveillance** activities.
- Managed multiple **regulatory compliance** projects simultaneously while maintaining **99.5%** accuracy standards, applying **CAPA** methodologies and **risk assessment** protocols to prevent data discrepancies.
- Developed customized client presentations and **regulatory intelligence** reports, demonstrating strong **technical writing** skills and ability to communicate complex regulatory requirements to diverse stakeholders including **QA** and **manufacturing** teams.

- Developed and implemented **SOPs** for chemical stability testing protocols, ensuring **FDA** and **EU** compliance with **ICH Guidelines** and **cGMP** regulations for pharmaceutical manufacturing operations.
- Managed laboratory **documentation** systems and maintained accurate record-keeping of chemical analyses per **21 CFR Part 210/211**, supporting **audit readiness** and regulatory inspection preparation.
- Participated in testing procedures requiring precise chemical analysis and **quality control**, contributing to **batch release** decisions and ensuring product safety for **regulatory submissions**.
- Assisted in reviewing **regulatory requirements** for chemical products across multiple markets including **FDA**, **EMA**, and **Health Canada**, supporting global regulatory strategy development and **market authorization** applications.

PROJECTS

Hemophilia Therapeutic Development Portfolio

FDA Submission • IND/NDA

- Orchestrated an end-to-end regulatory submission package for a hemophilia therapy—drafted Pre-IND strategic plan, led IND application (Form 1571), defined Pre-NDA strategy, prepared NDA/BLA submission (Form 356h), managed promotional compliance (Form 2252), and implemented safety-labeling changes—to demonstrate comprehensive FDA submission expertise and cross-functional coordination.

Multi-Regional eCTD Submission for Fentanyl Citrate

eCTD • Global Harmonization

- Led assembly of electronic Common Technical Document (Modules 1–5) for fentanyl citrate across FDA, EMA and TGA, tailoring regional content and formatting requirements to harmonize global regulatory submissions and accelerate international approvals.

Comprehensive Post-Market Surveillance Program

PMS • ISO 14971 • EU MDR

- Designed and deployed a proactive post-market surveillance framework for Class I/II devices—developing PMS plan/report and integrating ISO 14971 risk management with FDA 21 CFR 803/820/822 and EU MDR Articles 83–86—to strengthen safety monitoring and ensure full compliance.

Medical Device Design Controls & Validation

21 CFR 820.30 • QMS

- Executed the complete design control and validation lifecycle for a Class II device—creating process diagrams, traceability matrix, SOPs, risk management plan, master validation plan and IQ/OQ/PQ protocols in line with 21 CFR 820.30 and FDA guidance—ensuring robust quality system adherence.

Cybersecurity in Robotic-Assisted Surgery

SaMD • FDA Cybersecurity

- Analyzed FDA cybersecurity guidance and conducted risk assessments for robotic-assisted surgical systems, recommending regulatory pathways for SaMD and post-market cybersecurity management strategies to mitigate vulnerabilities in connected devices.

Pharmaceutical IP & Regulatory Strategy

Regulatory Exclusivity • IP Strategy

- Evaluated the interplay between regulatory exclusivity and patent protection in the Moderna vs. Pfizer/BioNTech case—analyzing global harmonization challenges and market dynamics—to inform strategic regulatory and IP decision-making.

Comparative Regulatory Intelligence

FDA vs EMA • Global Strategy

- Conducted a side-by-side analysis of FDA vs. EMA approval pathways—assessing clinical trial requirements, accelerated approval mechanisms, post-approval commitments and mutual recognition agreements—to optimize global submission strategies.