

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. <i>Regulatory Affairs Project Associate</i>	04/2025 – 06/2025 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 <i>Regulatory Affairs Project Coordinator Intern</i>	07/2024 – 08/2024 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 <i>Regulatory Affairs Intern</i>	04/2024 – 06/2024 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 <i>Regulatory Data Analyst</i>	11/2022 – 08/2023 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.