**ALIFIYA PAREKH, MTech, RAC (Devices), RCC-MDR**  
San Francisco Bay Area, CA | (408) 702-5207 | [parekhalifiya@gmail.com](mailto:parekhalifiya@gmail.com)

**SUMMARY**

Results-driven Quality Regulatory Specialist with 5.5+ years of professional experience in FDA/EU submissions (510(k), MDR), technical documentation, and quality compliance for Class II/III medical devices, SaMD, and diagnostics as well as R&D and technical documentation in Biotech industry. Proven track record in authoring GSPR, CERs, PMS, risk management files and IFU, labeling review while ensuring adherence to ISO 13485, 21 CFR 820, and EU MDR/IVDR. Adept at supporting regulatory strategy, gap analyses, and post-market surveillance to drive compliance and accelerate approvals. Strong technical writing, cross-functional collaboration, and detail-oriented skills. RAC (UCSC) and RCC-MDR (RAPS) certified. Authorized to work in the U.S. without sponsorship.

**CORE COMPETENCIES**

* **Regulatory Submissions and Technical Writing:** 510(k), EU MDR Technical documentation, GSPR, IFU and labels, Clinical and post market surveillance, SOPs, Work Instructions, Change control, CAPA, Deviation, Risk management, Design control file and Process validation plan
* **Regulatory Frameworks & Quality Standards:** EU MDR 2017/745, US FDA guidance documents, ISO 13485, 21CFR 820, 21CFR Part 11, ISO 14971, ISO 15223-1, ISO 20417, EU-IVDR, IMDRF, and other ISO/ IEC standards
* **Tools & Databases:** MS Office suite, Adobe Acrobat, Adobe express, Canva, Notion, Veeva, Smartsheet, SharePoint, SAP, Virje, JIRA, Loom, BSI Compliance Navigator, GUDID, EUDAMED, FDA database, e Star Forms, Nyquist AI, IQVIA database, e Lab notebooks, MDCG
* **Languages:** Fluent in English, Hindi, Gujarati, Basic proficiency in Urdu, Arabic, Sanskrit, Marathi

**PROFESSIONAL EXPERIENCE**

**Regulatory Operations Specialist**  
Shockwave Medical *|* Santa Clara, CA, USA | July-Aug 2024

* Contributed to FDA/EU submissions; ensured document compliance and formatting resulting in fully compliant documentation using Microsoft word and Adobe Acrobat
* Conducted weekly regulatory intelligence updates and managed SharePoint revisions resulting in informed regulatory decisions for the entire team
* Reviewed work instructions and flagged errors to be corrected to ensure clarity and correctness

**Regulatory Consultant**  
Antrix Inc. | Sunnyvale, CA, USA | May-July 2024

* Built a regulatory intelligence database covering eight diagnostic categories resulting in faster preparation of submission dossier
* Synthesized 40+ regulatory and testing requirements from FDA, EU, and CLSI sources
* Standardized QSR training materials to ensure quality and accuracy

**Senior Engineer – Quality & Regulatory Affairs**  
Tata Elxsi (Client: Zimmer Biomet) | Pune, India | July 2020–Apr 2021

* Developed EU MDR-compliant technical documentation for Class IIa, IIb, III devices, including SaMD (imaging software)
* Collaborated with team to create gap analyses between EU MDD and EU MDR requirement
* Redlined Instructions for use (IFUs) and labels as per ISO standards
* Authored multiple General Safety &Performance Requirements (GSPR), Clinical evaluation Plan (CEP), Post Market Surveillance plan (PMS) and Periodic safety update Report (PSUR) Trained junior team members on regulatory processes

**Senior Research Associate – Technical Documentation**  
USV Pvt Ltd | Mumbai, India | Jan 2019– Apr 2020

* Authored and managed lab instrument SOPs, SAPs, CAPAs, and GMP compliance records
* Conducted internal trainings, GMP audits, and coordinated lab maintenance with engineers
* Provided streamlined project documentation by creating custom Excel trackers

**Sr. Scientific assistant and Sr. Executive– R&D**   
INTAS Biopharma & Zydus Cadila | Ahmedabad, India | Aug 2015–May 2018

* Led analytical and method development for biosimilars using HPLC, IEF, SDS-PAGE, FTIR, CD, Spectro fluoroscope and ELISA techniques
* Established lab infrastructure and ensured lab documentation with 21 CFR Part 11 compliance
* Managed laboratory equipment’s qualification (IQ, OQ, PQ) and procurement workflows in SAP

**KEY PROJECTS completed as part of RAC CERTIFICATE PROGRAM at UCSC, Silicon Valley, USA**

* Authored 510(k) submission, technical documentation, CEP, CER, PMS Plan and PMS report, and labels for a flexible bronchoscope per EU-MDR
* Developed regulatory strategy for U.S., EU, and Canadian markets, design control file and process validation plan for a digital stethoscope
* Authored FDA Warning letter related to design control deficiencies for a medical device firm and authored Noncompliance findings for another medical device firm

**EDUCATION & CERTIFICATIONS**

**MTech, Biotechnology Engineering** | Vellore Institute of Technology | GPA: 8.51/10

**B.E., Biotechnology Engineering** **|** Gujarat Technological University | GPA: 7.73/10

**RAC - Regulatory Affairs Certificate**| University of California (UCSC) Silicon Valley, USA | 2024 (9 months)

**RCC - MDR Certification** | Regulatory Affairs Professional Society (RAPS), USA | 2025

**PROFESSIONAL AFFILIATIONS & VOLUNTEERING**

**Regulatory Project Management (Sessions’ designer, Technical Presenter, Coordinator, Moderator, Mentor)** Global Remote Study Group | Mar-May 2025

* Designed and led a 7-session study group focused on US, EU and International medical device regulations with 15+ active participants resulting in enhanced understanding of the medical device regulations for the participants.
* Developed and delivered technical content including agendas and quizzes; collaborated with 8+ SMEs
* Provided peer mentoring for transitioning professionals entering MedTech regulatory role

**Panel Speaker**, RAPS SF Chapter, UCSF (Apr 2025): Shared career insights on transitioning into MedTech

**Volunteer**, RAPS SF Chapter (Dec 2024–Present): Member and event registration support

**Member,** California Medical Instrumentation Association- Bay area Chapter