**ALIFIYA PAREKH, MTech, RAC (Devices), RCC-MDR**  
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**SUMMARY**

Curious, driven, and dedicated Biotech Engineer & former R&D Scientist turned MedTech Quality and Regulatory professional, with over 6.5 years of hands-on experience in quality, compliance, and regulatory affairs. Proven expertise in Class II/III medical devices, diagnostics, and Software as a Medical Device (SaMD) (US FDA and EU MDR) as well as R&D and technical documentation across the biologics industry. Authorized to work in the U.S. without current or future sponsorship.

**CORE COMPETENCIES**

* **Regulatory Submissions and Technical Writing:** 510(k), EU-MDR Technical documentation, GSPR, IFU, Labels, Clinical and post market surveillance, SOPs, Work Instructions, Change assessment, CAPA, Deviation, Risk management, Design control file and Process validation plan
* **Regulatory Frameworks & Quality Standards:** EU-MDR, 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, BSI Compliance Navigator, GUDID, EUDAMED, FDA database, e Star Forms, Nyquist AI, IQVIA database, Canva, e Lab notebooks, MDCG
* **Languages:** Fluent in English, Hindi, Gujarati, Basic proficiency in Urdu, Arabic, Sanskrit, Marathi

**PROFESSIONAL EXPERIENCE**

**Regulatory Learning sessions’ Architect (Technical Presenter, Coordinator, Moderator, Mentor)**  
Independent Consultant | 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

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

* Contributed to FDA/EU submissions; ensured document compliance and formatting resulting in clean, structured and compliant documentation
* Conducted weekly regulatory intelligence updates and SharePoint revisions resulting in informed regulatory decisions for the entire team
* Identified and corrected 10+ errors in work instructions

**Regulatory Consultant**   
Antrix Inc. | Sunnyvale, CA, USA | May-Sep 2024 | Project based role

* Built a regulatory intelligence database covering five diagnostics categories resulting in faster preparation of submission dossier
* Synthesized 40+ regulatory 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
* Led gap analyses between EU-MDD and EU- MDR requirement
* Redlined Instructions for use (IFUs) and labels as per ISO standards
* Authored 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 instruments SOPs, SAPs, CAPAs, and GMP compliance records
* Conducted internal trainings, GMP audits and coordinated lab maintenance with engineers
* Streamlined project documentation with 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**

* Authored 510(k) submission for flexible bronchoscope, including substantial equivalence and performance data
* Created design control file and process validation plan for a digital stethoscope
* Developed regulatory strategy for U.S., EU, and Canadian markets for a digital bronchoscope
* Authored CEP, CER, PMS Plan and PSUR, labels, and IFU for an orthopedic implant per EU-MDR
* Authored FDA Warning letter related to design control deficiencies and authored Noncompliance findings for a 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

**Regulatory Affairs Certificate (RAC)**| **University of California (UCSC) Silicon Valley, USA | Apr- Dec 2024**  
Successfully completed 6 courses: Design Control, Process Validation, EU-MDR- Clinical and Post Market surveillance, Quality Management Systems, Global Regulatory Strategy and submissions, Reg Submissions: Device and diagnostics

**RCC-MDR Certification** | **Regulatory Affairs Professional Society (RAPS), USA | Oct- Jan 2025**  
Successfully passed the EU-MDR credentialing exam

**PROFESSIONAL AFFILIATIONS & VOLUNTEERING**

* **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