**ALIFIYA PAREKH, MTech, RAC- Medical devices, RCC-MDR**

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**SUMMARY**

Master of Technology in Biotechnology Engineering with over 5 years of experience in quality compliance and regulatory affairs for medical devices (all classes) and diagnostics, as well as R&D and technical documentation within the biologics industry. Committed to delivering the highest quality of service while prioritizing the safety and effectiveness of medical devices for end users. Open to relocation.

**SKILLS**

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| Category | Details |
| Computer Skills | MS Office, Adobe Acrobat, Canva, Smartsheet, SharePoint, Virje, SAP, Atlassian JIRA, SQL, Electronic Lab Notebooks |
| Tools & Platforms | BSI Compliance Navigator, IQVIA database, and Nyquist, EUDAMED, GMDN, GUDID, FDA database. |
| Writing | 510k, Technical documentation, GSPR, IFU, Labels, Clinical and post market surveillance, SOPs, Work Instructions, Change assessment, CAPA, Deviation. |
| Worked with | 21CFR 820, 21CFR Part 11, ISO 13485, FDA QSR’s, ISO 14971, ISO 15223-1, ISO 20417, ISO 11137 and ISO 11135, FMEA, Design Control Table, EUMDR, EU IVDR |
| Public Speaking | International Toastmasters Club Member – India |
| Languages | Proficient: English, Hindi, Gujarati, Urdu Basic: Arabic, Sanskrit, Marathi |
| Other Skills | Critical Analysis, Methodical Documentation, Visual Communication, Simplification of Complex Concepts, Curiosity and Lifelong Learning, Attention to Detail and Organization |

**PROJECTS**

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| **Projects** | **Description** |
| [**Noncompliance Finding**](https://docs.google.com/presentation/d/1higKgAy4Xv4I02skzdPMe9SXY8Fr2XxI/edit?usp=sharing&ouid=116934547648437151116&rtpof=true&sd=true) | Conducted gap analysis and documented a noncompliance finding for a medical device firm, aligning with regulatory requirements. |
| [**510(k) Submission**](https://drive.google.com/file/d/1soQ3FGSUrH-3yWkW2YEIn6XBuigFSYLb/view?usp=sharing) | Authored a complete 510(k) premarket notification for a flexible bronchoscope, including device description, substantial equivalence, and performance data. |
| [**Design Control File**](https://drive.google.com/file/d/1aIhn8BXeaBi48X0N8IaeKNcbd0QuNPOs/view?usp=sharing) | Created and organized the Design Control File for a digital stethoscope, covering design inputs, outputs, verification, and validation. |
| [**Process Validation Plan**](https://drive.google.com/file/d/1Z9UIShFuOek8sqOjretk1UY5A4_y9Xuq/view?usp=sharing) | Developed a comprehensive process validation plan for the manufacturing of a digital stethoscope. |
| **Orthopedic Implant Documentation** | Prepared technical documentation including the Clinical Evaluation Plan (CEP), Clinical Evaluation Report (CER), Post-Market Surveillance (PMS) Plan and Report, and product labeling for an orthopedic implant. |
| [**Regulatory strategy document**](https://drive.google.com/file/d/19gHxJA2TmtPljxhy6YEdAA1zuCqqj07i/view?usp=sharing) | Prepared regulatory strategy for launching digital bronchoscope to US, EU and Canada |

# **ACHIEVEMENTS & LEADERSHIP**

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| **Role** | **Description** |
| **Organizer, RAC-Devices Global Study Group (March 2025–Present)** | Led 30+ member global study group on US, EU, and global medical device regulations. Developed session agendas, coordinated SMEs, created regulatory quizzes. |
| **Panel Speaker, “Evolving in Regulatory” – RAPS SF Chapter, UCSF (April 2025)** | Shared professional journey and discussed regulatory education gaps for job seekers. |

**CERTIFICATIONS**

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| Category | Institution | Program/Certification | Year | Details |
| Certification | Regulatory Affairs Professionals Society (RAPS) | RCC – MDR Certification | 2025 | Successfully cleared the EU-MDR exam |
| Certificate program | University of California, Santa Cruz – Silicon Valley Extension | Regulatory Affairs Certification (RAC) | 2024 | Successfully completed the credits for the certificate program with the coursework: |

**PROFESSIONAL EXPERIENCE**

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| --- | --- | --- | --- | --- |
| **Position** | **Company** | **Location** | **Year** | **Work Summary** |
| **Regulatory Operations Specialist** | Shockwave Medical (acquired by Johnson & Johnson MedTech) | Santa Clara, CA | 2024 | • Supported US and EU regulatory submissions by formatting and preparing documents. • Conducted weekly searches on FDA and MDCG databases for updated guidance documents and updated SharePoint documentation. • Identified and redlined errors in Work Instructions, leading to improvements in content compliance. |
| **Regulatory Consultant** | Antrix Inc. | Sunnyvale, CA | 2024 | • Created a regulatory database for 4 IVDs and Class I/II devices (510(k) & EU IVDR 2017/746). • Researched FDA, EU, and CLSI documents and documented detailed regulatory attributes. • Formatted QSR training materials for accuracy. |
| **Senior Engineer, Quality & Regulatory Affairs** | Tata Elxsi (Zimmer Biomet) | Pune, MH | 2020 – 2021 | • Developed EU MDR documentation for Class IIa, IIb, and III devices. • Conducted EU MDR vs MDD gap analysis. • Created/redlined IFUs and labels as per ISO standards. • Authored GSPR, Clinical Evaluation, PMS & PSUR. • Conducted team training on process compliance. |
| **Senior Research Associate, Technical Documentation** | USV Pvt Ltd | Mumbai, MH | 2019 – 2020 | • Lead author for SOPs, SAPs, CAPAs, COAs. • Delivered lab equipment’s SOP training. • Conducted internal GMP audits and coordinated equipment maintenance. • Created Excel tracker for streamlined project file archival. |
| **Senior Executive, R&D – Biologics** | INTAS Biopharma | Ahmedabad, GUJ | 2017 – 2018 | • Main analyst for analytical method development for monoclonal antibodies. • Used SDS PAGE, IEF, HPLC, HCP, HCD analysis. • Managed lab inventory and procurement using SAP. |
| **Senior Scientific Assistant, R&D – Biologics** | Zydus Cadila | Ahmedabad, GUJ | 2015 – 2017 | • Set up laboratory and performed method development and qualification (IQ, OQ, PQ). • Conducted sameness evaluation using CD, FTIR, and Spectro fluoroscope, Compiled lab documents in compliance with 21 CFR Part 11. |

**VOLUNTEER EXPERIENCE**

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| Role | Organization | Duration | Summary |
| Volunteer & Member | RAPS San Francisco Chapter | 2024 – Present | Supporting the membership and registration team as an active volunteer. |