Revanth kumar kanneganti

857-544-8964 kanneganti.r@northeastern.edu www.linkedin.com/in/revanthkanneganti Boston, MA, 02120

Education

Northeastern University **July 2023 – Present**
Master of Science in Regulatory Affairs *Boston, MA*

Osmania University **September 2018 – August 2022**
Bachelor of Science in Pharmacy *Hyderabad, India*

Skills

Certificates: GCP for investigations of devices, HIPAA Certificate, eCTD v4.0—The Future of Regulatory Submissions.
Regulatory: SaMD, 510(K), Gap Analysis, 21 CFR 820, CMDR, eCTD, PMA, IDE, IND, NDA, BLA.
Clinical: GCP/ICH guidelines, informed consent forms, real-time CTMS, Investigator's Brochure.

Professional Experience

Straumann Group **October 2024 – December 2024**
Quality Assurance Capstone

- Developed a comprehensive matrix mapping 21 CFR 820 and cMDR regulatory requirements to the organization's quality system elements focused on dental medical devices.
- Conducted a detailed gap assessment of the quality management system by linking regulatory requirements to existing quality system documents, identifying potential gaps, and recommending updates to address areas of non-compliance.
- Identified gaps and ensured audit readiness with a compliance gap analysis, supporting FDA and Health Canada audit preparedness and improving regulatory strategies.

MEYS Pharmaceuticals **May 2022 – September 2022**
Quality Control Intern

- Executed CAPA processes to investigate deviations, conducting root cause analysis with tools like 5 Whys, Fishbone and FMEA to ensure GMP compliance.
- Conducted quality audits and risk assessments based on ICH Q9 guidelines, ensuring regulatory compliance in pharmaceutical operations.
- Developed and validated SOPs and work instructions in alignment with FDA 21 CFR Part 11, ensuring regulatory compliance for pharmaceutical operations.

Projects

SaMD- EU MDR Regulatory Strategy

- Devised EU market entry strategy for LunaAI, a Class III implantable SaMD, while adhering to MDR standards.
- Outlined details including UDI implementation, risk management, cybersecurity, post market surveliance strategies.
- Created a flow chart to easily comprehend risk benefit analysis and risk management.

Comparative Analysis of Regulatory frameworks

- Documented 3 case studies of implantable devices withdrawn due to non-compliance and adverse outcomes. Outlined how gaps in pre-market testing and risk assessment led to device failure and compromised Standards of Care.
- Illustrated the regulatory consequences of product failures that led to stricter compliance measures and improved Pre-Market Testing. These changes ultimately improved standards of care across the medical device industry.

Benefit Risk Framework for medical devices

- Assessed medical device risk using multiple factors, including severity of harm (from non-serious injuries to fatalities), probability of device failure and patient harm, number of non-conforming devices in the market, patient exposure duration, and diagnostic accuracy (false positives/negatives).
- Explored risk assessment and regulatory reporting across the medical device lifecycle.Covered pre-market processes (PMA, 510(k)) and post-market surveillance strategies.Analyzed tools including FDA Form 3500A, MAUDE, MDR systems, 21 CFR 803, and RMPs.
- Studied medical device classification systems (Class I, II, III) as per FDA and EU regulations.Reviewed device risk levels, approval timelines, and examples across all three classes.

Leadership/Extracurricular

RAPS Member | *Volunteer*
ClinGRO Solutions | *Clinical Trial Management System and Social Medial Management* | *Volunteer*
American Red Cross | *Blood Donation Ambassador* | *Volunteer*