Revanth kumar kanneganti

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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 Associate Intern ***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.

eCTD Templetes

- Designed standardized eCTD templates to ensure structured, consistent, and audit-ready regulatory documentation across all technical modules.
- 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.

Leadership / Extracurricular

RAPS Member | *Volunteer*

American Red Cross | *Blood Donataion Ambassador* | *Volunteer*

Community Servings | *Digital Literacy program, kitchen* | *Volunteer*