Revanth kumar kanneganti

857-544-8964 kanneganti.r@northeastern.edu linkedin.com Portfolio

Education

Northeastern University
Master of Science in Regulatory Affairs *Boston, MA*

Osmania University
Bachelor of Science in Pharmacy *Hyderabad, India*

Skills

Certificates: GCP for device investigations, HIPAA certificate, eCTD v4.0: The Future of Regulatory Submissions

Regulatory: SOPs, SaMD, 510(K), Gap Analysis, 21 CFR 820, CMDR, eCTD, PMA, IDE, IND, NDA, BLA, Combination Product Development & Lifecycle Management, Regulatory strategy design, Regulatory Compliance

Software tools: Canva, real-time CTMS, Content writing, editing skills, template creation, Visual Assets, AI

Professional Experience

Rhizome AI **September 2025 – Present**
Regulatory Affairs Intelligence ***Part-time Remote***

- Developed and curated regulatory intelligence question sets spanning global authorities and databases (EMA, FDA, Health Canada), covering approval pathways, inspections, enforcement actions, and policy developments.
- Supported comparative regulatory analyses between FDA and EMA evaluations for drugs, devices, and combination products, synthesizing findings into structured insights for internal stakeholders.
- Researched and summarized inspection and enforcement data, including Form 483 observations, CRLs, and site-specific inspection histories, to support risk awareness and compliance strategy development.
- Authored and refined precedent-based, policy-oriented, comparative, and date-driven regulatory questions to assess approvals, clinical trial timelines, inspection outcomes, and key submission milestones.
- Reviewed and verified regulatory guidance interpretations and citations to ensure outgoing regulatory information was accurate, current, and aligned with U.S. and international regulatory expectations.
- Designed and maintained a structured regulatory question lifecycle (draft, review, finalized) to support quality control, traceability, and accuracy benchmarking of regulatory intelligence outputs.
- Executed SEO optimization for regulatory content, improving discoverability and alignment with real-world regulatory search queries and user intent.

ScieGen Pharmaceuticals **September 2021 – Present**
Quality Assurance Reviewer ***Hauppauge, Newyork***

- Performed comprehensive batch record reviews to ensure compliance with cGMP, SOPs, and regulatory standards, facilitating timely product release.
- Executed room and equipment clearance approvals prior to manufacturing activities, ensuring readiness, compliance, and prevention of cross-contamination.
- Managed Elemco software for process documentation, electronic records, and workflow tracking to maintain data integrity and compliance.
- Conducted in-process verifications and quality checks to monitor product quality and ensure process consistency.
- Maintained detailed and accurate GMP documentation to support regulatory inspections and internal audits.
- Reviewed manufacturing activities in real time to provide timely quality oversight and minimize production delays.

Combination Products Consulting Services LLC **June 2025 – September 2025**
Regulatory Affairs Associate ***Saint Johns, Fl***

- Developed and authored a comprehensive bridging strategy to support the transition from a variable-dose manual pen injector to a fixed-dose, spring-based autoinjector for a GLP-1 biologic combination product.
- Identified Critical Quality Attributes (CQAs), Critical Material Attributes (CMAs), and Critical Process Parameters (CPPs) for an Fixed dose autoinjector, while applying Use-Related Risk Analysis (URRA) and use-related Failure Modes and Effects Analysis (uFMEA) for risk mitigation.
- Conducted a regulatory landscape assessment to identify applicable FDA guidances, 21 CFR regulations, and submission requirements for combination product modifications.
- Mapped quality system elements, including design controls, risk management, and change control, to support premarket regulatory submissions.
- Developed an Standard Operating Procedure (SOP) for purchasing controls of combination products, ensuring compliance with FDA regulations including 21 CFR Part 4 and 820.50.

- Researched FDA, CFR, and ICH guidelines to support IND submissions and assist in preparing FDA meeting packages (Type B, INTERACT) under supervision, ensuring compliance with regulatory requirements and timelines.
- Assisted in the creation of SOPs in alignment with ANSI/AAMI/ISO 13485:2016 Quality Management System standards.
- Developed and managed social media content and articles to enhance the company's online presence and engagement.

Straumann Group **October 2024 – December 2024**

Regulatory Affairs and Quality Assurance Capstone ***Andover, MA***

- 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.