GANDHALI SALVI

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SUMMARY

I am a results-oriented graduate student pursuing MS in Regulatory Affairs for Drugs, Biologics, and Medical Devices from Northeastern University. Throughout my academic career, I have accrued over 1.5 years of professional experience. More recently I completed my 6 months Regulatory Affairs Co-op at Activ Surgical and had the privilege of assisting in the submission of a 510k. Prior to that, I worked for Tata Consultancy Services as a Pharmacovigilance Case Processor following my undergraduate studies, where I acquired valuable proficiency with data collection and analysis, patient safety, regulatory compliance, Microsoft office, and Argus 8.1 database. I intend to expand upon my academic skills in the health care setting by gaining further exposure to the regulations and guidelines necessary for bringing safe and effective products to the market.

EDUCATION

Northeastern University, Boston, MA **July 2021**
Master of Science in International Regulatory Affairs for Drugs, Biologics and Medical Devices
Bombay College of Pharmacy, Mumbai, India **May 2018**
Bachelor of Pharmacy

PROFESSIONAL EXPERIENCE

Regulatory Affairs Intern| Capstone Project: Activ Surgical, Boston, MA **April 2021-Present**

- Authored a post-market surveillance plan for a Class IIa medical device in accordance to Annex III of the MDR

Regulatory Affairs Associate (Co-op): Activ Surgical, Boston, MA **July 2020-December 2020**

- Took lead on preparing General Safety and Performance Requirements (GSPR) checklist as per Annex I from EU MDR 2017/745 for a Class IIa device
- Issued Declaration of Conformity for class II device required for 510(k) submission
- Examined and compiled the Q-sub documents for the FDA submission
- Assisted Quality Assurance/Document Control team on External Standards Listing by reviewing standards and determining status (current, superseded, or obsolete) to comply with Quality Management System (QMS)
- Assessed and imported requirements such as FMEA's in several Helix Documents
- Contributed with preparing for ISO 13485 and CE Certification audits
- Supported the Director of Regulatory Affairs and Quality Assurance by drafting a few sections of 510(k) submission for class II Software in a medical device
- Participated in phase 1 of ISO 13485 audit with the Notified Body necessary for the CE certification
- Participated in daily and weekly meetings to keep project timelines on track
- Drew strategies for the FDA and EU regulatory submissions including testing requirements, submission pathways, and anticipated clearance/approval timelines for target markets along with regulatory team

Pharmacovigilance Associate: Tata Consultancy Services, India **July 2018-June 2019**

- Extracted relevant information from routine source documents from project's affiliates via the Argus LAM or from E2B messages
- Conducted preliminary evaluation and assessment of case reports for seriousness, global listedness and causality of all serious and non-serious adverse events onto project's global PV safety Argus 8.1 database according to project's User Manual
- Created comprehensive case descriptions (narratives) in English language extracting relevant PV information from routine source documents
- Verified accuracy of MedDRA and WHO-DD coding of reported adverse events, concomitant drugs
- Performed amendments in case of case corrections and marked it significant or non-significant amendments in accordance with an internal SOP
- Carried out deletion of cases as per requirement including initial deletion, deletion identified with follow up information or deletion due to duplication of cases

Research and Development Intern: Ajanta Pharma Limited, India **May 2017-June 2017**

- Assisted in unit operations such as granulation, drying, milling, and blending, compression, coating, packaging of various dosage forms and preparations by following Good Manufacturing Practices (GMPs)
- Performed IPQC tests (dissolution, disintegration, friability, and hardness) for raw materials, excipients, active pharmaceutical ingredients (APIs), and dosage forms
- Explored different types of SOPs (Quality Assurance, Quality control, Manufacturing, Calibration, Microbiology, Warehouse, and Production), dossiers, and gained hands-on experience in types of equipment such as High-Performance Liquid Chromatography (HPLC), Thin Liquid Chromatography (TLC), and Gas Chromatography

SKILLS

Regulatory Skills

- Regulatory submissions: 510(k)
- Working knowledge and experience with 21 CFR 820, ISO 13485, ISO 14971, IEC 60601-1, EU MDD 93/42/EEC, EU MDR 2017/745, MEDDEV, Quality Management System (QMS), Quality System Regulation (QSR), FDA guidance, 510k database, ClinicalTrials.gov, Drugs@FDA.gov, PMA database, Federal Register, PMS requirements post-marketing surveillance (PMS) requirements for both US and EU
- Familiar with PMA, IDE, EUA, EU IVDD 98/79/EC, EU IVDR 2017/746, UDI, labelling, CE marking process, technical file, STED, eCTD, IND, CTAs, NDA, ANDA, ICH GCP guidelines, review processes, registration requirements

Technical skills

- MS Office, MS Excel, MS PowerPoint, MS teams, Outlook, Adobe Acrobat, Argus 8.1 database

Other skills

- Extremely organized, team player, work independently, detail-oriented, good interpersonal skills, time management and writing skills, adaptive, ability to work in fast-paced environment, ability to communicate across cross-functional departments effectively

ACADEMIC PROJECTS

- Developed regulatory strategy for drugs and medical devices by incorporating 21 CFR parts, FDA guidance, and ICH Guidelines
- Authored Inform Consent Form (ICF) and Clinical trial protocol for Aczone 7.5% gel in treatment of truncal acne vulgaris complying with 21 CFR 50
- Utilized CDER New Drug Reviews and Drug@FDA.gov to research FDA marketing application approval trends
- Drafted letter to FDA Commissioner explaining potential benefits and limitations of Prescription Drug User Fee Act (PDUFA)
- Leveraged knowledge of various 21 CFR parts, ICH Guidelines, and FDA Guidelines for providing IND and NDA consulting service for a hypothetical pharmaceutical company developing a drug intended to treat Alzheimer's disease
- Simulated mock warning letter for Opternative and provided Corrective and Preventive Action (CAPA)
- Developed regulatory strategy for a Class IIb medical device to market in the EU and presented it to senior management of organization