Maanya Venigalla

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EDUCATION

Northeastern University, Boston, MA — **Sep 2022 - Dec 2024**
Master of Science in Regulatory Affairs (Medical Devices) — GPA : 3.8

Vishnu Institute of Pharmaceutical Education and Research , India — **Jul 2018 - Jul 2022**
Bachelor of Pharmacy — CGPA : 3.7

CERTIFICATIONS & POWER SKILLS

Certificates: Six Sigma: White Belt and Green Belt, Drug Discovery (UC San Diego - Coursera)
Regulatory: 21CFR , ICH guidelines, Regulatory Submissions(EU MDR, 510(k), PMA, IND, NDA, MAA, CTD), CE Marking, Labeling changes, ISO 15223, ISO 20417, IEC 60601, IEC 62353, IEC 62366, IEC 62304, SaMD, Technical Writing, GDP
Quality: ISO 9001, ISO 13485, ISO 14971, SOPs, CAPA, Root Cause Analysis, FMEA, MRB, RMA, Trace Matrix, GMP, GCP
Laboratory: FTIR, HPLC, Spectrophotometers, Automatic Titrators, Gas Chromatography, Micro-pipettes handling, GLP
Technical: Microsoft (Word, Excel, SharePoint, PowerPoint), Adobe CC, BarTender, Monday.com, Veeva Vault, Minitab

PROFESSIONAL EXPERIENCE

Exergen Corporation — **Jan 2024 - Dec 2024**
Quality Engineer & Regulatory Affairs Co-op — Boston, MA

Quality Engineer Responsibilities

- Redesigned 100+ labels & IFUs integrating UDI data matrix/CE Marking requirements to comply with ISO 15223, IEC 60601, ISO 20417, FDA standards and validated label art proofs using 2D Barcode Reader.
- Performed shelf-life validation for caps, documented the validation plan and results improving product reliability by 15%.
- Conducted product accuracy tests, ensuring IEC 60601 & 62353 conformity for MDR certification across European markets.
- Implemented CAPA processes and root cause analysis techniques (PDCA, Fishbone, 5 Whys) to resolve quality issues, contributing to continuous improvement projects, improved product quality and enhanced operational efficiency.
- Executed NCMR investigations and dispositions as part of MRB & RMA activities, evaluating non-conforming products to maintain quality standards and minimize waste.
- Engineered risk management files and initiated FMEAs for 3 products to identify & mitigate risks adhering to ISO 14971.
- Revised company's quality system plan to align with FDA's QMSR (21CFR 820), ISO 13485, and MDSAP audit criteria.
- Prepared and processed 25 ECOs/TCOs, to reflect changes in WIs, MPs, SOPs, and TDs to maintain quality documentation.

Regulatory Affairs Responsibilities

- Supported ISO 13485 and INMETRO 384 recertification audits, preparing key documentation to ensure QMS compliance.
- Reviewed and updated Exergen's Technical Files during MDD to MDR transition, establishing linkages and documenting objective evidence to conform with EU MDR 2017/745 requirements for CE Mark certification.
- Managed EU MDR submission by compiling regulatory, biological (BEP, BER), and clinical (CEP, CER, PMS, PSUR) documentation for TemporalScanner™ thermometers.
- Re-evaluated products and 50+ suppliers' qualifications, updating TDs to meet RoHS, REACH, and CA Prop 65 regulations.

Adept Pharma and Bioscience Excellence Private Limited — **Sep 2021 - Nov 2021**
Quality Control Internship

- Developed 25+ SOPs, test methods, and result reports ensuring QC documentation compliance with laboratory requirements and industry standards by 100%.
- Formulated over 150 samples, reagents, buffers, and references for HPLC, Spectrophotometers, and Gas chromatography during instrumental analysis of drugs and cosmetic products while following GLP.
- Registered and managed sample data entry, accurately recording raw data and results in an analytical test data sheet.

Pellets Pharma Limited — **Apr 2021 - Jun 2021**
Regulatory Affairs Internship

- Compiled regulatory documentation for extended, delayed, and immediate-release pellets by coordinating with QA and manufacturing departments accelerating MAA and CTD preparation by 30%.
- Utilized Veeva Vault (EDMS) to organize MAA documents, create a workflow to review CTDs, track the status of regulatory submissions, and generate reports on submission progress.
- Assessed inspection readiness and data integrity through internal audits, communicated scientific concepts to internal and external stakeholders, and established regulatory & GMP compliance programs.
- Monitored CAPA progress, assisted in developing and executing CAPA plans, leading to a 20% reduction in recurring issues.

ACADEMIC PROJECTS

Northeastern University — **Oct 2022 - Dec 2024**

- Devised regulatory strategy for LunaAI, a Class III SaMD, while adhering to EU MDR and FDA regulations; executed risk-based classification, premarket submission planning, and post-market surveillance protocols for successful market entry.
- Prepared Traditional 510(k) submission for Class II SaMD, Sleep Image System's wireless data transmission feature, including detailed software description, risk analysis, and V&V summary, ensuring FDA compliance for software changes.
- Crafted Design Control and Development Plan, including trace matrix, for Bellafertility Pregnancy Kit (Class-II MD).