# 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, Quality Management for Operational Excellence, Drug Discovery
**Regulatory**: 21CFR , ICH guidelines, Regulatory Submissions(EU MDR, FDA, 510(k), UDI, PMA, MAA, CTD), CE Marking, Labeling changes, ISO (15223, 20417, 80601), IEC (60601, 60751, 62366, 62304), SaMD, Technical Writing, Clinical trial, GDP
**Quality**: ISO (9001, 13485, 14971), SOPs, CAPA, Root Cause Analysis, FMEA, MRB, RMA, NCMR, Trace Matrix, GMP, GCP
**Technical**: Microsoft (Word, Excel, SharePoint, PowerPoint), Adobe CC, BarTender, Monday.com, Veeva Vault, Minitab, HTML

## PROFESSIONAL EXPERIENCE

**ComeBack Mobility** — **Feb 2025 - Present**
**Regulatory Affairs Specialist/Volunteer** — New York, NY

- Guide FDA and EU MDR classification processes for Smart Crutch Tips as Subject Matter Expert (SME).
- Prepare clinical documentation in Veeva Vault, including study protocol, patient information sheet, ICF, IB, CIP & CRF.
- Manage clinical trial registration process in Germany, including application submissions through DMIDS for ethics committee review and BfArM approval.
- Execute software validation protocols per IEC 62304 to ensure data integrity & regulatory compliance of CBM mobile app.

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

**Quality Engineer Responsibilities**

- Redesigned 100+ labels and 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 temperature accuracy tests, ensuring IEC 60751, ISO 80601 & ASTM standards conformity for CE marking.
- Implemented CAPA processes and root cause analysis techniques (PDCA, Fishbone, 5 Whys) to resolve quality issues and customer complaints contributing to continuous improvement projects and enhanced operational efficiency.
- Executed NCMR investigations and dispositions as part of MRB and RMA activities, evaluating non-conforming products and raw/in-process materials 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, & 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 TemporalScanner™ Technical Files during MDD to MDR transition, establishing linkages and documenting objective evidence to conform with EU MDR 2017/745 requirements.
- Authored EU DoC and compiled regulatory, biological (BEP, BER), clinical (CEP, CER, PMS, PSUR) documentation to support EU MDR/FDA submissions, device registrations/renewals with notified body and international regulatory agencies.
- Re-evaluated 50+ suppliers' data & qualifications, updating TDs to meet RoHS, REACH, and CA Prop 65 regulations.
- Managed internal and external requests for CFG, Health Canada Medical Device Licenses and FDA device listings.

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

- 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 and GMP compliance programs.
- Coordinated and prepared responses to CDSCO inquiries regarding regulatory compliance, policies & submissions/approvals.

## 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 PMS protocols for successful market entry.
- Authored Traditional 510(k) for Class II SaMD, Sleep Image System's wireless data transmission feature, including detailed software description, risk analysis, and verification & validation summary, ensuring FDA compliance for software changes.
- Crafted Design Control and Development Plan, including trace matrix, for Bellafertility Pregnancy Kit (Class-II MD).