NANDHINI G

Medical Device Regulatory Affairs
Biomedical Engineer



PERSONAL PROFILE

Biomedical Engineer and medical-device R&D professional with practical exposure to Regulatory Affairs and regulatory submission activities. Experienced in working with regulatory consulting firms and internal technical teams to support preparation, review, and submission of medical-device regulatory documentation. Working knowledge of CDSCO / Medical Devices Rules, EU MDR 2017/745, US FDA medical-device regulations, ISO 13485, ISO 14971, medical-device classification, technical documentation, clinical evaluation, and regulatory compliance. Seeking to transition into a dedicated Medical Device Regulatory Affairs role with greater responsibility for regulatory submissions and product registration.

CONTACT DETAILS

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CORE COMPETENCIES

- Medical Device Regulatory Affairs
- CDSCO / Medical Devices Rules, 2017
- EU MDR 2017/745
- US FDA Medical Device Regulations
- Medical Device Classification
- Regulatory Submission & Registration
- Technical Documentation
- Regulatory Compliance
- Regulatory Requirements Assessment
- Regulatory Consultant Coordination
- ISO 13485
- ISO 14971 / Risk Management
- Clinical Evaluation / CER / CEP
- PMS / PMCF
- Regulatory Documentation Review
- Medical Device Manufacturing & Quality Requirements

EMPLOYMENT HISTORY

Biomedical Engineer

Mercatus IMEA | 2024 - Present

- Support medical-device Regulatory Affairs activities, including preparation and review of regulatory and technical documentation.
- Coordinate with external regulatory consultants for preparation and submission of regulatory dossiers.
- Review regulatory requirements and coordinate product-specific information for registrations and compliance.
- Support regulatory activities under CDSCO, EU MDR 2017/745, and US FDA requirements.
- Contribute to technical documentation, including device information, intended use, specifications, manufacturing, risk management, and supporting evidence.
- Support CER/CEP activities through literature review and assessment of clinical evidence.
- Working knowledge of ISO 14971 and ISO 13485 requirements for risk management and QMS compliance.

Project Manager/Research Fellow

Andhra Pradesh Medtech Zone | 2022 - 2024

- Managed technical and project documentation across multiple medical-device manufacturing and technology facilities.
- Prepared and reviewed technical reports for medical-device R&D and manufacturing activities.
- Developed documentation for endoscopes, digiscopes, CBCT systems, cancer detection kits, and other medical-device technologies.
- Coordinated technical information across multidisciplinary R&D and manufacturing teams.
- Supported documentation aligned with equipment, safety, process, and quality requirements.
- Prepared scientific and technical reports for project and technical review.
- Gained exposure to diverse medical-device technologies, manufacturing processes, and documentation requirements.

Publications:

- Radioactive Waste Management in a Medical Cyclotron Facility - A Review, International Journal of Health Technology and Innovation.
- Bone Plate Fabrication through 3D Printing: A Review of Methods and their Applications in Bone Regeneration, International Journal of Health Technology and Innovation.
- Multimodal Image fusion and segmentation using stationary wavelet transform

Patent:

- An Angulation locking unit for flexible endoscopes

Research Intern

Andhra Pradesh Medtech Zone | 2021 - 2022

- Prepared technical documentation and reports for research and medical-technology projects.
- Conducted literature review, technical analysis, and scientific documentation supporting research activities.

Research Intern

FIBSOL Life Technologies Pvt. Ltd | 2019

- Documented process optimization and experimental work involving electrospinning and biomedical materials.

ACADEMIC PROFILE

Amrita Vishwa Vidyapeetham

M. Tech in Biomedical Engineering, Class of 2022

Publications:

- Multimodal Image fusion and segmentation using stationary wavelet transform
- Chronic Kidney Disease prediction using machine learning techniques

Projects:

- Breast Cancer detection through the utilization of Hadoop environments

Amrita Vishwa Vidyapeetham

Integrated M. Sc Physics, Class of 2020

Publications

- Study of Polycaprolactone/Curcumin Loaded Electrospun Nanofibers on AZ91 Magnesium Alloy

Projects:

- Green synthesis methods for silver nanoparticles and their subsequent characterization.

REGULATORY FRAMEWORKS

- India: CDSCO / Medical Devices Rules, 2017
- European Union: EU MDR 2017/745
- United States: US FDA Medical Device Regulations
- Standards: ISO 13485, ISO 14971