

Subislena P

Medical devices Regulatory Analyst

These 2 years of experience has ability to ensure a quality management system enforces the required standards of Medical devices, quality, compliance and accreditation.

Personal information:

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- Address: Tirunelveli, Tamilnadu, India.

SKILL:

- QMS 13485.
- QMS 9001.
- Medical device.
- Self-learning capabilities
- Excellent analytical, conceptual, interpersonal and management skills

EDUCATION:

- Master of science-Biochemistry (2017 to 2019)
- Vels University.

SYSTEM KNOWLEDGE:

- Microsoft office.
- Windows 7 & 8
- SAP & Documentum (DCM)

ADDITIONAL QUALIFICATION:

- Advance certificate in clinical research, Data Management, pharmacovigilance and Medical Coding at Bangalore

WORK EXPERIENCE

Medical Device Regulatory Analyst

Currently working in **HCL Technologies Ltd.** Chennai as a **Regulatory affair (MTS)** for Medical devices

Nov-2019-Present

- Preparation and Review of **Technical File, GSPR, PEP, PER, CPR, APR** and **SVR** of EU Market.
- Gap Assessment of GSPR and Technical file Remediation of In-Vitro diagnostics and medical devices as per the 2017/746 & 2017/745 Regulations (IVDR & MDR)
- Knowledge about QMS **ISO 13485, 14971** Risk Management and 21 CFR Part 820 (QMS).
- Post market surveillance and Product Labeling (**UDI**)
- Additional skill like White Paper, Global registration and NB submission.
- Comprehensive Knowledge on classification of **IVD/ medical devices**.
- Documents, Rationales and Technical Justification reports.
- Train the sub ordinates according to the project requirements and providing knowledge transfer to the team by conducting interactive training session.
- Knowledge of writing **CER** for **medical devices**.
- Gap assessment and preparation of tech documents for Medical and IVDR regulations; Analysis of IVD reagents, remediation
- Performance evaluation study of IVD accessory products
- IVDR reagents and sustenance, product sustenance
- SOP preparation for testing and evaluation studies; Team management

Personal Profile

- Date of Birth : Jan, 30 1997
- Languages : English (Professional)
- : Tamil (Native)
- Nationality : Indian
- Marital Status : Unmarried

CERTIFICATES

- Worked as a Trainee (01 May 2019 – 22 October 2019) in “Indian Health Care BPO.” for 6 month on training related to clinical research, Data Management, pharmacovigilance and Medical Coding.