K. RENUKA GOUD

Design Controls

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Hyderabad, Telangana.

Professional Summary

Strongly reliable and focused Design Controls and Regulatory Affairs tasks with experience in medical device review and evaluation. Efficiently independent worker as well as excellent coordinator with other team members of regulatory affairs.

Core Qualifications

- Considerable experience in Design Controls, Technology Transfer and regulatory affairs work environments for Medical Devices projects
- Created and maintained of Design Controls documents for In-Vitro Medical Devices
- Thorough understanding of **MDR, EU, FDA** regulations & requirements, and revised the technical files as per the regulatory requirements
- Implementing the regulatory requirements and procedures to ensure that the regulatory compliance is maintained or enhanced
- Supported for technical files of **Class B & C In-Vitro Medical Devices**
- Prepared and submitted **dossier files** and supporting documentation for In-Vitro Medical Devices
- Strong knowledge of In-Vitro medical devices testing practices and principles

Skills

- Medical Devices Rules – 2017
- CDSCO
- 21 CFR (Code of federal regulations)
- ISO 13485:2016 Medical Devices Quality Management
- Product Development
- Device History Files and Design Dossiers
- MS Office and WPS
- US FDA regulations
- EU MDR
- ISO 14971:2019(en) Medical Devices Risk Analysis
- Q7 regulations
- GMP and cGMP Practices
- Medical Devices Technical Files
- Technical Documentation and Technology Transfer

Experience

Technical Writer for Design Controls
Cyient Ltd – Hyderabad
(06/01/2022 - Present)

- Performing gap assessment for Design Controls as per EU MDR and FDA
- Gap assessment for Medical Devices DHF's and Technical Files

Member Technical Staff

HCL Technologies Ltd - Chennai, Tamilnadu
(31/06/2021 – 05/01/2022)

- Supported for IFU optimization for IFU project.
- Optimization of manuals and providing the improvement areas.
- Re-phrasing and Re-alignment of contents of IFU.

Technical Writer for Design Controls

Sensa Core Medical Instrumentation Pvt. Ltd - Hyderabad, Telangana
(18/08/2018 – 30/06/2021)

- Created and maintained the **Design Controls documents, Risk Management File** and **DHF** for Blood Gas Analyzers, Electrolyte Analyzers and Blood Glucose Measuring System manufactured by Sensa Core Medical Instrumentation Pvt. Ltd.
- Preparing and submitting the product transfer documents from R&D to Technology Transfer team.
- Review of document required for Regulatory Bodies (Process Validation reports & protocols, Stability data and coordination with other departments like Validation, QA, QC and Engineering and Project Management for various regulatory documents requires for **dossier submissions**.
- Experience with filing **CE, CDSCO and DCA files submissions** and **technical files** for In-Vitro Medical Devices.
- Implements the regulatory requirements for new and modified medical devices.
- Pre-authorized **Safety Data Sheets (SDS)** for In-Vitro Medical Devices manufactured by Sensa Core Medical Instrumentation Pvt. Ltd.

Education

Diploma

Diploma	: Electronics and Communication Engineering - 2017
College	: VNR VJIET, Bachupally, Hyderabad.
University/Board	: State Board of Technical Education and Training

SSC

School	: Rama Krishna High School - 2014
University/Board	: Board of Secondary

Personal Profile

Marital Status : Unmarried

Languages Known : English, Hindi, Telugu and Tamil

Hobbies : Reading Novels and writing poetry

I hereby declare that the information furnished above is true to the best of my knowledge and belief.

Place: Hyderabad
Date:

Ms. Renuka Goud