MURALI ANNAMALAI

Senior Regulatory Affairs Engineer

PROFILE

Regulatory compliance and quality assurance professional with 9+ years of experience in medical device industry, driving project to achieve compliance with applicable Quality and Regulatory requirements.

CONTACT

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+91 9843787027

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AREA OF INTREST

EU MDR 2017/745
ISO 13485
ISO 14971
ISO 15223-1
ISO 9001

TRAININGS & CERTIFICATIONS

Certified internal auditor for ISO 13485 (BSI)
Certified internal auditor for MDSAP (BSI)
Completed training for ISO 9001, Six sigma

WORK EXPERIENCE

HCL Technologies Ltd - Senior Regulatory Affairs Analyst
July 2017–Till date
Supported customer project – BD

- Preparation of Projects Weekly status report, SMR Presentations and Assessment Checklists as per Regulation
- Handling review meetings and customer calls, as required by the project team.
- Preparation of Project proposals which includes Scope of Work, Risk assessment, Input requirements.
- Conduct regulatory gap assessment, technical documentation for both medical devices.
- Identification of applicable regulatory standards and requirements.
- Remediate the medical device technical documentation/ STeD per regulation requirement like EU MDR 2017/745, MD Directive 93/42/EEC.
- Creating SSCP for class III and Implantable medical devices based on EU MDR 2017/745 & MDCG recommendation.
- Preparation of DOC as per Annex IV, Device classification as per Annex VIII, Material of concern Memos based on Medical Device Regulation. (Device: Pre-filled syringes, Spinal Needles)
- Submitting remediated STeD to EU notify body for CE mark approval.
- Reviewing of remediated labels and IFU documents per applicable regulatory and standard requirements.
- Responding to the notify bodies queries regarding submitted STeD's.
- Conducting Internal SA/Quality audits per Organization requirements.
- Training of associates who newly joined into the team.

Major accomplishments

- Completed 15+ numbers of remediated technical documentation and submitted NB for final CE approval.
- Been part of the core team for ISO 13485 recertification approval.
- Been part of the core team for GSPR creation automated tool.

TOOLS

PLM's
ERP
PM Smart
PITSA
pcMRP

EDUCATION

Bachelor of Engineering in Electrical and Electronics Engineering
NPR College of engg & tech, 2008-2012
Higher Secondary Certificate
Govt, Her, Sec, School., Dindigul, 2006-2008
Secondary School Leaving Certificate
Govt, Her, Sec, School., Dindigul, 2005-2006

PERSONAL PROFILE

Date of birth:
04-Jun-1991
Marital status:
Married
Nationality:
Indian

Avalon Technologies Pvt Ltd – Quality Assurance Engineer
July 2012–July 2017

- Creating an incoming material quality plan for incoming inspection
- SCAR preparation and follow up for incoming material & supplier issues
- Responsible for conducting on-site Supplier system and special process audit for record and retention, production process and work procedures
- Responsible for creating and maintaining Supplier Rating System (SRS)
- Coordinating with Development team to prepare FAIR, PPAP for new product development and approval process
- Responsible for developing Control plan chart based on the FMEA against customer requirement
- APQP timing plan follow-ups with engineering team
- Coordinating with development team on engineering changes & revision changes
- Responsible for monitoring cost of poor quality (COPQ) indicators and corrective action follow-ups
- Conducting awareness and training programs to train new members in team
- Creating & maintaining skill matrix and gap analysis against training plan

Major accomplishments

- Led ISO certification and surveillance effort, which grant on the first attempt.
- Driven the initiative to implement SAP PM's and PITSA tools.
- Driven the team to process improvement and saved around 0.2M worth of material cost.

I here declare that all the information furnished above are completed and true to the best of my knowledge.

Murali Annamalai