

Sanjay Venkatraja S N

Product Compliance Engineer

To apply my multi-domain knowledge in material analysis of medical devices and effectuate my efforts in a healthcare industry, engage myself towards contributing to the growth of human health and safety through my apex tenacity. To work in an organization where my proficient knowledge and applicative mindset can be best utilized.

More than two years of industrial experience in Medical Devices Industry as a toxicologist and product compliance lead and also having two years of experience in solid tire manufacturing, curing and calendaring process.

Professional Background

- More than two years of experience in product compliance, materials analysis and biocompatibility for medical devices.
- Provided responses to the inquiries from different medical device manufacturers, hospitals, group purchasing organizations, etc. regarding Materials of Concern (MOC) and aiding them in safer product purchase and for product registrations in new regions.
- Providing confirmation on presence or absence of hazardous substances in medical devices after thorough analysis of the products material construction.
- Verifying the compliance of the devices with respect to the different regulations that are applicable to medical devices- Eu REACH, RoHS, Eu MDR, California Proposition 65.
- Capable of handling customer queries regarding the product compliance.
- Experienced in handling offshore & onsite projects, interacting with onsite teams and clients spread across different geographical locations.
- Having aptitude knowledge and reasoning Skills.
- More than two years of experience in Solid tire manufacturing, Curing, Bumping Loading and Unloading (BLU) operations and calendaring operations.
- Preparing SOP's for green tire building, BLU operations and curing station operations.
- Ensuring the final delivery inspection, incoming material inspection and tire dimensional analysis.

Contact and Personal Details

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Date of Birth
13 May 1995

Skills

Material specific regulations – Eu REACH, RoHS, WEEE Directive, California Proposition 65, Conflict Minerals, Biocidal Products Regulation.

Work History

Aug 2019 – Present **Product Compliance Engineer**

HCL Technologies, Chennai, Tamil Nadu

- Leading a product compliance team consisting of 6 direct staffs and 3 indirect staffs.
- Providing Materials of Concern (MOC) declarations to multiple customers like other medical device manufacturers, hospitals, etc. thus aiding them in safer product purchase and for product registrations in new regions.
- Confirming the presence/absence of hazardous materials in the devices after a thorough analysis of the products' material construction.
- Verifying the compliance of the devices with respect to the different regulations that are applicable to medical devices – Eu REACH, RoHS, Eu MDR (CMR/ED), California Proposition 65, WEEE Directive, Biocidal Product Regulation (BPR), etc.
- Addressing various customer queries on medical devices through the Materials of Concern (MOC) questionnaire forms.

European Medical Device Regulation (Eu MDR) and its transition from Medical Device Directive (MDD).

ISO standards - ISO13485, ISO10993, ISO22442.

Materials of Concern (MOC) impacting the safety of medical devices.

Biocompatibility of medical devices and toxicological risk evaluation.

Microsoft Office.

Personal skills:

Quick Learner, Compassionate, Skilled in communication, Team player and a motivational person with a positive attitude.

Leadership Skills:

I can handle projects by maintaining a professional relationship with clients and proactively interact with teams to resolve the challenges faced in my daily work routine; with my soft skills and hard skills, I believe I can handle projects in a smart manner.

Language

Tamil

English

Telugu

- Providing Environmentally Preferable Purchasing (EPP) responses highlighting the regulatory compliance and informing the presence of hazardous substances in products on a timely basis.
- Responsible to collect the BOM information through Agile.
- Conduct California Prop 65 risk assessments for relevant products sold in California.
- Critically analyzing, contributing to and writing reports and scientific papers.

Jul 2017 –
Jul 2019

Process Quality Engineer

TVS (Solid Tire Division), Pudukottai Tamil Nadu

- Testing the specific gravity of rubber material to arrive the weight standards of green tires.
- Testing the rubber to know the flow properties and rheological properties of rubber on Moving die rheometer.
- Analyzing the product defect wise failure data and laboratory test results to determine the cause of problems
- Responsible for defect and process wise customer complaints.
- Organizing monthly review meetings, cross-functional team meetings on defect analysis.
- Preparing SOP's, work instruction, one point lessons for calendaring operations.
- Ensuring whether the bumping pressure, locking pressure and bumping counts are at the permissible levels.

Education

Jul 2013 – May 2017 Bachelor of Technology: Polymer technology
Kamaraj College of Engineering and Technology - Madurai,
Tamil Nadu, India.

I, Sanjay Venkatraja S N, hereby declare that the information provided in this resume is true to the best of my knowledge.