

NIJU MATHEW

Experienced Biomedical Engineer | Quality & Regulatory Specialist
Certified PRRC Compliance Expert | Medical Device Management & Maintenance Specialist

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Germany



A highly skilled Biomedical Engineer with over 8 years of extensive experience in managing, maintaining, and troubleshooting medical devices across diverse healthcare environments. Specialized in quality assurance, regulatory compliance, and operational efficiency, I am adept at ensuring compliance with global standards, including ISO 9001-2000, and PRRC. Proven track record in leading and managing teams of 7-10 biomedical engineers and support staff, optimizing operational processes, and maintaining medical devices in critical departments such as Radiology, ICU, OT, and Dialysis. Certified in PRRC Compliance (2024), I have a strong foundation in audit, process control, and continuous improvement to ensure all technical aspects meet both international and local medical device regulations. Experienced in coordinating product support, conducting technical training, and managing vendor relations for medical equipment maintenance and calibration. Passionate about enhancing patient safety and optimizing the performance of diagnostic and therapeutic medical devices.

SKILLS PORTFOLIO

Medical Device Support	<div></div>
ISO Standards	<div></div>
Sales of Medical Devices	<div></div>
Service Engineering	<div></div>
Client Coordination.	<div></div>
Biomedical Equipment Maintenance	<div></div>
Troubleshooting	<div></div>
Product Lifecycle Management	<div></div>
QA, RA, and PRRC Compliance	<div></div>
Preventive Maintenance	<div></div>
Medical Equipment Calibration	<div></div>
Compliance with Regulatory Standards	<div></div>
Team Coordination	<div></div>

VALUE ADDITION

- Certified PRRC:** Certified in PRRC compliance (2024), ensuring all biomedical engineering practices meet European Union medical device regulations.
- Medical Device Expertise:** Extensive experience in managing, maintaining, and troubleshooting various medical devices, including diagnostic and therapeutic equipment across multiple healthcare settings.
- Quality & Regulatory Compliance:** Specialized in quality assurance, regulatory affairs, and compliance with ISO 9001-2000, NABH, and PRRC standards for medical devices.
- Audit and Process Control:** Experience in conducting internal audits, process optimization, and continuous improvement initiatives to ensure adherence to standards and regulations
- Team Leadership:** Managed and led teams of 7-10 biomedical engineers and support staff, ensuring high-quality service delivery and operational efficiency..

WORK EXPERIENCE

Akkna Tek GmbH, Saarbrücken, Germany (Jul 2023 – Present)

Designation: Quality and Regulatory Specialist

Roles Handled: PRRC, QA, RA

- Overseeing quality assurance (QA) processes, ensuring compliance with regulatory standards for medical devices and healthcare products.
- Managing regulatory affairs (RA) to maintain adherence to international standards, including CE marking, FDA, and other relevant certifications.
- Overseeing the quality and regulatory compliance of medical devices, ensuring PRRC standards are met.
- Analyzing regulatory requirements to ensure compliance and identify areas for process improvement.
- Supporting internal audits to enhance compliance, identify risks, and drive operational efficiency.
- Assisting the project team in maintaining medical device regulatory conformity, ensuring streamlined project delivery and compliance.
- Acting as the Person Responsible for Regulatory Compliance (PRRC), ensuring that the organization's products meet all necessary legal and regulatory requirements.
- Developing, implementing, and maintaining the quality management system (QMS) in alignment with ISO 13485 and other applicable standards.
- Conducting internal audits and risk assessments to ensure the company's products meet quality and safety standards.
- Collaborating with cross-functional teams to manage product lifecycle from development to post-market surveillance.
- Reviewing and approving technical documentation to ensure compliance with regulatory requirements and support submissions.

CONFERENCES ATTENDED

- Workshop on New Challenges and Opportunities in Health Care, organized by Biomedical Engineering Society of India, 2014
- UDGAM, Organized by Indian Institute of Technology (IIT) Guwahati, 2014
- BME Explore 4th & 6th National Level Student Symposium, 2013

ACADEMICS

- Master's in Biomedical Engineering, Lithuania, Europe | 2021
- Bachelor of Engineering in Biomedical Engineering, Bapuji Institute of Engineering and Technology, Davengere, Karnataka | 2014

COMPUTER SKILLS

- MS Office Suite (Word, Excel, PowerPoint)
- MATLAB
- CAD Software
- Understanding FDA and ISO standards for medical software

- Managing interactions with regulatory bodies and ensuring timely submission of product dossiers for market access.
- Monitoring and tracking changes in regulatory requirements, ensuring that the company remains compliant with evolving standards.
- Leading investigations of non-conformities and implementing corrective and preventive actions (CAPA).

Diamond Diagnostic's – Budapest, Hungary (Nov 2021 – Mar 2023) | Product Support Engineer / Technical Support

- Resolved technical issues for diagnostic equipment, ensuring uninterrupted performance and client satisfaction.
- Conducted training sessions and developed comprehensive user manuals to enhance customer knowledge of equipment operation.
- Performed routine maintenance and managed spare parts inventory to ensure equipment reliability and minimize downtime.
- Strengthened client relationships through exceptional service and proactive feedback collection to drive process improvements.
- Coordinated product support and ensuring the operational functionality of advanced medical equipment, including diagnostic and therapeutic tools.
- Conducted technical training sessions for the team to enhance skills in maintaining medical devices and ensuring quality standards.
- Ensured all technical aspects comply with regulatory standards for medical device management.

Krishna Hospital and Research Center – Uttarakhand, India (Aug 2018 - June 2019) | In Charge Bio-medical Engineer

- Led and managed the Biomedical Engineering department, overseeing the installation, maintenance, and calibration of all medical equipment.
- Coordinated technical audits and worked with external vendors for annual maintenance contracts, ensuring quality and efficiency.
- Managed and led a team of 3 employees in biomedical engineering, improving operational processes.

Mediheal Group of Hospitals – Eldoret, Kenya (Feb 2017 - Aug 2018) | Head of Department - Biomedical Engineering

- Led the Biomedical Engineering Department, aligning operations with hospital goals to enhance efficiency and service delivery.
- Oversaw the procurement, commissioning, and maintenance of medical equipment, ensuring clinical reliability and operational excellence.
- Managed preventive and corrective maintenance schedules, reducing downtime and enhancing equipment performance.
- Supervised a team of engineers and technicians, providing mentorship, training, and fostering a culture of continuous improvement.
- Optimized budget and inventory management, achieving cost efficiency and ensuring the availability of critical spare parts.
- Led the Biomedical Engineering department, ensuring seamless operation and maintenance of medical equipment across all hospital units.
- Developed and implemented preventive maintenance schedules, minimizing equipment downtime and ensuring compliance with safety standards.
- Coordinated with procurement teams to evaluate, purchase, and install advanced medical technologies, optimizing hospital capabilities.
- Managed a team of engineers and technicians, providing training, performance reviews, and guidance to enhance productivity and expertise.
- Collaborated with clinical staff to address equipment needs and resolve technical issues, improving patient care and operational efficiency.
- Ensured adherence to regulatory requirements and accreditation standards for medical devices and hospital infrastructure.
- Conducted cost analysis and budgeting for equipment repairs, upgrades, and acquisitions, achieving a 15% cost reduction.
- Streamlined documentation and reporting processes, improving tracking of maintenance records and compliance audits.

Life Health Care Pharmacy – Dubai, UAE (Jul 2016 - Dec 2016) | Sales and Service Engineer

- Identified and targeted healthcare providers to drive sales of medical equipment, achieving revenue growth and client retention.
- Installed and tested medical devices at client sites, ensuring optimal performance and customer satisfaction.
- Performed maintenance and repair services to ensure the reliability and compliance of medical equipment with safety standards.
- Stayed updated on the latest technologies, leveraged product knowledge to present innovative solutions and provide expert support.
- Achieved a 20% increase in sales by promoting healthcare products and services to customers effectively.
- Conducted technical demonstrations to showcase product features, enhancing customer understanding and satisfaction.
- Resolved customer issues promptly, improving service turnaround time and ensuring high customer retention rates.
- Optimized inventory management processes, reducing stock shortages and enhancing product availability.

Sunshine Global Hospital – Baroda, India (Jun 2014 - Jun 2016) | Biomedical Service Engineer

- Conducted installation, calibration, and troubleshooting of a wide range of medical equipment including ventilators, infusion pumps, diagnostic imaging systems, and patient monitors.
- Collaborated with clinical and technical teams to ensure the optimal functioning of medical devices in patient care settings, contributing to patient safety and care quality.
- Assisted in the selection and evaluation of new medical technologies, ensuring their integration into hospital systems without compromising patient care.
- Conducted regular inspections and managed documentation for compliance with hospital protocols and industry standards.

PERSONAL NOTE

With over 8 years of extensive experience in the biomedical engineering field, I bring a proven track record of ensuring the optimal performance, maintenance, and compliance of critical medical devices. My expertise in managing teams, overseeing quality assurance and regulatory compliance, and implementing preventive maintenance strategies has consistently contributed to the enhancement of patient safety and the efficiency of healthcare operations. I am passionate about advancing the performance of diagnostic and therapeutic devices, committed to continuous professional growth, and adept at adapting to evolving regulatory requirements. My certifications, including PRRC compliance, and hands-on experience in diverse healthcare environments position me as a key asset for any medical device management or quality assurance role.

PERSONAL DETAILS

- Date of Birth: June 23, 1990 | Marital Status: Married | Nationality: Indian | Languages Known: English, Hindi, Malayalam, Tamil, Kannada, Kiswahili, German, Arabic, Magyar, and Marathi