KT NAVEEN

DOMAIN - HEALTHCARE TECHNOLOGY

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Profile

Dedicated and experienced medical device with a background in product development and Product verification. Proven expertise in product design and verification, ensuring requirements traceability and test coverage. Skilled in collaborating with design teams, managing test protocols and implementing continuous improvement initiatives. Adept at using project management tools and adhering to quality management systems. Knowledge in Standards . additionally, served as an innovation fellow at AIIMS Stanford India Bio design, drove projects in infectious diseases and pediatric healthcare. Demonstrated abilities in project management, stakeholder engagement, and regulatory compliance testing. Possess a solid foundation in research and development, with expertise in product design, prototyping. Strong problem-solving skills and a track record of delivering innovative solutions.

Employment History

Senior software Engineer, Cepheid, Bengaluru

October 2023 — Present

- Develop and execute Verification plans and protocols and Summary Reports.
- Ensure conformity of the design process with applicable regulation
- Working in an Agile environment, testing requirements
- Review and Approve verification documentation related to the products
- Create and compile design control deliverables for regulatory submissions – Traceability Analysis
- Collaborating with distributed, cross-functional teams to ensure products meet quality,
- performance, scalability, reliability and scheduled goals
- working closely with the software development team, the software quality team, the functional manager and the project manager.
- Ensure compliance to organizational policies, procedures, and regulatory requirements such as FDA, ISO 13485

Senior Engineer, L&T Technology Services Limited, Bengaluru

December 2021 — October 2023

Project: Renal care Unit - Client - Baxter Innovations & Business Solutions Pvt Ltd

- Worked on New product development Dialysis machine, system verification & system integration level.
- Effectively Communicated daily, weekly, and monthly updates of activities reported to manager and Team.
- Responsible for understanding the product requirements & developing, Updating the test protocols & procedures for the new and existing products at Sub system and System level.
- Co-ordinates with design & development team to start the testing early in the design cycle to ensure the requirements test-ability, traceability & test coverage. Identify issues early to fix the same. Refine the test plans and procedures through pre-verification activities.
- Develop and manage processes and tools required to support the verification and validation activities. Providing technical support as applicable.

Links

Linkedin - naveenkt

Research gate - Naveen-K-T

Skills

Teamwork

Product Development

ISO 13485 QMS

Medical device and Management

Leadership

Strategic Thinking and Planning Skills

Patent

Communication and Listening

Time management

Languages

English

Hindi

Tamil

Hobbies

Digital Sketching, Music

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- Clear understanding and proven experience on basic requirements of unit, integration and system level verification and validation requirements
- Understanding the user requirements, therapy requirements, user interface function to develop the test design and protocol document.
- Endeavor in V&V process continuous improvement and test automation activities and supported.
- Adheres to Quality Management system and support audits and external inspections as applicable.
- Identify and report any quality or compliance issues during verification & validation activities.
- Worked on Test Design Creation, used Backbox test design techniques.
- Worked on Test Design Review, Update, creation, protocol publish in RV&S and ALM. Tool
- Worked on Test case development and Requirement mapping and analysis.
- Worked on Test method strategy for the requirements.
- Worked on Dry run and Formal run testing for system verification & system integration level.
- Worked on Test method validation and supporting for setup planning and executions.
- Worked on Verification Points Service manual and operating manual.
- Used project management tool like ALM, RV&S, Jira, DCC, ELN, Figma, Minitab, team center (TCU), PDLM – windchill.
- Ensures the good document practice and guidelines as per the requirement are in the V&V process project.
- Equipment used for testing Flow meter, Pressure gauge, weighing scale, Hydra Series III Data Acquisition System/Digital Multi-meter.
- Experience in IEC basic safety, EMI-EMC standards

Innovation Fellow, AIIMS, New Delhi

January 2021 — December 2022

Project: Infectious Diseases -NPD Indigenous Production of Novel Personal Protective Equipment for Healthcare Personnel

- Worked on Product development of a technological development in infectious diseases product.
- Worked on Project management through daily, weekly, and monthly communication of project progress with higher leadership and Team.
- Responsibility on Managing stakeholders, vendor development, supplier and material handling and budget for the project.
- Assist stakeholder with the project issues or risks, and resolve them in a team setting, so that the outcomes are acceptable to everyone. Come up with creative solutions to the problems so that the impact on the project is minimized.
- Worked standard to the Product with concepts development, Cad development, and drawings and prototyping and tested for Safety and efficacy.
- Followed and performed testing as per the NIOSH Standard related, air flow testing, air quality test, drop test, pressure test, device wearable test.
- Worked on Formative evaluation as IEC 62366-1 standard with product versions of prototypes by using rapid prototyping and iterative testing for the clinical benefits.
- Worked on AIIMS ethical approval and ethical protocols for the product testing in clinical performance.
- Worked usability testing test as per the IEC 62366 formative and summative with different user and doctors connected feedback for improvement.
- Performed Testing as per the IEC 60601-Part1 Safety pre-compliance testing requirements in inhouse, Leakage currents: Clause 8.7 2. Dielectric strength: Clause 8.8.3 3. Excessive temperature in ME Equipment: Clause 11.1.

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- Collaborated with TUV Bangalore to perfume the Product as per IEC 60601-Part1 of Safety pre-compliance testing as per the NIOSH requirements for the product tested and supported for documented needs.
- Collaborated with SITRA Coimbatore to perfume the test Particle Filters Used in Respiratory Protective Equipment as per the standard IS 15322:2003.
- Manage and Collaborated with the manufacturing industry for the production worked closely of Design for manufacturing (DFM), cost reduction, as per medical devices — ISO 13485 Quality management system standard.
- Manage the Equipment and purchase for the Project.
- Contributed the Strategies for regulatory approval, ethical approval played a crucial role to commercialization.
- As following the Iso13485 clause :7.3.6 & 7.3.7 clauses product verification and validated
- Worked on verifying specifications, product user manuals and service manuals, labelling and Packaging on verification as per the regulatory requirements.
- Business development and product pricing strategy for the Equipment and consumable products for a new product to market

Project: Pediatrics -NPD (Amblyopia treatment)

- Clinical Immersion in department of Pediatrics and Clinical Immersion in Neonatal ICU (NICU), Pediatric ICU (PICU), Pediatrics Causality, Day care, Emergency, Wards, Dialysis and Endoscopy.
- Worked on the Treatment digital technology, Problems solving, Selecting Clinical need criteria, Finalization user need specification.
- Brainstormed the top need with the Clinician, Doctors and Patients study the need and validate the clinical need.
- Research document in kidney dialysis about Problem statement, Disease State, Current Solutions, Shortcomings of Current Solutions, Stakeholders Involved, Potential Market studies.
- Led the International Doctors the survey of the clinical need validation and user need for the finalized clinical need.
- Worked usability studies and translating into user-needs/requirements and design solutions related to the user interface.
- Worked on Ophthalmology digital technology solution in Conceptual level design in adobe-XD, prototyping and Usability Studies and feedback and tested with clinicians.
- Test GUI design with User and iteration he designs for improve the safety and efficacy.

Project Research Assistant - IDC, IIT Bombay, Industrial Design Center , Mumbai

February 2018 — December 2019

- Worked in Industrial design center for NPD projects
- Assistance in research and development activities and NPD, Product design development and tools
- Designed products, prototyping, and testing the prototype.
- Designed of jigs, mold, and fixtures for products
- Worked on Vacuum casting and laser cutting to develop the product and tools.
- Delivered Cad, drawing preliminary sketches, generating detail drawing and computer assisted design/drafting in, solid works.

Education

Postgraduate Diploma in Medical Device and Management, IGMPI, New Delhi

2022 — 2023

Innovation Fellow, School of international Biodesign, New Delhi

2021 — 2022

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Fellowship in Medical device innovation

BE. Mechanical Engineering , Thiagarajar College of Engineering, Madurai
2014 — 2017

Patent Portfolio

Full body personal protective equipment for healthcare personnel with built-in ventilation support

Portable grain lifter cum sack filling machine

Portable coconut peeling machine

Automatic ceiling fan blade cleaning attachment

Courses

ISO 13485:2016 - internal auditing for quality management system for medical devices, TÜV SÜD

Fundamentals of medical device single audit program (MDSAP) , TÜV SÜD

Quality Management for Business Excellence, Udemy

Product Development & Systems Engineering, Udemy

Requirements Engineering (IREB / INCOSE), Udemy

Master Course in Corporate Laws, Enhelion