Manish Kumar Sharma

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Biomedical Engineer with 3+ years in medical device development, clinical support, and data analysis, skilled in CAD, FEA simulation, and device optimization. Proven in troubleshooting, regulatory compliance, and technical training to enhance patient outcomes. ISO 13485 and Lean Six Sigma certified, with a detail-oriented approach to process improvement and innovation in healthcare technology. Eager to bring expertise in advancing healthcare technology.

PROFESSIONAL EXPERIENCE

Case Western Reserve University — Cleveland, OH
Research Assistant | Med Infectious Disease — June 2024 – February 2025

- Led the design and development of novel microfluidic lab-on-chip devices, including the Advanced Microfluidic Engineered Screw (AMES) for point-of-care diagnostics, using SolidWorks, CorelDRAW, 3D printing, laser cutting, and CNC machining to achieve precise fluid control and seamless reagent integration.
- Enhanced device performance through experimental validation and sensitivity optimization, achieving 85% reagent recovery and a 0.1 pg/mL detection limit for IgG quantification, while ensuring compliance with functional and quality standards.
- Evaluated advanced deep learning and machine learning models for microfluidic image classification using visual attention maps and ablation studies, improving detection accuracy and interpretability.
- Collaborated with multidisciplinary teams in chemistry and biology to refine sensor sensitivity and signal output across disease states and conducted reliability testing with root cause analysis to optimize system robustness for real-world deployment.

George Washington University — Washington, DC
Instructional Technologist — Jan 2024 – Mar 2024

- Optimized the Law School's event scheduling system and video processing workflows, boosting event participation by 20%.
- Delivered on-site technical and AV support to faculty and staff, resolving 90% of IT tickets within 24 hours to minimize classroom disruptions.
- Led technical training sessions for new hires each semester, resulting in a 30% reduction in recurring tech-related issues.

George Washington University — Washington, DC
Technical Support Assistant — May 2022 – December 2023

- Enhanced the ticket management workflow, achieving 20% faster processing of technical support calls compared to the team average.
- Decreased the volume of support tickets by 15% through proactive identification of recurring problems and implementation of preventive measures.
- Managed the department's YouTube channel, overseeing all video content, scheduling, editing, and privacy compliance to improve user experience..

Tata Main Hospital — Jamshedpur, India
Biomedical Intern — June 2019 – July 2019

- Conducted rigorous testing and calibration of biomedical equipment in compliance with industry quality standards, reducing equipment downtime by 15%.
- Provided hands-on assistance to the maintenance team in real-time troubleshooting and component replacement, improving device uptime by 10%.
- Maintained precise documentation for device performance, stock levels, and calibration reports, resulting in a 20% efficiency gain during quality assurance audits.

ACADEMIC AND RESEARCH PROJECTS

Pulse Detection with Syntouch Biotac & JACO Robot — Jan 2023 – Aug 2023

- Developed a telemedical robot equipped for pulse and temperature detection using the Kinova Gen 2 robotic arm and Syntouch Biotac sensors.
- Enhanced the device's sensitivity and accuracy through algorithmic controls developed in MATLAB and Robot Operating System (ROS), achieving a 99.5% detection accuracy rate.
- Designed this solution to maintain patient confidentiality and data integrity, contributing to secure remote health diagnostics with advanced sensing capabilities.

MRI Brain Tumor Detection — Aug 2022 – Dec 2022

- Spearheaded the development of a brain tumor detection and segmentation process using MRI imaging, focusing on precision and reliability in diagnostic workflows.
- Designed and implemented a MATLAB-based algorithm with advanced noise reduction and segmentation functions, improving detection accuracy to 80% and reducing processing time by 75%.
- Collaborated with medical imaging specialists to validate the system, ensuring adherence to industry standards and readiness for clinical deployment through rigorous testing and documentation.

A Novel Strategy for Neuroblastoma Treatment — Jan 2022 – Aug 2022

- Engineered and optimized neuroblastoma treatment devices using COMSOL Multiphysics to simulate and analyze joule heating for safe, effective thermal performance.
- Improved thermal safety and efficiency through finite element analysis, ensuring compliance with regulatory requirements.
- Developed energy-efficient circuit designs in EAGLE PCB to enhance device precision.

MRI Thermal Effects Analysis — Jan 2022 – Aug 2022

- Conducted an in-depth study on MRI thermal risks for patients with implants, simulating RF-induced heating effects on various implant types.
- Utilized Sim4Life software to model specific absorption rates (SAR) and analyze implant temperature changes, enhancing safety protocols in MRI procedures.
- Created a detailed safety protocol guide based on this study to support clinicians in minimizing thermal risks for implant patients, improving overall MRI safety by accurately predicting thermal effects

EDUCATION

George Washington University — Master of Science - ***Biomedical Engineering*** — GPA: 3.70/4 — Washington, DC
Medical instrument design, Cell & molecular imaging, Socially assistive robotics – Telemedical, Bioelectromagnetic — Dec 2023

Sharda University — Bachelor of Technology – ***Biotechnology*** — GPA: 3.30/4 — Greater Noida, India
Macromolecular Biology, Immunology, Stem Cells, Plant & Animal Biotechnology, Enzymology, Biosafety regulations, and IPR — May 2021

SKILLS

Design, Simulation & CAD: SolidWorks, Fusion 360, COMSOL (FEA), Sim4Life, Eagle PCB, Design for Reliability and Manufacturability (DRM), Microfluidic Device Design, Point-of-Care Device Development.
Software & Data Analysis: MATLAB (Image & Signal Processing), Python (Scripting, Data Analysis), Robot Operating System (ROS), Minitab.
Quality & Regulatory: ISO 13485, IQ/OQ/PQ, FDA 21 CFR, Lean Six Sigma, FMEA/DFMEA/PFMEA, GMP, Medical Device Risk Management (MDR), Quality Management Systems, Technical Report Writing.

CERTIFICATIONS

Medical Device Process Validation (FDA, 21 CFR, ISO 13485): Focused on **validation, compliance, and risk analysis.**
Lean Six Sigma Foundation: Focused on **process improvement methodologies, statistical analysis, and waste reduction.**
Quality Management Certification: Focused on **quality assurance, process standardization, and optimization for efficiency.**
Operational Excellence Foundations: Certification focusing on principles of process optimization**, waste reduction, and achieving operational efficiency.**
Biomedical Equipment Repair and Maintenance: Certified by Delft University of Technology, **focusing on critical device upkeep.**
Healthcare Technology Management: Certified by Delft University of Technology, **trained to enhance performance and safety in clinical settings.**