Dr Kow Jun Wai

Medical Device Development Engineer
PhD Mechanical Engineering in Soft Robotics: Surgical Technologies & Medical Devices
BEng, MSc Mechatronics & Robotics Engineering

Email LinkedIn Web CV Tel: +4407741151955

Work Experience

Medical Device Auditor – EIMEA Client Manager – BSI (May.2024 – Present)

Medical Device Auditor for ISO 13485 Quality Management Systems and processes against BSI standards and legal requirements, such as the Medical Devices Directive MDD 93/42/EEC. The role covers clients based across Europe, India, Middle East and Africa regions, apart from the UK. To help medical device companies improve on performances, compliancy and safety on their products according to standards.

- Conducting compliant quality management system assessments at client locations in the EIMEA (Europe, India, Middle East & Africa) region and as well remotely.
- Establish and develop an effective partnership with BSI stakeholders, which secures the commercial relationship and encourages opportunities for business development and increased client satisfaction.
- Manage, Plan and Maintain workloads to provide accurate prompt information to support services.

Medical Device Development Engineer – Atlas Endoscopy Ltd (Aug.2020 – May 2024)

Lead systems developer towards device integration, and management of operator controls on a robotic endoscope platform for a novel robotic arm assisted endoscopic capsule device.
Atlas Endoscopy, UK, spin-off company from STORM Labs, University of Leeds.

- Lead the design, development, and testing of advanced endoscope systems, with a focus on colonoscopes.
- Oversee the integration of cutting-edge technologies such as imaging, optics, and robotics to improve colonoscope functionality and performance.
- Directed and executed detailed design reviews and performance design FMEAs, ensuring compliance with MDR standards for regulatory submissions and approvals (MHRA, UK; IRB/FDA, US).
- Led device development and integration of endoscopic robotic systems with NHS hospital systems, fostering seamless compatibility and collaboration with Leeds General Infirmary and St James University Hospital (UK), as well as Vanderbilt University Medical Center (US).
- Oversaw usability and validation tests with partnered clinical staff to evaluate the efficacy of product design requirements, aligning development with user needs and clinical best practices.
- Lead cross-functional reviews to conduct risk assessments, quality management, and validation activities, ensuring that all products meet or exceed regulatory expectations and ensured adherence to rigorous regulatory standards including ISO 13485, IEC 60601, ISO 8600, ISO 14971, ISO 15189, ISO/IEC 17025, and ISO 10218, safeguarding product conformity and quality.
- Led as a systems and software engineer for the inception and development of a ground-up colon simulator training kit, demonstrating prowess in innovative medical training technology development.

Research Associate in Medical Device Development – STORM Labs (Oct.2019 – Aug.2020)

Prior to completion of my PhD, was scouted into a budding spin-off company to drive the development of a robotic endoscope platform and design system integration devices to existing hospital technologies and operations for clinical investigation.

- Engineered and designed an ergonomic hand-held device to control a 6-DOF robotic arm (LBR MED - KUKA Robotic Arm), integrating onboard electronics, demonstrating adeptness in medical device design and development.
- Orchestrated the seamless integration of standard endoscopic ancillary functions into a bespoke hand-held device on a robotic platform, ensuring optimal functionality and clinical compatibility.
- Executed comprehensive risk management plans, assessments, and analyses on project sub-systems, ensuring adherence to regulatory requirements and mitigating potential hazards.
- Oversaw the operational effectiveness of system development and deployment, ensuring alignment with project goals and objectives while maintaining compliance with industry standards.
- Collaborated on pre-clinical assessments of developed systems in animal and/or cadaveric models in partnership with clinical collaborators, enabling real-world validation of system performance and safety.
- Provided expert guidance and support on bespoke soft-manufacturing methods for ongoing research work within STORM Labs, contributing to the advancement of innovative medical device technologies.

- Adhered to regulatory standards such as ISO 13485, ISO 8600, and IEC 6060-1, ensuring that all developmental activities align with international medical device regulations and quality standards.

Education

University of Leeds, School of Mechanical Engineering (UK): 2016-2020

PhD Mechanical Engineering in Soft Robotics: Surgical Technologies

Thesis Title: Development of a Fabrication Technique for Soft Planar Inflatable Composites

University of Leeds, School of Electronics & Electrical Engineering (UK): 2014-2015

MSc Mechatronics & Robotics Engineering- ***Pass with Distinction***

MEIBioEng15: Towards Self-Tuning Lower Limb Prothesis

University of Leeds, School of Electronics & Electrical Engineering (UK): 2011-2014

BEng Mechatronics & Robotics Engineering- ***First Class Honours***

Dissertation Title: Artificial Intelligence Based Control on a Solar Energy System

Certification & Training

- BSI – ISO 13485:2016, ISO 9001:2015, MDR(EU 2017/745), MDD(93/42/EEC), AIMDD(90/385/EEC), UK MDR 2002.
- Quality Management System for Medical Device Directives - PA Consulting, UK
- Certified SOLIDWORKS Associate (CSWA) Graphic
- Certified LabVIEW Associate Developer (CLAD), National Instruments UK & Ireland
- Code-cademy- Web Development (HTML, CSS, JavaScript) and Python 2/3
- ALLSAFE-Food Hygiene Distance Learning course, Advance Food Safety Ltd, UK

Interests & Skills

- **Manufacturing Experience:** Additive manufacturing (FDM, SLA, SLS, CL); Laser cutting/engraving; CNC machining; Vacuum casting; Moulding and Casting (Including Extrusion, Die and Injection);
- **IT Competency:**
  - **Programming languages**: C/C++ ; MATLAB; NI LabView; Python; HTML; CSS; ROS;
  - **Computer Aided Design**: Solidworks; SketchUP; OpenSCAD; Autodesk Fusion 360;
  - **Graphic Design**: Adobe Illustrator; CorelDRAW; Inkscape;
  - **Electrical/Electronic Design**: NI Multisim; Eagle PCB;
  - **Finite Element Analysis (FEA)**: Abaqus FEA.
- **Productivity:** Microsoft Office suite- Slack; Trello; Obsidian; VSCode, Notion.