AVEREE CHANG

VENTRIC HEALTH *Los Angeles, CA*

Vice President, Product Strategy Nov 2023-Present

Reports directly to the Chief Executive Officer.

Key Areas of Expertise

- Develop and execute a comprehensive product strategy aligned with teh company's overall vision, goals, and market dynamics
- Define product roadmaps, prioritize feature development, and establish product requirements based on market insights, customer feedback, adn business objectives
- Monitor product performance adn market trends, gather customer feedback, and iterate on product strategies to continuously improve product offers adn drive business growth

VEKTOR MEDICAL *San Diego, CA*

Vice President, Product May 2022-Nov 2023

Reports directly to the Chief Executive Officer.

Key Areas of Expertise

- Led a cross-functional team consisting of software, hardware, and manufacturing engineers throughout all stages of development and launch for vMap v.1.2, vMap's next-generation hardware and software iteration, ensuring timely delivery and adherence to FDA standards.
- Defined project scope, objectives, and milestones while allocating resources efficiently for a complex project spanning 18 months.
- Coordinated with stakeholders, including senior executives and KOL advisers to understand requirements, address concerns proactively, and ensure alignment with strategic goals.
- Managed end-to-end strategic planning cycles, overseeing budget allocation, resource allocation, and performance tracking, resulting in a streamlined planning process and improved alignment across departments. • Led strategy sessions with senior leadership, providing counsel on planning and budgeting activities and increasing product-market fit.
- Hosted product feedback meetings and implemented mechanisms where internal team members and customers could provide feedback about the product. Additionally, collaborated in IRB and research partnership to incorporate KOL and customer needs into the product roadmap.

Director, Product Development Oct 2021-May 2022

Reports directly to the Chief Operations Officer. Managing, implementing, and monitoring Vektor Medical's product development and related processes.

Key Areas of Expertise

- Oversaw the entire product life cycle from ideation to end-of-life stage, proactively gathering customer feedback through surveys and user testing.
- Collaborated with departmental leaders to identify key value levers, resulting in an increase in developmental efficiency within six months.

Director, Quality Systems June 2020-Oct 2021

Responsible for implementing and maintaining Vektor Medical's Quality Management System according to regulatory requirements and company policies.

Key Areas of Expertise

- Acted as Management Representative responsible for scheduling and conducting comprehensive quality system reviews, ensuring compliance with 21 CFR 820, ISO 13485 standards, and internal policies.
- Oversee all aspects of the Quality Management System (QMS), including process establishment, implementation, and maintenance, resulting in a streamlined workflow and enhanced efficiency.
- Supported company goals and objectives by implementing and maintaining policies, procedures, and Good Manufacturing Practices (GMP), resulting in a successful FDA and ISO compliance record.
- Proactively updated the executive team on work status, identified areas for improvement, and provided actionable recommendations that led to enhanced quality control processes and reduced errors.
- Played a pivotal role in external audits conducted by notified bodies, ensuring thorough preparation, accurate documentation, and effective communication, resulting in consistent compliance and zero non-conformances.

APPLIEDVR *Los Angeles, CA*

Sr Director, Quality Nov 2020-May 2021

Reports directly to the Chief Executive Officer.

Key Areas of Expertise

- Managed end-to-end strategic planning cycles, overseeing budget allocation, resource allocation, and performance tracking, resulting in a streamlined planning process and improved alignment across departments. • Reviewed and integrated corporate strategies to support a 10-site uptake objective while ensuring punctual delivery, efficient resource utilization, and adherence to strict quality standards.
- Led strategy sessions with senior leadership, providing counsel on planning and budgeting activities and increasing product-market fit.

EXPERIEN GROUP *San Diego & San Jose, CA*

Software Quality Engineer Manager Sept 2019-May 2020

Reports directly to the Chief Quality Officer.

Key Areas of Expertise

- Manages and executes software projects for Quality Management System (QMS) development, implementation, and compliance beginning in the product design phase and continuing through submissions, regulatory approvals, and commercialization activities.
- Experienced Software Quality Engineer with more than eight years of experience in the medical device industry, working in a wide variety of product areas and supporting device development. • Oversees design development programs to comply with FDA and CE Marking requirements including biocompatibility ISO 10993 series, design verification, and validation testing requirements. • Oversees and implements Design Control software projects and Software Lifecycle Management. • Expert in compliance to EN ISO 14971:2012, IEC 62304, FDA's Electronic Records; Electronic Signatures 21 CFR Part 11, FDA's Quality System Regulation 21 CFR Part 820, IEC/TR 80002-1:2009, Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software, ISO/TR 80002- 1:2017, Medical device software – Part 2: Validation software for medical device quality systems, AAMI TIR45:2012, Guidance on use of AGILE practices in development of medical device software and NIST SP800 series, cybersecurity.
- BSI Lead Auditor certified in compliance with ISO 13485:2016, general requirements for basic safety and essential performance collateral standards for IEC 60601 electrical equipment series of standards and IEC 82304-1:2016 Health Software.
- Expert in software validation, including software validation within design controls (verification/validation) and computer systems validation (CSV) (i.e., validation of SAP, SDFC), software lifecycle management, and experience in usability engineering standards.
- Serves as client companies' Acting Head of Quality and performs Quality Management Systems activities with extensive expertise in compliance for Class I and II medical devices.
- Supports compliance with medical device usability/human factors requirements.
- Oversees compliance with IEC 60601 electrical equipment series of standards.
- Expert in cleaning validation/process validation and validation of EM monitoring systems such as Siemens Design CC.
- Experience in supporting projects for controlled environment room commissioning, qualification, maintenance, and controlled environment monitoring.
- Institutes manufacturing process validation risk-based approach, including process validation protocol report development for installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ); established controls for changes in process and product and is also familiar with the design of experiments (DOE).
- Serves as project leader, manages Design Control process, and manages cross-functional teams. • Manages and directs Document Control activities.
- Performs gap analyses and internal audits of client companies' Quality Management Systems and generates subsequent reports.
- Confirms regulatory strategies and develops device master test plans, including bench testing, human factors, software verification/validation, sterilization, and Part 11 testing (e.g., authentication/authorization, audit trails).
- Possesses significant product experience with significant risk technologies, non-significant risk technologies, In

Vitro Diagnostics (IVDs), capital equipment, software as a medical device, and combination products, including intraoperative Neuromonitoring Equipment (e.g., electromyographic, motor evoked potentials, and somatosensory evoked potentials), Computer Assisted (CAS) surgical systems, customized SDFC system, ERP systems, MES systems, mobile applications for iPhones and Androids, SaaS/PaaS/Iaas cloud-based systems, and systems with single sign-on (SSO) and active directory (AD) account capabilities.

ILLUMINA *San Diego, CA*

Senior Software Quality Engineer Sept 2017-Aug 2018

Represented the company in software quality management activities and supported company software releases.

Key Accomplishments

- Involved in software configuration management, release management, software development lifecycle, risk management, and computerized system validation process improvement initiatives, aligning current procedures and practices with ISO 13485:2016 requirements.
- Conducted code reviews, drove defect tracking, and implemented CI/CD tools.
- Worked alongside software developers to implement efficient deployment processes and collaborated with test engineers to set up automation.

NUVASIVE *San Diego, CA*

Senior Quality Engineer Mar 2016-Aug 2017

Ensured compliance and product quality to update the company's Design Control procedures and documentation.

Key Accomplishments

- Led design control activities throughout NPI product design, development, and production transfer. • Supported the company's surgical platform for intraoperative neurophysiological monitoring (IOM) during spinal surgery and for assessing and restoring spinal deformities.
- Maintained cloud-based streaming technology, allowing physicians to monitor patient vitals in real time. • Supported the company's CAS technology.
- Implemented software reliability model (Rayleigh's) to forecast software reliability and establish a quantitative threshold for quality acceptance, defining "ready for release", and thus reducing post-launch complaints and non-conformances by 40%.
- Revamped the company's Design Control Standard Operating Procedure (SOP) to align with current software development practices and ensured utilized software development methodologies were managed and controlled within QMS requirements.
- Provided quality support for CAPAs related to designated products and product lines.

Validation Engineer April 2014 – Feb 2016

Key Accomplishments

- Led validation for software medical device systems and provided documentation (design and development plans, risk assessment reports, user/functional requirements, test protocol/reports, trace matrices, design reviews) and executed validations for 510(k) clearances, clinical evaluation releases, and subsequent product launches.
- The managed qualification process for semi-automation of the NuVasive Loaner Product Inspection/Acceptance Criteria (LPAC), outlining processes by which the company received, stored, and issued materials from the program.
- Oversaw data migration efforts from Documentation and Sharepoint 2010 company's Sharepoint 2013 platform.
- Collaborated with IT to create a new IOS site within the company's platform, providing wireframes, designating permission groups and levels, generating workflows, and validating and implementing commercial off-the-shelf electronic signature software.
- Conducted verification and validation to measure anatomical pelvic parameters and assisted with premarket clearance for the company's medical mobile application.

PSC BIOTECH *Pomona, CA*

Consultant Feb 2013 – Mar 2014

Managed various qualification processes for Sales Force Automation and performed Quality Review of IT Infrastructure Network user acceptance tests.

Key Accomplishments

- Responsible for gathering user requirements from relevant stakeholders, user acceptance testing, formal

validation testing, defect tracking and resolution, training, and change in management.

- Managed gathering and finalizing user and functional requirements and master validation strategy. • Led qualification process and generated QMS deliverables for QC Analysis Software, AAA- Amino Acid Analysis Project.
- Conducted qualification process in HP Quality Center for cloud-based Sales Force Automation (mobile application DocuSign).
- Managed the qualification process for Data Loss Prevention System including on-premise data discovery, monitoring, and enforcement.
- Assisted in the development of QMS deliverables for ERP system (SAP).
- Collaborated on development qualification protocols for virtualized server environments that serve as an Infrastructure-as-a-Service (IaaS).
- Performed Manufacturing Equipment Qualification and developed, reviewed, and executed validation protocols (IQ/OQ/PQ) for equipment used in the production of tablets, caplets, ointments, and gels. • Performed Equipment Cleaning Validation; developed and executed cleaning protocols for industrial mixers and triturate tablet machines.
- Conducted Laboratory Equipment and Computerized Systems validation.
- Performed Process Validation; developed and executed validation for sterilization process utilizing SAP and multiple distribution centers in CA and MA.
- Ensured all validation documentation complied with company policies/SOPs and regulatory standards such as Annex 11, Annex 15, 21 CFR Part 11, cGMP, cGAMP, GDP, and ICH.

EDUCATION

University of California, Berkeley *Berkeley, CA* Bachelor of Sciences, Bioengineering 2012

PUBLICATIONS AND PRESENTATIONS

- **Proof-of-Concept Forward-Solution Mapping of a Focal Atrial Tachycardia Origin using the Outpatient 12-Lead Electrocardiogram**
  Liu, T. I., Villongco, C., Chang, A., Chen, C.-I., Bhatnagar, P., Schulte, C., Kirkland, L., Aiello, N., Márton, C., Ho, G., & Krummen, D. E. (2023). MP-453088-7 proof-of-concept forward-solution mapping of a focal atrial tachycardia origin using the outpatient 12-lead electrocardiogram. *Heart Rhythm*, *20*(5). https://doi.org/10.1016/j.hrthm.2023.03.476
- **Comparison of Array Comparative Genomic Hybridization (aCGH) to FISH and Cytogenetics in Prognostic Evaluation of Chronic Lymphocytic Leukemia**
  O'Malley DP, Giudice C, Chang AS, Chang D, Barry TS, Hibbard MK, Chen R, Chen ST. International Journal of Hematology. 2011;33(3):238-44
- **DLBCL and the 2008 WHO: What Does Subclassification Cost?**
  AS Chang, C Giudice, D Chang, TS Barry, S Chen, MK Hibbard, R Chen, LABORATORY INVESTIGATION 90, 290A-290A