Thi Nguyen, MBS, RAC (US), CQE, CSQE
(510) 304-5465
habit2mindset@gmail.com

STANDARDS AND REGULATIONS

Quality System (ISO 13485, FDA 21 CFR 820); Risk Management (ISo 14971); Software Development (ISO 62304); Medical Electrical Equipment testing (ISO 60601); Material regulations (RoHs, Reach, Prop 65)

CERTIFICATIONS

Lead Auditor ISO 13485:2016	Issued 2017 (BSI)
Certified Quality Engineer	Issued 2012 (ASQ)
Certified Software Quality Engineer	Issued 2013 (ASQ)
Regulatory Affairs Certification US	Issued 2018 (RAPS)

EXPERIENCE SUMMARY

Implemented Quality Systems for rapid new product development
Expert in Design Controls, ISO, CE for Class I, and II medical devices in durable electronics and sterile disposables
Systems used: Arena, Enzyme, GreenLight Guru, Jama, Jira, ManufactPro, ALM SAP, Agile, Trackwise, Virje

EXPERIENCE

Director of Quality, Head of Quality (*promoted from Sr Manager, QE)* Dec 2019 - Jan 2024, Mountain View, CA
Willow: Wearable breast pump

- Management Representative.
- Lead Quality engineer for hardware and software development for breast pumps.
- Planned and led 60601 and biocomp assessment and testing.
- Managed production issues, production releases, and supplier evaluations and issues.
- Improved complaint processing and assisted with complaint assessments.
- Planned and led internal audits and external audits (MDSAP) ending in no major non conformances.
- Written a traditional 510(k) for a new product and for an existing product.

Quality Assurance Director Jan 2018 - Dec 2019, San Francisco, CA
TheraNova, LLC: Incubator; Practical solutions to large markets with unmet needs.

- Management Representative and managed multiple Quality Systems.
- Prepared quality system statistics to share with senior management and departments.
- Provided regulatory pathway guidance for feeding tube and respiratory controller.

Design Development Quality Officer (Consultant) Jan 2016 - Dec 2017, Best, the Netherlands
Philips Healthcare: Image Guided Therapy business unit focusing on software for interventional procedures

- Defined clear expectations with R&D.
- Supported company-first augmented-reality surgical navigation NPI for EU release.
- Key quality officer in the innovation unit developing investigational devices for clinical studies.

Quality Assurance Manager Mar 2014 - Jan 2016, San Francisco, CA
TheraNova, LLC: Incubator; Practical solutions to large markets with unmet needs.

- Maintained two completely separate Quality Systems (TheraNova and its spinoff company).
- Lead representative for two internal audits, resulting in 0 non-conformances.
- Product received 510(k) clearance in 4 months. Supported 4 IRB studies.

Quality Engineer Oct 2012 - Jan 2014 Menlo Park, CA
Velomedix, Inc (start-up): Induce mild therapeutic hypothermia in heart attack patients.

- Established risk management (ISO 14971) and software development (IEC 62304).
- Developed a new process to comply with the introduction of RoHS regulation.
- Revamped the Tool Control process to reduce confusion on how to maintain validated tools.

Quality Engineer III Jun 2008 - Sep 2012, Sunnyvale, CA
Stellartech Research Corp.: Contract design, development, and manufacturing of capital and disposable devices.

- Successfully obtained first 60601-1 3rd Ed certification and compiled a compliant IEC 62366 usability file.
- Created an in-house Track Training Software, which resulted in reduction of late training.
- Improved Service and Complaint database to address findings and to improve reporting.

EDUCATION

Keck Graduate Institute of Applied Life Sciences (KGI), The Claremont Colleges
Master of Bioscience (MBS), *Focus:* Medical Devices & Diagnostics

University of California, Davis
Bachelor of Science, *Major:* Biological Systems Engineering, *Minor:* Technology Management