QIAOCHU (ANDY) ZHANG

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EXPERIENCE

Abbott, Heart Failure — *Pleasanton, CA*
Senior Regulatory Affairs Specialist — *Apr 2023 - Present*
Regulatory Affairs Specialist I, Specialist II — *Jun 2019 - Aug 2021, Aug 2021 - Apr 2023*

- Leads regulatory strategy for global product commercialization and software development and system design changes to the HeartMate Touch Communication System for clinical monitoring of LVAD patients
- Coordinates regulatory affairs activities and directly interfaces with regulatory agencies for CAPA and FSCA resolutions
- Directs Heart Failure business unit decisions and resources for division-wide regulatory procedure harmonization and development collaboration and regulatory intelligence activities
- Maintains Class III active implantable product registrations and regulatory documentation, supports site quality and compliance activities, and participates in audits as regulatory subject matter expert
- Supported successful EU MDR registration and CE Marking of the HeartMate 3 LVAS by leading cybersecurity, software, and non-clinical testing areas of the Class III implantable technical file
- Provided regulatory support and strategy for new product development activities including Pre-submission for battery testing plan for the fully implantable HeartMate 3 LVAS which received FDA Breakthrough Device designation
- Authored and successfully obtained approval for 25+ regulatory submissions for PMA, IDE, AIMDD, and EU MDR pertaining to software, design, manufacturing, and labeling changes
- Mentors junior specialists on ongoing projects and procedure and regulatory compliance
- Chairs chapter of the ALCN employee network for site-wide DEI, development, and community outreach initiatives

Equalize Health (formerly D-Rev) — *San Francisco, CA*
Design Engineering Intern — *May 2018 - Aug 2018*

- Developed a neonatal CPAP device to lessen the burden of clinicians in under-resourced hospitals
- Assembled proof of concept prototype for field testing and clinician feedback from hospitals in India
- Designed digital and physical user interfaces for user testing at Stanford Children's Hospital

Procyrion — *Houston, TX*
Product Development Consultant — *Mar 2017 - May 2018*

- Designed fixtures and performed functional testing for the Aortix system prior to successful first-in-human testing

LivaNova, Neuromodulation — *Houston, TX*
Regulatory Affairs Intern — *May 2017 - Aug 2017*

- Registered Class III VNS devices with NMPA for expansion into Chinese market of 36 million patients
- Led initial efforts for EU MDR remediation for Class III implantable technical files of the VNS product line
- Assisted in FDA IDE submission for new feature resulting in clinical feasibility trial launch in 2018

SKILLS

Regulatory Strategy, Regulatory Assessment, Regulatory Submissions, Regulatory Intelligence, Project Management, Procedure Development and Training, **Medical Device Standards:** Quality Management Systems (ISO 13485), Risk Management (ISO 14971), Software Lifecycle (IEC 62304), Embedded Software (IEC 60601-1), Software as Medical Device (IEC 82304-1), Human Factors and Usability (IEC 62366), Biological Evaluation (ISO 10993)

EDUCATION

University of California, Berkeley — *Berkeley, CA*
Master of Engineering in Bioengineering — *Aug 2018 - May 2019*

Rice University — *Houston, TX*
Bachelor of Science in Bioengineering, Minor in Global Health Technologies — *Aug 2014 - May 2018*