ANDREW MOK

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EDUCATION

***Bachelor of Science: Biomedical Engineering*, The College of New Jersey**
Honors: Dean's List
Activities: The College of New Jersey Men's Tennis Team (Team Captain), Delta Tau Delta Fraternity (Member)

TECHNICAL SKILLS/CERTIFICATIONS

- SolidWorks
- ANSYS
- Computational Fluid Dynamics (CFD)
- C++
- HTML, CSS, JavaScript
- Git
- Microsoft Office Suite
- Minitab
- MATLAB
- Technical Report Writing
- Certified Lean Six Sigma Green Belt (December 2022)

PROFESSIONAL EXPERIENCE

Sustaining Engineer, Cook Medical (October 2021-October 2022)

- Managed over 5 design history files (DHFs) and pushed late projects ahead by 3-6 months through proactive task management and streamlined workflow for anticipated EUMDR, APAC, and FDA submissions
- Collaborated and coordinated with cross-functional working groups consisting a total of 12 people including R&D, subject matter experts, regulatory affairs, quality engineering, medical affairs, and strategic business unit to push deadlines for project tasks
    - Presented information and completed tasks to senior management
    - Reviewed and provided feedback for over 20 technical documents which aided in pushing projects ahead of schedule
- Worked within a quality management system (QMS) and built project plans, standard assessments, technical analysis, clinical evaluation assessments, instructions for use content, hazard analysis (severity, probability, harms caused by identified hazardous situations, and risk scoring), failure mode and effects analysis (FMEA), biocompatibility reports, design verification and validation test plan (V&V), and other technical documents
- Utilized working knowledge of various policies including cGMP, ISO 13485, ISO 14971, and 21 CFR 820 in a FDA-regulated environment to efficiently create documents within the DHFs
- Monitored status of documents in Agile Product Lifecycle Management (PLM) and pushed over 30 documents to its released stage with the cooperation of other cross-functional teams

Community Advisor, TCNJ

- Integrated safety policies and built a community for 58 residents on my floor by initiating community events and developing core values of diversity respect, and relationships amongst the residents
- Assisted, resolved, and provided resources for all social conflicts that arise among residents

ENGINEERING PROJECTS

Senior Design Project: Enhance Fixation of Hip Implants

Mentored by Dr. Christopher Wagner

- Implemented the engineering design process to create a novel hip implant with increased life-span by reducing aseptic loosening caused by stress shielding
    - Worked within Design Control Process (21 CFR 820.30)
- Created technical reports for FDA Regulation documentation including validation and verification testing protocols (V&V) to ensure product function and meets specifications
- Built technical documents such as standard assessments, user requirement specifications, and risk analysis (design failure mode and effects analysis (DFMEA) and use failure mode and effect analysis (UFMEA)
- Managed a $500 budget on Excel involving the ordering of material
    - Successfully designed a mechanically viable hip implant utilizing SolidWorks techniques to address aseptic loosening
    - Communicated with biomedical engineering advisors to develop design inputs and design solutions
    - Updated website weekly to showcase and present the team's progress and accomplishments http://engprojects.tcnj.edu/femoralstem-21/