

Education

University of Pennsylvania -School of Engineering & Applied Science (Expected 2024)

- Master of Computer and Information Technology, GPA 4.0

University of California – Berkeley (2017- 2020)

- Bachelors (double major) in Molecular & Cell Biology and Economics, GPA 3.761, Dean's list & graduation with honor

Selected Skills

- Knowledge and experience with Python, Java, C, JavaScript, HTML/CSS, React.js, REST API, Node.js, MongoDB, SQL, R/RStudio, Stata, Git/GitHub
- Highly skilled in computer applications (Microsoft Office, G-Suite, Veeva, SAP GTS)
- Extensive regulatory affairs (FDA, MDR), operations, and product development experience for medical devices (inc. SaMD)
- Expert in technical writing, collaboration, critical thinking, effective communication, and project management

Selected Software Projects (Portfolio: <https://chenwmichael.github.io/portfolio-website/>)

Syzygy Custom-Search Engine (2023)

- Engineered a Java-based multi-threaded web crawler emphasizing resource efficiency and data comprehensiveness.
- Implemented advanced indexing with Key-Value Store, utilizing TF-IDF and PageRank for relevant search result ranking.
- Developed a user-friendly frontend using HTML/CSS and JavaScript, featuring live suggestions and cached/nested pages.
- Enhanced security with XSS attack safeguards and scalability for increased traffic handling.
- Created a responsive UI design for optimal performance across various devices and screen resolutions.
- Introduced unique functionalities like SEO diagnostic mode and image search.
- Utilized asynchronous JavaScript and integrated RESTful APIs for dynamic content and efficient data handling.

Group Sports Queue (2024) - <https://github.com/ChenWMichael/group-sports-queue>

- Engineered a full-stack application for real-time game queuing in group sports, adaptable across various sports.
- Developed the backend using Node.js and Express.js, integrating RESTful APIs for dynamic content delivery.
- Crafted a responsive frontend with React.js and asynchronous JavaScript, featuring a draggable/droppable queue
- Optimized for mobile browsers, ensuring a seamless user experience on various devices.
- Utilized MongoDB Atlas Cloud for robust data services and Fly.io for global deployment and performance.
- Implemented live update functionality to synchronize user sessions in real time.

React-based Portfolio Website (2023) - <https://github.com/ChenWMichael/portfolio-website>

- Rapidly developed a React-based interactive portfolio website, demonstrating accelerated skill acquisition.
- Implemented dynamic UI components and state management in React to create an interactive and responsive user experience.
- Utilized Email.js for establishing direct user communication features, facilitating integration of contact functionality.
- Employed CSS techniques and JavaScript for creating visually appealing and intuitive clickable images and popups.
- Integrated social media links using React components, enhancing connectivity and user engagement with external platforms.

Work Experience

Regulatory Affair Specialist, Abbott, Medical Device Business Units

Aug. 2021 – Apr. 2023

- Medical Device Regulatory Affairs Development (RAD) Program
 - Global Regulatory Service Division: Managed global product licenses, international remediation plans, KPIs, and QMS processes. Collaborated with cross-functional teams worldwide
 - Structural Heart Division (Amplatzer Devices): Led MDR submission for TorqVue 2 Delivery Sheath; supported various MDR submissions, FDA annual reports, and regulatory documentation for Occluders and Delivery Sheath devices
 - Heart Failure Division (CardioMEMS Devices): Oversaw FDA and Health Canada annual reports, TUV change notifications, and Quality Lifecycle Management for software and devices. Product development for SaMD and next-generation devices.
- Education and Coordination
 - Conducted monthly lunch and learn sessions on SaMD FDA regulations for non-regulatory staff.
 - Coordinated various RAD Program activities, earning multiple gold/silver excellence performance awards.

Regulatory Medical Writer & Project Coordinator, International Consulting Group Inc., San Jose, CA

Oct. 2020 – Aug. 2021

- Crafted and revised key regulatory documents (clinical trial protocols, study reports, pre-IND briefings, INDs, IBs, PMRs) for diverse healthcare products (biologics, pharmaceuticals, medical devices, combination products).
- Produced research materials (manuscripts, abstracts, posters, presentations) for academic journals and conferences.
- Performed QA/QC audits on various clinical and regulatory documents, ensuring accuracy and regulatory compliance
- Managed communications with over 14 clients, trained new staff, and efficiently handled multiple project coordination.

Undergraduate Internships

- Market Research Analyst, FightPandemics, Inc.
- Student Intern - Mental Health Ambassador, Neolth, Inc.
- Undergraduate Researcher for Economics, Prof. Hawkins, Dept. of Economics, UC Berkeley
- Undergraduate Researcher for Molecular Biology, Stahl Lab, Dept. of Nutritional Science and Toxicology, UC Berkeley