Michael Chen
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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, 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

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.

Data Analysis Application for COVID-19 and Property Data (2023)
- Developed a Java application for in-depth analysis of COVID-19 statistics, property values, and demographic data, with advanced parsing of CSV and JSON formats for actionable insights.
- Implemented efficient data structures and design patterns (Singleton, Strategy) for robust, scalable application architecture.
- Utilized N-tier architecture for clear modularization, improving maintainability and data processing efficiency.
- Integrated comprehensive error handling to maintain data integrity and reliability, essential for real-world datasets.
- Efficient data management and memory optimization techniques including memoization, to handle large datasets effectively.

LC4 Reverse Assembler and Memory Management Tool (2023)
- Developed a C program for reverse assembling .obj files from PennSim into LC4 assembly
- Dynamic linked list to model LC4's program and memories, mirroring PennSim's functionality for memory management.
- Implemented advanced bitwise operations for accurate translation of binary instructions into LC4 assembly
- Incorporated robust error handling, GDB debugging, and used Valgrind for memory leak prevention, ensuring tool reliability.
- Focused on proficient memory management, addressing challenges in allocation to maintain tool integrity and performance.

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