Shinichi Miyakawa

miyakawashi@gmail.com ❖ (614) 578-2539 ❖ Columbus, OH

WORK EXPERIENCE

PSC Biotech **Feb 2021 – Present**

CSV Consultant – Veeva Systems *Columbus, OH*

- Ensure the compliance of computerized systems to regulatory requirements, including but not limited to 21 CFR Part 11.
- Provide authoring, review, and approval of validation documents developed by validation teams, ensuring that software meets functional requirements and quality standards.
- Draft and execute validation documentation, qualification test scripts (IQ/OQ/PQ) and reports.
- Translate system requirement specifications into executable validation protocols with an emphasis in base application functionality, Quality Management Systems (QMS), and Regulatory Information Management (RIM) applications.
- Organization of business and functional system requirements, providing traceable historical data and construct linkage to relevant validation documentation.
- Participate in an Agile Development Scrum team consisting of validation leads, project management, and validation directors.

CSV Consultant – PSC Biotech – Internal Services

- Classification of FDA Form 483 inspection records to produce accurate supervised learning input data.
- Assessment of pre-mapped FDA inspection records for input accuracy.

EDUCATION

The Ohio State University **May 2020**

Bachelor's of Science, Applied Physics *Columbus, OH*

TOOLS/TECHNOLOGIES & INTERESTS

- **Tools & Technologies:**
  - Languages: Mongo.db, Express.js, React.js, Node.js (MERN Stack), Jquery, Selenium, Git, MS Office.
- **Interests:** Astronomy & Physics; Electric Bass; Snowboarding & Skateboarding