

Eric Chiu

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Quality Engineer with 4+ years of experience in the medical device industry seeking transition into Software Documentation Engineer roles within medical devices.

PROFESSIONAL EXPERIENCE

ALCON, Irvine, CA

Jul 2018 – Present

Product Line Quality Engineer

- Developed and revised procedures for clean room manufacturing in response to audit findings and corporate requirements
- Reduced amount of nonconforming material on production line by 54% (\$194,000) by validating potentially defective parts to be used for production
- Led investigation on supplier quality issue that involved components in manufacturing and final product, and facilitated communication between supplier and manufacturing team to resolve issue
- Determined root cause for complaint investigation that affected product on global scale and implemented CAPA and effectiveness checks to resolve and monitor issue from manufacturing standpoint

JOHNSON & JOHNSON MEDICAL DEVICES, Irvine, CA

Nov 2016 – Mar 2018

Quality Engineer Technician

- Conducted preventative maintenance and facilitated equipment calibration with vendors for 120 laboratory assets, as well as performing out of tolerance NCIs
- Performed instrument validation and PQ testing on equipment to be used for QA product release
- Reviewed and released engineering change orders for manufacturing plant setting
- Led change orders regarding hazardous waste mitigation strategy for QA test procedures

TAKEDA PHARMACEUTICAL COMPANY, San Diego, CA

Nov 2013 – Jun 2015

Pharmaceutical Lab Intern

- Led project to initiate electronic chemical inventory system for pharmaceutical lab
- Synthesized target compounds using wet laboratory techniques while documenting results in an ELN
- Performed daily system suitability of HPLCs and ran diagnostic tests for operational issues
- Provided wet laboratory and safety training for incoming interns in the department

AREAS OF EXPERTISE

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|--|---------------------------------|
| • Technical Writing for SOPs, Protocols, etc. | • Project Management |
| • Change Orders in Windchill & Veeva | • Root Cause Analysis |
| • Process & Equipment Validations (IQ, OQ, PQ) | • Python, Java, JavaScript, SQL |
| • ISO 13485 and FDA Quality Standards | • SAP & JDE ERP Systems |

EDUCATION

OREGON STATE UNIVERSITY

2020 - Present

B.S. Computer Science

GPA: 4.0

Courses taken: Intro to Java & Python, Database Admin, Computer Architecture & Assembly Language

Projected Graduation in 2022

UNIVERSITY OF CALIFORNIA, SAN DIEGO

2012 - 2016

B.S. Chemical Engineering, Minor in Business