

GENE J. YU

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EXPERIENCE

Validation Specialist

Dec 2020- Present

ALK-Abello Pharmaceutical Inc

Port Washington, NY

- Ensured company's equipment performs according to quality standards and that manufacturing processes are capable and qualified.
- Established validation protocols ensuring compliance with global regulations and corporate standards
- Authored, executed and followed up on closure documentations for Installation (IQ) Operational (OQ) and Performance (PQ) Qualifications
- Prepared summary reports, temperature mapping reports, gap analysis, risk analysis, failure mode & effect analysis, traceability matrices.
- Interfaced with levels of the organization on a daily basis observing the site's compliance to current Good Manufacturing Practices (cGMPs)

EDUCATION

Boston University College of Engineering

May 2020

Bachelor of Science in Mechanical Engineering, Concentration in Mechanical Engineering

Boston, MA

RELEVANT COURSEWORK

Product Design

Production Systems Analysis

Instrumentation

Product Quality

Supply Chain Engineering

Automation and Manufacturing

TECHNICAL SKILLS

Programs: XpertLog, Kaye Validator, AutoCAD, SolidWorks, CREO, MATLAB, MS Excel, LabView, Gibbs Cam

Machining: CNCs, mills, lathes, drill presses

PROJECTS

Senior Design Capstone Project: Functional Printing Station

Sep 2019 - May 2020

- Collaborated in a team of 2 to develop a functional printing station into upon the client's request
- Managed the operation of CREO and Solidworks in the team and design 2/3D prototype models
- Changed the structure of the printhead adapters to be sturdier
- Fixed previous team's designs of the electrical component stations, devising functional prototypes

Design and Implementation of an Optical Sensor

Sep 2019 - Dec 2019

- Utilized a mid-range distance DT50 sensor to measure the temporal and frequency responses of a mechanical 2nd- order oscillator
- Accurately analyzed system in free decay and steady state with MatLab and Excel
- Created a detail report and presented our findings to the class and professor

Jewelry Box Manufacturing Project

Jan 2019 - May 2019

- Manufactured a jewelry box operating a manufacturing cell involving scheduling, budgeting, and building
- Programmed UR5 robot's operations throughout the assembly line
- Planned the product's cost and schedule
- Milled the product using the Hass Mini Mill

Arduino Controller

Jan 2019 - May 2019

- Built a product that uses a sensing device that uses real-world input to interact with entities in a virtual environment
- Designed the controller causing that housed the Arduino and the accelerometer sensor using CREO

OTHER EXPERIENCES

Media Service Student Manager

Jan 2018 - May 2020

BU Law Academic Media Services

Boston, MA

- Administered all classrooms, courtroom technology, and the School of Law's AV equipment
- Coordinated events, such as video conferences, lecture recordings, and all other events while overseeing a team of 13