

# Allen Kalampukattusery

San Jose, CA | allenjgk@gmail.com | 781-325-6568 | linkedin.com/in/allen-kalampukattusery | github.com/akalampukattusery

Quality control professional with 2+ years in cGMP-regulated pharmaceutical and biotech laboratories. M.S. in Bioinformatics (SJSU, 2025). Skilled in SOP authorship, batch record review, regulatory audit readiness, BSL-2 operations, molecular diagnostics, and bioinformatics pipeline development.

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## EXPERIENCE

### Quality Control Supervisor Sep 2021 – Jan 2023

*Lucira Health, San Jose, CA*

- Maintained cGMP-compliant QC operations for single-use molecular COVID-19 diagnostic devices in a BSL-2, ISO 13485-regulated medical device laboratory, working directly with SARS-CoV-2 positive clinical samples.
- Performed and supervised testing and data review on hundreds of diagnostic devices daily; verified accuracy, completeness, and compliance with specifications.
- Authored and revised SOPs, technical reports, and quality documentation to reflect current cGMP and ISO 13485 requirements; supported CAPA and deviation management.
- Reviewed batch records and QC data packages; performed complex data analysis and calculations to verify test results prior to product disposition.
- Supported regulatory audit readiness; established QC lab operations during production ramp-up. Calibrated instrumentation, troubleshooted method failures, and trained a team of 18 lab technicians on QC procedures, EHS protocols, and documentation standards.

### Research Associate Jan 2023 – Jul 2023

*Genista Biosciences Inc, San Jose, CA*

- Performed pathogen detection testing via DNA/RNA extraction, PCR, gel electrophoresis, and microbiological methods including plating, streaking, culturing, and isolation.
- Operated custom automated liquid handlers to process up to 800 samples per run; maintained calibration records, prepared media/buffers/reagents per SOPs, and refined workflows to improve reproducibility.

### Undergraduate Researcher Jun 2020 – May 2021

*Bennett Lab, UC Merced*

- Performed RNAi experiments in planthoppers including RNA/DNA extraction, PCR, gel electrophoresis, and Qubit fluorometry for nucleic acid concentration and purity quantification.
  - Assembled and curated 3 bacterial endosymbiont genomes from raw sequencing data; conducted pairwise evolutionary divergence analysis using codeML and R.
  - Maintained live insect colonies and host plant cultures; designed and built containment enclosures for experimental rearing. Applied R and Python for statistical analysis and reporting.
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## PROJECTS

### Gel Image Segmentation via CNN-ViT Hybrid SJSU M.S. Bioinformatics, 2025

Designed and trained a PyTorch deep learning pipeline combining a convolutional neural network with a Vision Transformer (ViT) for automated segmentation of gel electrophoresis images. Benchmarked model performance on annotated datasets using standard segmentation metrics.

*PyTorch, CNN, Vision Transformer, Image Segmentation, Python*

### Long-Read Sequencing Artifact Detection Pipeline SJSU M.S. Bioinformatics, 2025

Built a reproducible Nextflow pipeline for detecting and characterizing artifacts in long-read human genomic sequencing data, covering QC, alignment, artifact identification, and automated summary reporting across configurable reference inputs.

*Nextflow, Long-Read Sequencing, Bioinformatics, Pipeline Development, Linux*

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## EDUCATION

### M.S. in Bioinformatics

San Jose State University | December 2025

### B.S. in Human Biology

University of California, Merced | May 2021

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## SKILLS

**Quality & cGMP:** cGMP Compliance, QC Testing, SOP Authorship, Batch Record Review, Data Review, Analytical Method Execution, EHS Compliance, Audit Readiness, CAPA Support, Deviation Management

**Laboratory:** DNA/RNA Extraction, PCR, Gel Electrophoresis, Qubit Fluorometry, RNAi, BSL-2, Aseptic Technique, Microbiology, Plating & Culturing, Media Preparation, Instrument Calibration, Liquid Handling

**Data & Software:** Python, R, SQL, PyTorch, NumPy, Pandas, Nextflow, Microsoft Office, AI/LLM Tools

**Professional:** Technical Writing, Staff Training, Cross-Functional Collaboration, Communication