# Carolyn Lim

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# **Professional Experience**

# Juul Labs | Program Manager

Jul 2019 - present

Collaborate with suppliers and engineers to implement quality system for new product introduction and expansion

- Lead Cleanroom Validation Program to ensure supplier adherence to FDA Guidance for Aseptic Processing
- Develop and streamline quality processes for contract sites to improve manufacturing quality and scalability
- Implemented walkthrough checklist and evaluation report for supplier quality assessments
- Work with cross functional partners to plan and schedule project deliverables, documentation, goals, and milestones for complex programs and/or multiple projects
- Create strategies for risk mitigation and contingency planning of assigned projects

### Gilead Sciences | Program Manager

Jul 2012 - Jun 2019

Partner with customers, business associates, engineers and sales to develop global product plan and strategy

- Collaborate with customers and global cross-functional teams (Engineering, Finance, Operations, Marketing) to create compliant product commercialization and supply strategy for product lifecycle
- Apply data analysis (Spotfire, Tableau) to generate reports for stakeholder endorsement on product strategy
- Worked with engineers to build web applications to conduct trend analysis on quality and delivery metrics which resulted in 35% increase to outsource delivery performance
- Performed opportunity assessment with target users to develop use cases, establish KPIs and design business cutover plan to launch Gilead's Product Lifecycle Management system

#### Impax Laboratories | Production Coordinator

Jun 2009 - Apr 2012

Planned and implemented manufacturing procedures in accordance with FDA compliance measures

- Wrote and maintained Standard Operating Procedures for production equipment and planning processes
- Developed and spearheaded strategy plan for inventory reconciliation and SOX compliance metrics
- Implemented system compliance program to improve audit trails in adherence to federal regulations

# **Projects**

## Gilead Companion | Product Manager

Application that provides information to help patients better understand their illness and available medications

- Conducted research on Hepatitis and learned of the frustrations of those undiagnosed and seeking treatment
- Researched patient stories and interviewed Hepatitis patients to create user stories and target personas
- Mocked a design sprint to create the product's wireframes modeled after product requirement document

Link: https://medium.com/@cllim1214/gilead-companion-36efb11343fb#.fs4bdrc1a

#### **Education and Certifications**

UCLA Anderson School of Management | M.B.A. with concentration in Health Technology ISO 13485: Lead Auditor Certification | Medical Device Quality Management Systems Product School | Product Management Certificate

Hackbright Academy | Software Engineering Immersive Program (SQL, Python, HTML)

University of California Davis | BS in Biological Sciences