# CURRICULUM VITAE

**Langly Gee**

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**OBJECTIVE: Seeking a challenging Senior Level Quality position that will enhance my twenty years of Quality Management.**

## EXPERIENCE

Quality Systems Manager — Tethys BioScience
Emeryville, CA — 2012-present

Establish, sustain and maintain a Quality System program and Quality goals in according to CLIA and NY regulations

- Manage, maintain and sustain the document control program ensuring practices are reflecting current SOPs and in compliance with CLIA and NY regulations
- Manage documentation including complaints, occurrences, CAPA and audit program
- Responsible for the approval of Validation, Change Controls, Studies Protocols and reports
- Establish, maintain and monitor QC compliance in all facets of laboratory, i.e. accessioning, testing and reporting
- Responsible for Regulatory activities including continual State Licensing submittals and renewals
- Project Manager for the IOPQ of the liquid handler, Hamilton STAR and the manufacturing of an Adiponectin panel used for reagent qualification
- Champion and monitor fingerstick samples from receiving, testing and reporting, conduct meetings with reference laboratory, Clinical Reference Laboratory
- Manage QC supervisor and Quality Assurance Analyst activities for the continuing improvement of laboratory processes
- Governed laboratory compliance and responsible for the proficiency program i.e. NY, AAB, CAP to ensure continual licensure
- Establish, sustain and responsible for internal audits. Analyze and ensure observation are resolved
- Conduct and present quarterly Quality Assurance Improvement Program to Senior Management

- Create and update incoming raw material specification for release and used of material
- Conduct supplier quality management to ensure the highest quality material for the lowest price
- Ensure, manage and maintain laboratory equipment are calibrated on time
- Monitor, track, resolve and ensure laboratory samples are reported within established turnaround time
- Champion with IT to improve processes, reducing time, effort and costs
- Champion with engineering in revising processes, calibration and validation

Quality Control and Materials Manager/BioSafety Officer Bio-Rad Laboratories
San Ramon, CA / Irvine, CA 2002-2012

- Managed day to day activities of the five staff positions in Quality Control and Shipping/Receiving Department
- Ensured department followed all FDA, ISO 13485 and European guidelines
- Coordinated manufacturing and quality control groups' activities to meet master production schedule to limit back order situations
- Coordinated activities with R&D and Regulatory Affairs to ensure proper transfer of new products to manufacturing
- Created, updated and archived SOPs as required to limit internal and external audit findings
- Created and signed off on Equipment Installation/Operational/Performance Qualifications
- Responsible for the final release testing of formulation bulks, in-process material, and finished goods ensuring all in-house specifications are met using ELISA, PCR, AxSYM, ARCHITECT and ECi testing following GMP and GDP
- Evaluated, trended and maintained performance of all released product through its shelf life to prevent non-conformances
- Maintained all calibration and maintenance records for instrumentations, pipettes, equipments and thermometers
- Served on Risk Management and FMEA team in creating and updating files on all products
- Project lead for the training and implementation of ERP System BaaN to group staff
- Responsible for maintaining the CAP program and in the process of incorporating ISO 15189
- Evaluated, negotiated, purchased, maintained and controlled incoming raw materials, plasma, labeling, instrumentations, freezers, reagents, test kits, chemicals and laboratory supplies necessary to meet manufacturing production schedule
- Responsible for all incoming material are logged, inspected, documented and has met established specifications before used in manufacturing

- Responsible for the final inspection of finished goods prior to shipping to customers
- Served on Bio-Rad Quality Review Board, Site BioSafety Officer and EH & S
- Conducted annual employee HazCom and Bloodborne Pathogen Training Program
- Maintained Contra Costa Environmental Health License and San Ramon Valley Fire Protection District through annual site inspections
- Administered the employee Hepatitis B vaccination program
- Responsible for maintaining a current Waste Management and OSHA Program
- Lead Emergency Responsible Team/CPR trained
- Evaluated, approved, monitored and ensured suppliers meet established qualifications before use
- Responsible for customer orders placed are processed, picked properly, double checked, packaged, shipped and delivered within specified courier time frame
- Managed and reviewed cycle and physical counts ensuring at least 95% compliance with explanation of variances
- Supported annual 15% sales growth of the past 3 years with no increase in staff

Alternate SAMHSA Responsible Person/Data Review Manager PharmChem Laboratories, Inc.
Menlo Park, CA / Fort Worth, TX 1997-2001

- Successfully, transferred operations from California to Texas
- Responsible for the management, direction and day-to-day operation of a 24/7 250 employee certified forensic urine drug testing laboratory
- Responsible for the development of the testing methodology and procedures used by the laboratory
- Managed departmental budget with cost saving of ten cents per sample or two hundred thousand dollars per year without sacrificing quality
- Maintained multiple laboratory accreditations through inspections, audits, proficiency and blind challenges
- Responsible for all final certified drug test results are accurate and defensible in a court of law
- Ensured test results released to the clients are transmitted and turn around times has been met
- Project leader for the design, testing, training and implementation of a new LIS
- Drafted, wrote, revised and implemented standard operating procedure
- Custodian of Records

Senior Laboratory Certifying Officer, PharmChem Laboratories, Inc.
Menlo Park, CA 1992-1997

- Responsible for the final certified drug test results released to the clients
- Reviewed testing methodologies and ensured all test performed in the laboratory met established SOPs

**EDUCATION AND AFFILIATIONS**

B.S., University of California Berkeley Biochemistry
Inspector for the College of American Pathology
International Air Transport Association Certified
Cardiopulmonary Resuscitation Certified
Seminar for Auditing Quality System for FDA and ISO Compliance