GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Paul Leander

BSc (Hons)
Senior Consultant

Recognised Areas of Expertise:

- 25+ years experience in Quality & Compliance worldwide
- Paul has led over 500 audits in the Americas, Europe and Asia
- Quality leader in a wide range of GxP audit functions working for Biogen, Takeda, Merck, Sanofi and Bluebird Bio
- Established global Quality Compliance team and GxP Audit Program in leading pharmaceutical companies
- In-depth knowledge of global health regulations and extensive expertise on GMP, GTP and GDP audits
- Specialized in cell and gene therapy, biologics and small molecule drug products. Experience in:
    - Apheresis and Cell collection Centres,
    - Infusion Sites,
    - Drug Product and Drug Substance
    - CDMOs,
    - Testing Laboratories,
    - Raw Material Suppliers,
    - Medical Device Manufacturers,
    - Packaging Sites,
    - Warehouse/Distribution Centres
- FDA mock inspections to ensure companies are in a state of inspection readiness
- Trained, mentored and coached employees in preparation for regulatory inspections

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited

- Director of independent GMP consultancy providing services for multiple pharmaceutical companies

Career History:

- **March 2020 to Present: President, Leander Biosciences Consulting LLC**
  - Conduct CDMO, laboratory, distribution centre, raw material supplier, packaging site, compounding pharmacy, apheresis collection and infusion site audits to ensure compliance with current GMPs, GDPs and GTPs
  - Perform gap assessments and mock inspections as part of inspection readiness activities
  - Provide general Quality Systems guidance and support
  - Assist companies with the development of key programs such as Audit and Auditor Qualification programs
  - Mentor and coach employees in preparation for regulatory inspections

- **April 2018 to March 2020: Director, Quality Compliance, BlueBirdBio**
  - Led the Quality Compliance function overseeing internal audits, external audits and inspections
  - Managed a risk-based GxP audit program, escalating issues as needed
  - Led inspection readiness activities
  - Developed and executed annual risk-based audit plan
  - Drove continuous improvement through the monitoring of audit metrics and relevant CAPAs
  - Maintained the Approved GxP Vendor List
  - Established and implemented the Auditor Qualification Program
  - Collaborated with various departments and levels of management to accomplish company objectives
  - Hosted and managed GxP regulatory and mock inspections
  - Provided performance reviews, development plans and set goals for department staff in alignment with company goals
  - Managed department budget
  - Collaborated cross-functionally to develop and implement a robust supplier quality program
  - Represented Quality at Quality Council, Quality Management Review and other management forums
  - Recruited, interviewed and onboarded staff at various levels
  - Enforced a strict company-wide Quality culture

- **Oct 2015 to Apr 2018: Associate Director, Global Quality Audit, Sanofi**
    - Ensured that Sanofi manufacturing sites, affiliates and third parties achieved, maintained and improved current levels of GxP and health regulated compliance
    - Determined quality and compliance deficiencies
    - Monitored corrective and preventive actions to closure
    - Provided independent advice, recommendations and solutions
    - Identified and communicated emerging GxP, regulatory and industry trends that identified, promoted, and communicated “best practices”
    - Planned, prepared and performed audits according to the schedule
    - Generated audit reports in a timely manner and distributed to relevant personnel
    - Performed routine follow up of executed audits in conjunction with site, affiliate or global function
    - Provided effective and timely reporting of compliance status of respective sites, affiliates or global functions to the Head of Global Quality Audits
    - Participated on due diligence activities when necessary
    - Managed the Global Auditor Qualification Program
    - Contributed to process improvement initiatives throughout Sanofi

- **Jun 2011 to Sep 2015: Associate Director, Quality Systems & Compliance, Merk & Co.**
    - Oversaw the GMP External and Internal Audit Programs in support of commercial and clinical products
    - Managed personnel regarding daily operations, budget, goal setting and development
    - Established and maintained risk-based audit schedules
    - Coordinated and executed qualification, surveillance and for-cause audits of drug product and drug sub- stance manufacturers, raw material suppliers, testing laboratories, cell banks and distribution centres
    - Managed the tracking, reporting, verification, and closeout of audits
    - Evaluated supplier responses ensuring appropriate CAPAs were implemented
    - Facilitated and managed mock PAI inspections of critical CMOs to ensure inspection readiness
    - Identified compliance gaps and developed and implemented plans to mitigate risks
    - Evaluated CMO deviations, investigations and effectiveness of CAPAs
    - Generated program metrics for senior management
    - Participated on various Failure Mode Effects Analysis (FMEA) teams
    - Developed staff to ensure compliance with applicable regulations, policies and procedures at Cubist CMOs

- Assured quality agreements were current as part of the CMO management process
- Implemented Supplier Certification Program
- Maintained the Approved GMP Supplier list
- Assisted with the management and coordination of drug recall activities
- Developed and maintained GMP auditor training and certification programs
- Responsible for preparing and hosting regulatory inspections and partner audits
- Managed budget within a 10% target

- **Aug 2009 to May 2011: Manager II, Corporate Audit & Compliance, Millennium Pharmaceuticals Inc.**
  - Conducted internal and external audits in accordance with internal SOPs, Corporate QA Audit and Compliance standards, applicable global health authority regulations and industry standards
  - Planned and prepared audits in collaboration with other members of the Commercial and Pharmaceutical Sciences departments
  - Managed the tracking, reporting, disposition, verification and closeout of audits
  - Effectively communicated audit findings and remedial actions to all levels of the management team
  - Evaluated corrective action responses to audit findings for adequacy, including root cause and timeliness
  - Assisted and supported regulatory inspections
  - Managed the Quality Assurance Audit Database (QAAD)
  - Supported the development and implementation of Corporate QA Audit and Compliance standards
  - Assisted with the management and coordination of drug recall activities
  - Provided guidance regarding compliance issues and interpretation of regulations
  - Developed and managed Auditor Certification Program
  - Mentored junior department members

- **Jul 2004 to Aug 2009: Manager II, Senior Supervisor, Global Quality Management, Biogen Idec inc.**
  - Oversaw RiskMAP Audit Program including the scheduling and execution of audits encompassing infusion sites, specialty pharmacies, central pharmacies and internal departments involved with the program
  - Developed audit plan and procedures supporting the RiskMAP Audit Program
  - Managed personnel within department regarding daily operations, goal setting and development
  - Led mock PAI inspections of manufacturing facility

- Coordinated and led internal and external audits evaluating GXP quality systems for drug, biologic and medical device products as well as contract testing laboratories
- Developed various training modules and conducted GXP training
- Managed the Vendor Audit Program database
- Assisted with the management of the Vendor Change Notification process
- Assisted with regulatory inspection activities

- **Aug 2003 to Jun 2004: Senior Specialist, Quality Assurance, Avecia Biotechnology Inc.**
  - Reviewed quality records including batch production records, validation protocols, deviations and CAPAs
  - Released intermediate and final products
  - Performed internal and external vendor audits
  - Implemented a company-wide GMP training program
  - Managed the Corrective and Preventive Action (CAPA) program
  - Responsible for the development and revision of QA procedures
  - Implemented Failure, Incident, and Deviation (FID) Investigation system
  - Assisted in the development and implementation of a new quality system aligned with the company's
  - strategic objectives to gain FDA registration and PAI inspection
  - Assisted with customer complaint handling

- **Jan 2002 to Dec 2002: Specialist, Quality Assurance, Serono Inc.**
  - Released commercial drug product for U.S. distribution
  - Inspected and reconciled clinical material
  - Performed internal and external vendor audits
  - Processed technical complaints
  - Provided team with GMP training
  - Coordinated repackaging operations

- **Jan 1999 to Dec 2001: Compliance Specialist, Quality Assurance, Bipure Corp.**
    - Reviewed intermediate and final product records
    - Inspected final product and packaged finished goods
    - Performed internal audits and supported external vendor audit activities
    - Identified system wide deviations
    - Developed and revised standard operating procedures
    - Assisted with the development of validation protocols
    - Responsible for investigations resulting from out of specification results
    - Provided GMP training to site

Education:

1997 - 1999

- University of Dartmouth, MA Batchelor of Science in Biology