GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Joseph Day

BSc (Hons), FRSB
Senior Consultant

Recognised Areas of Expertise:

- Thorough understanding of International cGMP Guidelines, Sterility Assurance principles and their practical application, (FDA / EMA / ICH / ISO / Health Canada).
- Expert in Sterility Assurance, Quality Assurance, Microbiology and Aseptic Manufacturing.
- Preparation of Quality and Manufacturing departments for FDA / EMA inspections
- Coaching and mentoring of Quality and Manufacturing personnel during FDA & EMA inspections
- Gap assessment against revised Annex 1
- Development of Contamination Control Strategy
- Expert in Warning Letter, 483 and other Regulatory Observation Remediation.
- Highly developed Operational Leadership, Management, Planning and Organisational skills.
- Extremely flexible and capable of making quick and calculated decisions.
- Drive, initiative, and capability to thoroughly research and accurately assess opportunity, feasibility, and risk.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Director of independent GMP consultancy providing services for multiple pharmaceutical companies

Career History:

- **Present Owner and President, Odin-Thor Consulting Inc.**
  - **Q3 2023 to Present, FDA Warning Letter Remediation:**
    - Water system assessment and remediation, (including sampling and laboratory)
    - Assessment of Complaints and recommended remediation
    - Quality system assessment and remediation, (CAPA, Investigations, Non-Conformances, OOS, Deviations)
    - Management Review assessment and remediation
    - Coaching and mentoring of Management, Quality, and Manufacturing personnel
  - **Q3 2023 to Q4 2023, Sterility Assurance SME, post FDA Inspection:**
    - Coaching and mentoring of Management, Quality, and Manufacturing personnel
    - Media Fill program upgrade
    - Smoke Studies – Assessment, revision, and execution planning
    - Facility Assessment and recommendations
  - **Q4 2022 to Q2 2023, Interim Head of Sterility Assurance and Microbiology departments, and preparation for FDA / EMA Inspections:**
    - Leadership and Management of Sterility Assurance and Microbiology departments, including hiring and training
    - Strategic and tactical analysis and decision making within Company Leadership Team
    - Preparation of Quality and Manufacturing departments for FDA / EMA inspections
    - Coaching and mentoring of Quality and Manufacturing personnel during FDA & EMA inspections
    - Gap assessment against revised Annex 1
    - Development of Contamination Control Strategy
    - Media Fill program upgrade
    - Environmental Monitoring program upgrade
    - Cleaning and Disinfection program upgrade
    - Deviations, Investigations, CAPA, and Change Control programs upgrade
    - Investigations, (EM, Water systems, product, intermediates, and buffers)
    - Liaison with, and direction of Engineering department with respect to Sterility Assurance
    - Hot Topics definition and preparation
    - Training of Management, Manufacturing, and Quality personnel
  - **Q3 2022 to Q4 2022, FDA 483 Remediation- API Manufacturer:**
    - Risk Assessment of manufacturing process
    - Environmental Monitoring program upgrade
    - Cleaning and Disinfection program upgrade
    - Deviations and Investigations program upgrade
    - Determination of Objectionable Organisms and update of relevant Quality systems
    - Training of Leadership, Management, Manufacturing and Quality personnel
    - Coaching and mentoring of Quality and Manufacturing personnel

- **Q2 2022 to Q3 2022, FDA 483 Remediation- CMO Steriles:**
  - Investigations and Batch Disposition – Review and Remediation Includes analysis and remediation of:
  - Root Cause Analysis
  - Historical Analysis
  - Impact Analysis
  - CAPA and Effectiveness Checks
  - Documentation
- **Q1 2022 to Q4 2022, FDA Warning Letter Remediation- CMO OTC:**
  - Investigations and CAPA Systems – System Review and Remediation Includes analysis and remediation of:
  - Investigations and CAPA systems
  - OOS reports
  - Investigation reports
  - Training and competencies
- **Q1 2022 to Q2 2022, Mock Audit, CDMO:**
  - Prepared and performed Mock FDA PAI Audit and reported findings, (inc. providing remediation recommendations) Quality Systems
  - Aseptic Manufacturing
  - Sterility Assurance
  - Facilities and Equipment
  - Materials Management
  - Personnel Qualification / Controls
- **Q2 2021 to Q3 2022, Vaccine Approval for Global Markets (Emergency Use):**
  - Writing CBER responses to requests for further information
  - Developing Post Approval Change Management Protocols (PACMP) as per ICH Q12, FDA and EMA
  - Sterility Assurance SME
  - Writing and reviewing eCTD submission segments and source document review: Process Validation
  - Media Fills
  - Sterilization and Depyrogenation
  - Microbiological Attributes
  - Container Closure Integrity
  - Filter Validation
  - Shipping Validation
- **Q2 2021 to Q4 2021, CMO Due Diligence & Selection Pre-Filled Syringes:**
  - Aseptic Processing / Microbiology / Sterility Assurance SME
  - Drafting RFP sections
  - Conducting virtual meetings with manufacturer and CMOs and writing questionnaires to determine capabilities and analyzing responses:
  - Facilities and equipment
  - Process Validation and Media Fills
  - Sterilization and Depyrogenation
  - Regulatory history
  - Quality Systems and Quality Culture

        - Training and Human Resources
    - **Q1 2021 to Q2 2021, Audit Remediation Steriles:**
        - Aseptic Processing / Microbiology / Sterility Assurance SME Included:
        - Analysis of Audit Reports and development of responses
        - Review of EM Programs
        - Development of EM PQs and Risk Analyses to satisfy global markets
        - Smoke Study review and report
        - Media Fill review and report
        - Media Fill failure investigation
        - Aseptic techniques / behaviours / practices
    - **Q3 2020 to Q1 2021, FDA Warning Letter Remediation (Multiple Sites):**
        - Process Validation Program Assessment – Program Director Included:
        - Leadership and corporate oversight
        - Metrics (corporate and sites) - inputs, applicability, analysis, decisions, outputs
        - Corporate to sites QMS Gap Analysis
        - Validation Life-Cycle utilization and compliance
        - Program execution Gap Analysis
        - Development and implementation of questionnaires, forms, and rubrics
        - Development and use of analytics for multi-site data
        - Prepare final Assessment Report
        - Recommend Remediation Plan
        - Quality System Assessment – SME providing enterprise-wide comprehensive QMS review and effectiveness determination: Included:
        - Commitment of Leadership and corporate oversight
        - Management Review / Quality Management Review
        - Metrics (corporate and sites) - inputs, applicability, analysis, decisions, outputs
        - Corporate to sites QMS Gap Analysis
        - Organisational and operational infra-structure analysis
        - QMS component linkages
        - Investigations and CAPA systems
        - Investigations and CAPA records, (inc. OOS, OOT, manufacturing, complaints, etc.)
        - Validation and Change Control
        - Suppliers and CMO programs
        - Training Programs
        - Documentation
        - Recommend Remediation Plan
    - **Q2 2020 to Q3 2020, Investigations Lead, Biopharmaceuticals:**
        - Ensure company can manufacture COVID-19 vaccine candidate for Clinical Trials: Included:
        - Managing Investigations of multi-disciplinary issues
        - Root-cause determinations
        - Review / determine mitigation strategies
        - Devise / verify multiple CAPAs
        - Determine Effectiveness Checks
        - Determine required Validation studies

        - Suppliers / Purchasing / Raw Materials
        - Training Programs
        - Documentation
    - **Q2 2020 to Q3 2020, Quality System Design & Development, (ensuring EMA / FDA 21 CFR parts 210, 211, 4, 660-680, 820 / ISO9001, ISO13485, ISO14644 / ICH / Global Compliance):**
        - Design, review and development of Quality Systems Policies and Procedures:
        - Investigations, CAPA, Change Control, Validation, etc.
        - Suppliers / Purchasing
        - Training Programs
        - Documentation
    - **Q1 2019 to Q1 2020, Aseptic Processes / Practices and Sterility Assurance – Team Lead:**
        - Monitor, recommend / develop improvements and provided Training relating to:
        - cGMP, (FDA / EMA / ISO / ICH / Global) Aseptic Behaviour and Techniques, Environmental Monitoring, Sterility Assurance practices, (equipment / material preparation and sterilisation / depyrogenation, Cleaning & Disinfection, Sterile Gowning, material / equipment / waste / product / personnel flows, facility and equipment issues and potential upgrades, labelling and line clearance).
        - Coaching, Training and Mentoring Manufacturing, QA, and Sanitisation personnel.
        - Investigation Support (Trackwise) – EM, Microbiology, Aseptic Production, Validation, Sterilisation.
        - Moist Heat Sterilization – Wet load remediation.
        - Observe, recommend, and develop improvements relating to the performance of:
        - Media fills and routine product batch production.
        - Recommendations to Leadership, Action Plans developed, and improvements made.
        - Designed, developed and initiated / Validated project that saved >$1million per year of consumables and created opportunity gain to fill >10 million extra units per year.
    - **Q2 2018 to Q4 2018, Aseptic Processes / Practices and Sterility Assurance:**
        - Create fully comprehensive Contamination Control / Sterility Assurance Training Program, specific to sites, ensuring compliance to FDA / EMA / ISO / ICH / Global cGMP regulations, including filtration, moist heat, and dry heat sterilisation.
        - Train all Operational Personnel in the above, (Production, Cleaning & Disinfection staff, Maintenance, QA, QC, Environmental Technicians and Validation).
        - Investigate systemic failures of infrastructure, equipment, (Water Systems – India), methodologies, performance.
        - Review and update all aspects of Cleaning & Disinfection Program, (inc. equipment, methodology, efficacy, frequency).
        - Gap Analysis and Alignment – Local versus Global Policies and Procedures, (EM, Microbiology, Processes, Validation, Cleaning & Disinfection and Sterilisation).

- **Q1 2018 to Q4 2018, Aseptic Processes / Practices and Sterility Assurance:**
  - Monitored, recommended / developed improvements and provided Training relating to:
  - cGMP, Aseptic Behaviour and Techniques, Environmental Monitoring, Water Testing, (microbial and endotoxin), Sterility Assurance practices, (equipment / material preparation and sterilisation / depyrogenation, Cleaning & Disinfection, Gowning (sterile and non-sterile), material / equipment / waste / product / personnel flows, facility and equipment issues and potential upgrades, labelling and line clearance).
  - Coached, Trained and Mentored Manufacturing, QA, and Sanitisation personnel.
  - Observed, recommended, and developed improvements relating to the performance of:
  - Sterilization, Validation, Media fills and routine product batch production.
- **Q1 2018 to Q4 2018, Mock Inspection & Mould Remediation:**
  - Prepared and performed Mock FDA PAI Audit and reported findings, (inc. providing remediation recommendations)
  - Analysis of Sterility Assurance practices and procedures, (inc. Environmental Monitoring, Seed bank control and Microbiological assays / tests). Recommendations delivered and implemented.
  - Investigate mould issues in Production facilities. Analysed and remediation plan developed and implemented.
- **Q2 2017 to Q4 2017, FDA Warning Letter Remediation- Steriles:**
  - Designed aseptic processes for filling and trained staff in aseptic techniques / behaviour to perform them reliably.
  - Designed and implemented APS (Media Fill) Policy, Strategies and Program, (inc. APS Protocols and logistics).
  - Regulatory Gap Analysis and update of QMS to ensure Compliance.
  - Developed Microbial Control Strategy and Risk Assessment to ensure Quality and Compliance.
  - Reviewed, improved, and updated Validation packages, (VMP, HVAC IOQ, Cleaning Validation, Smoke Studies, Cleanroom Qualification, Aseptic Processes, Moist Heat Sterilization).
  - Reviewed and improved Environmental Monitoring (EM) processes and trained / coached Technicians.
  - Performed Risk Assessments relating to Processes, Equipment and Legacy Facilities – Recommended remediation.
  - Coached and mentored Quality / Manufacturing staff in the writing of Deviations, CAPAs and Change Controls.
  - Cleanroom classification, Cleaning & Disinfection and Gowning Program harmonization.
  - Developed improved material / equipment / waste / product / personnel flows, SOPs, and drawings.
  - Reviewer and Final Approver for Quality System documents, (Policies, Strategies, Protocols, Reports and SOPs).
  - Observed, recommended, and developed improvements relating to the performance of:

        - Engineering runs, water batches, media fills, routine batch production and Line Clearance.
    - **Q1 2016 to Q2 2017, FDA Warning Letter Remediation- Steriles:**
        - Monitored, recommended, and developed improvements and provided training relating to:
        - Aseptic behaviour, Sterility Assurance practices, (equipment / material preparation and sterilization / depyrogenation, (moist heat and dry heat) gowning (sterile and non-sterile), material / equipment / waste / product / personnel flows, facility and equipment issues, labelling, line clearance).
        - Coached and mentored Manufacturing Supervisors and QA Shop-Floor staff.
        - Observed, recommended, and developed improvements relating to the performance of:
        - Engineering runs, water batches, media fills, routine product batch production.

- **Q4 2012 to Q1 2016, Director: Sterility Assurance (Site Quality Operations and Global Sterility Assurance Council), Sanofi Pasteur**
    - Led all corporate and regulatory inspections from Sterility Assurance perspective, (5x Health Canada, 3x FDA plus multiple foreign inspections and Global Quality Group)
    - Crafted Regulatory responses with in-house and external Quality and Legal teams, developed strategies, CAPAs, Change Controls and led remediation projects to completion.
    - RESULT: FDA WARNING LETTER LIFTED AND HEALTH CANADA LICENCE REINSTATED
    - Successful Project development and implementation for all site CAPEX / OPEX projects, (inc. major renovations) – member of Steering Committees and Operational teams, (inc. 3x Global new facility construction projects and design of multi-product bulk vaccine facility).
    - Led and revised site policy for moist heat sterilization, (including load configurations, documentation, and cycle development).
    - Developed and implemented HACCP risk analysis tools for failures and process improvements.
    - Initiated and led Value Stream Mapping & 5S activities, resulting in significant process improvements and savings.
    - Sourced, validated and implemented single-use closed-system technologies for Manufacturing platforms.
    - Led multi-functional teams that determined root-causes of product & raw material failures and developed CAPA's.
    - Led teams to perform over 1,300 Investigations and develop successful CAPAs.
    - Compliantly managed and remediated multiple system and facility failures.
    - Reduced closure time of Deviations and achieved 0% overdue, whilst improving the quality of Deviation reports.
    - Simplified and improved site Policies, Procedures and Training.
    - Developed Environmental Trending process and reports, resulting in best practice within the Sanofi network, (incorporating USP <1116> guidelines and aligning process with Global policies).

- Implemented site-wide automation of non-viable particle monitoring system / software / equipment.
- Identified potential causes of contamination / cross-contamination and implemented procedures to eliminate them.
- Environmental Monitoring, (including trending)
- Environmental Validation
- Utilities Testing, Trending, and Investigations, (Water systems, clean steam, and gases)
- Deviations and Investigations
- CAPAs and Change Controls, (Trackwise)
- Oversee and develop all Sterility Assurance programs and activities in Canada, reporting directly to Site Head of Quality and Regional Quality Head of Biologics platform.
- Founding member of Global Sterility Assurance Council, responsible for decision making within Sanofi Pasteur.
- Development, prioritisation & tactical execution of operational strategies & plans to ensure consistent quality & supply, continuously liaising with Operational and Manufacturing departments and reducing cycle times.
- Quality and Operational member of the following teams:
- Site Change Control Committee – permanent member
- Site Quality Operations – permanent member
- Quality Enhancement Program – Work-stream Lead
- Site Quality Council – permanent member
- Global Sterility Assurance Council – founding and active member
- Global Quality Steering Committee – Sterility Assurance advisor
- Responsible and accountable for all Sterility Assurance related programs – over 350 Cleanrooms on site:
- Process simulations, (including Media Fills)
- Operator Training programs, (Contamination Control, Microbiology, Operator behaviour, etc.)
- Gowning, personnel, and equipment flows
- Cleaning & Disinfection, (including disinfection efficacy)
- Ensure that facility meets & maintains compliance with regulatory requirements, (ISO14644 / EMA / FDA 21 CFR parts 210, 211, 660-680 / ICH / Health Canada).
- Rapid response advice and support for infra-structure, facility and equipment failures.
- Support sister sites relating to project development and failure investigations.
- Gap analysis and remediation against Global Quality documents.
- Recruitment, retention & performance management of team of >20 Sterility Assurance subject matter experts and >50 Sanitation Technicians.
- Quality and Sterility Assurance support for R&D team operations and CAPEX / OPEX projects.

- **Q2 2009 to Q4 2012, Vice President: Manufacturing Operations, bioLytical Laboratories**
    - Directed team that overhauled the QMS, (CAPA, Change Control, Investigation, Complaints, etc.), according to FDA 21 CFR 820 / CE / ICH / ISO9001 / ISO13485 / HC Guidelines resulting in full compliance with FDA pre-market and post-market inspections, (including fronting 3 FDA cGMP Inspections, 4 Notified Body Inspections and 1 WHO Inspection).
    - Developed PMA and CLIA Waiver studies and submissions to CFR Guidelines, collaborating with FDA.
    - RESULT: EU, WHO, FDA AND CLIA APPROVALS AND LICENSURE IN 65 COUNTRIES
    - Successfully directed cross-functional team to fulfil short & long-term internal, customer & regulatory requirements through strategic planning and implementation activities.
    - Developed and maintained meaningful KPIs, (e.g., on-time Batch Record completion and Right First Time).
    - Dramatically increased efficiency of Manufacturing Facility via projects, continuous improvement, and lot matching.
    - Led multi-functional investigation teams that determined root-causes of product & raw material failures and developed CAPA's.
    - Planned, initiated & managed the scale-up of Production (Production Floor and Lab) from 20K kits / month to 350K kits / month and prepared detailed proposals (inc. costs) to scale-up to over 20M kits / year with multiple products.
    - Planned & commissioned full Facility, Systems, Equipment & Processes Validation via VMP.
    - Developed products & processes via Design Control & Design Change to improve performance & quality.
    - Identified, developed & implemented more robust QC testing methodologies and QA SOPs.
    - Identified potential causes of contamination / cross-contamination and implemented procedures to eliminate them.
    - Identified, built & maintained partnerships with key suppliers, (inc. contract negotiations & quality improvements).
    - Lead and manage Manufacturing Facility operations (Production Floor & Lab., QC/QA, Engineering & SCM), reporting directly to President and CEO.
    - Integrate departments to create & maintain a cohesive company structure.
    - Development, prioritisation & tactical execution of operational strategies & plans to ensure consistent quality & supply of goods & services.
    - Strategically develop & manage the scale-up of commercial production capacity.
    - Direct Production, Quality, Regulatory, SCM & Business Development functions to achieve business objectives.
    - Ensure that facility meets & maintains compliance with regulatory requirements, (ISO / CE / FDA / Health Canada).
    - Develop & implement organisational, manufacturing & quality policy & objectives.
    - Lead validation programme and ensure calibration & maintenance programs are adhered to.
    - Conduct all internal & external (supplier) audits and lead inspection readiness activities and product / process / complaint investigations.

- Recruitment, retention & performance management.
- Key member of R&D team to support current products and develop pipeline, liaising with external organisations.

- **Q1 2007 to Q4 2008, Manager: Microbiology, Clean Room Control & Quality Assurance, Tekmira Pharmaceuticals**
  - Presented strategies & data to business partners to secure investment / negotiate Manufacturing Agreements.
  - Commissioned & Qualified ISO5/6/7/8 Production Suite & implemented cGMP Environmental Monitoring Program.
  - Designed & implemented IQ/OQ/PQ Validation Program equipment to achieve cGMP compliance.
  - Maintained compliance, led Investigations, and solved quality, equipment & process issues, assigning & performing CAPA's, (inc. determining source of bulk product contamination).
  - Audited CMO facility during Fill / Finish operations and performed Technical Supplier Audits. Reported findings to achieve cGMP compliance and initiate Continuous Improvement Program.
  - Designed & performed Sanitization Study of manufacturing equipment trains and implemented improvements.
  - Updated and reprogrammed Quality & Environmental Monitoring Systems to achieve compliance - Trained staff.
  - Coordinated transfer of systems and equipment from site to site during company merger.
  - Company Aseptic Process and Microbiological expert for all Manufacturing activities.
  - Manage & supervise operations of Clean Room & Microbiology facilities.
  - Supervise bulk manufacturing campaigns for liposomal formulations, whilst ensuring Microbiological Quality.
  - Training Production Operators and Scientists in Aseptic Manufacturing Techniques.
  - Develop Vendor, Contract Labs and CMO's relationships / partnerships.
  - Coordinate Staff & Contractors to perform Preventative Maintenance, Calibration and Validation.
  - Upgrade and Commission Controlled Environment Suites, (facilities, services, equipment and environment) for Toxicology and Phase I Bulk Manufacturing.
  - Represent Manufacturing & Quality Groups during internal and external cGMP audits.
  - Maintain and improve Corporate Validation Program.
  - Write, update, and review all types of cGMP documents, as per regulatory guidelines.
  - Assess & upgrade / replace company QMS Software and Databases.
  - Manage Environmental Monitoring Programme, (static & dynamic).
  - Company Health & Safety Team Member and controller of Hazardous Waste Disposal.
  - Thermal Monitoring of Depyrogenation Oven & cGMP Controlled Chambers.

- **Q4 2004 to Q1 2007, Head of Microbiology, QLT Inc.**
    - Key member of multi-functional team to Design, Build, Commission and Validate a state-of-the-art Manufacturing Facility, (cGMP compliant ISO8 Clean Room with fully integrated ISO5 Isolator technology, including robotic syringe filler) following ISO14644, ICH / EMA / FDA guidelines and 21 CFR parts 210 and 211.
    - Quality Control's representative in CMC teams, responsible for the development & filling of Aseptic (vials & syringes), Terminally Sterilized & Non-Sterile (including API) Clinical Trial & Commercial materials.
    - Performed several successful cGMP Media Fill Validations.
    - Designed, performed, streamlined, and trended Environmental Monitoring Program of Manufacturing Facility / Systems to allow 'Production' and 'Sleep' modes saving $110K / month.
    - Introduced 'Best Practices' to Microbiology & Quality Control Departments.
    - Solved numerous technical issues regarding manufacturing processes & equipment.
    - Managing, budgeting & organising staff, SCM and operations of Microbiology Function.
    - Ensure cross-functional team cohesion and provide support and expertise to Manufacturing, Validation, Engineering, Facilities & QA to ensure Quality and Health & Safety Compliance.
    - Technical Transfer, Product Transfer & Process Optimization.
    - Ensure Regulatory Compliance and front audits for the Microbiology Group.
    - LIMS development, beta testing and implementation.
    - Recruiting, training, mentoring & performance monitoring of QC and Manufacturing Personnel.
    - Validate methods, materials, manufacturing processes & equipment (IQ/OQ/PQ).
    - Lead Investigation teams, write & review cGMP documents, (SOP's, Validations, MPR's, ECR's etc.).
    - Design, establish and maintain Environmental Monitoring program, (inc. trending through LIMS).
    - Implement & maintain Microbiological & LAL programs for Stability, Product, Raw Material & Water Testing.
    - Implementation of Microbiological Identification System.
    - Validation of sterilization systems, (moist heat and dry heat).

- **Q2 1998 to Q2 2004, Microbiologist (Technical Officer), GlaxoSmithKline**
    - Designed and implemented strategies and methodologies for the validation of heat-labile terminally sterilized products, (moist heat). Work was incorporated into PDA Technical Monograph No. 1.
    - Coordinator of PharMIG Steam Sterilisation Action Group (UK Industry-wide).
    - Rapid Microbiological Methods: Achieved approval for Celsis Rapiscreen in 19 days (record) by FDA via PAT & PAS, leading to future NDAs.
    - Developed & validated new methods for BI challenging / thermal monitoring of CIP/SIP & Isolator systems, using Lean Sigma principles and saved approximately $100K / year on-site. Methods adopted globally by GSK.
    - Seconded to New Product Introduction (NPI) Department to scale up dermatological products.

- Ensured continual validated status of all sterilisers across multi-functional manufacturing site, (approx. 1,400 staff).
- Validation of BIER vessel conversion from PC to PLC control.
- D Values, Biological Indicators (BI's), Sterilizer Validation (Company expert).
- Sterilization validation of all equipment, Clinical and Commercial products, (vials, syringes & ampoules).
- Lean Sigma Representative for Technical Support and Microbiology groups.
- Validation, development, and support of VHP decontaminated Sterility Testing Isolators.
- Validation and development of all new microbiological technology, autoclaves, thermal tunnels, CIP/SIP systems and PoF CIP/SIP.
- Review proposed PDA, FDA, PharMIG and Parenteral Society guidelines prior to publication.
- Reviewed and updated Quality Management Systems (QMS).
- Microscopic, macroscopic, and biochemical microbiological identifications.
- Sterility & Product Testing in an Aseptic area and Environmental Control of Aseptic & Non-Aseptic areas.
- Microbiological Testing, (Water systems, TAMC, Efficacy, Stability, media challenge, container integrity).
- Training QP's, established & new staff in all of the above.

Education:

1992 – 1995

University of Durham BSc(Hons) Microbiology, Biotechnology, Chemistry & Engineering

- Fellowship status of the Royal Society of Biology awarded, (FRSB suffix) - 2018
- Odin-Thor Consulting Inc.: 11th & 14th Annual PDA Global Conference on Pharmaceutical Microbiology, 2017 GMP by the Sea, GROW Coaching & Mentoring Certification 2019, (Pfizer).
- Sanofi Pasteur: Lean Academy Graduate, HSE, cGMP, Management of Unionised Staff, Finance, HR, Compliance.
- bioLytical Laboratories: ISO 9001/13485, CMDCAS, 21 CFR 801, 803, 820 and CE Medical Device Auditor.
- BC Centre for Disease Control (PHSA): Containment Level 3 Training.
- Tekmira Pharmaceuticals: cGMP, WHMIS, HSE, TDG, 2nd Annual PDA Global Conference on Pharmaceutical Microbiology, PDA Environmental Monitoring.
- QLT Inc.: Foundations of Effective Management I, II and III, cGMP, WHMIS, HSE, Regulatory, Microbiological Identifications (Biolog external course), Managing the Microbiological Quality of Non-Sterile Pharmaceutical and OTC Drug Products (PDA).
- GSK: Management Training, Lean Sigma, Train the Trainer, Business Writing, cGMP, Safety, Regulatory, Global Validation Practices, Fire-Fighting.
- Parenteral Drug Association Membership