Phillip Lynch

Senior Quality Assurance Consultant

Core Competencies

- ASQ Certified Auditor
- Biologics/Sterile Products
- GxP Quality Systems
- GMP Audit Procedures
- Biologics API
- CMO/CRO Management
- Clinical QA Design
- Vendor Qualifications
- Quality Agreements
- QA/QC Validation
- Project Management

Professional Summary

Mr. Lynch is a results-driven quality professional with over 30 years of leadership in the pharma, biotech, medical device, and consumer industries. Products include liquids, solids, suspensions, aseptic LVP/SVP processing/filling, lyophilized products, biologics, vaccines and automated/serialized packaging. He also has strong background in Regulatory body and QMS management.

Phil has a track record of enabling business through the principles of quality as a competitive advantage, ensuring that products are available on time with superior quality. He is a decisive, innovative and pragmatic leader who works collaboratively and cross functionally across organizations to deliver strategic value for Quality, Operations, Supply Chain, and R&D.

Mr. Lynch served has an executive with leadership experience in both large and small organizations. He brings his strong knowledge and application of (c)GMP's, Health Canada Policies/Regs, FDA/EU GMP, ICH guidelines, and ISO 9001/13485/CMDCAS. He holds a degree in Chemistry with a minor in Economics from McMaster University.

Education

B.S.	Chemistry, Minor in Economics	McMaster University

Professional Experience

Design Space InPharmatics, LLC **2021 - Present**

Senior Quality Assurance Consultant

- Products - liquids, solids, suspensions, aseptic LVP/SVP, processing/filling, sterile compounding, biologics, vaccines, automated/serialized packaging,
- Strong knowledge and application of (c)GMP's, Health Canada Policies/Regs, FDA/EU GMP, ICH guidelines, ISO 9001/13485/CMDCAS, SAP/Oracle ERP systems,
- Recognized by Health Canada for industry best practice in execution, timeliness and compliance while minimizing impact to the customers and patients.

Canopy Growth **2018 - 2020**

Head of Quality and Regulatory Affairs

Successfully developed an engaged, pragmatic Quality and RA organization through cultivation of strong, trusting collaborative relationships both within the Quality team as well as all internal and external customers.

- QMS re-design (Deviation Management, CAPA, Change Control) providing GMP Certificates in Europe/Australia and record revenue year over year,
- Support strategic initiatives and overall company direction including:
  - Elimination of overdue deviations and CAPAs in 6 months,
  - Operational improvements including Right First Time from 30 to 80% and on time release from 40 to 95+%,
  - 100% Budget achievement every year.
- Collaborated with the Canadian and Global Executive teams in developing and executing key elements of the business plan, leading to an increase of 100% revenue year over year,
- Recognized by CEO for enabling commercial excellence supporting Operations and Sales (label management, "high and tight", Right First Time, Returns Management) sales increases from 30 million to 135 million quarterly.

Sanofi Pasteur **2013 - 2018**

Senior Director, Quality Operations

Successfully developed the Shop Floor team through cultivation of strong, trusting collaborative relationships across the organization. Responsible for leading and managing all aspects of the QO teams including organization, long range planning, and budget management.

- Lead remediation pillar activities for re-license of suspended aseptic facility and lifting of FDA warning letter,
- Supported strategic initiatives and overall site direction including:
  - OQ Organizational Development,
  - Aseptic filling line improvements (closed systems),
  - Toronto Site Work Stream Lead for the FDA committed Quality Enhancement Program (Deviation Management pillar) achieving all commitments on time,
  - Global Deviation Management Steering Committee Lead,
  - Bulk Manufacturing Steering Committee member.
- Globally recognized for improvement initiatives: deviation backlog and cycle time reduction (55% reduction year one), real time investigations, 100 % concurrence per Warning Letter commitment, Human Error Deviation reduction (50%), LEAN/SMS implementation,
- Created new "Ways of Working" including rapid minor deviation closure, focus factory structure, rapid response Quality teams, real time batch record review.

Baxter International **2008 - 2013**

Director of Quality - VP level role

As a member of the Canadian Leadership Team, provided leadership, commercial support, and strategic direction for all of the Quality activities and resources across multiple sites. Directly supported the country commercial operations including new product launches (drugs and devices).

- Provided business continuity and growth to over $200 million revenue annually - 80% market share- through leadership of a Health Canada mandated accelerated software deployment for 30,000 + Infusion Pumps across Canada,
- Managed the rapid identification and qualification of a new cold chain (-20C) logistics provider to support first to market opportunity launch for Baxter resulting in 90% market share year one,
- Change Management Leader for Lean/Business Excellence implementation,
- Regional Quality Representative for Gambro Business Integration Strategy (Largest acquisition),
- Key member of Baxter's Hospital Aseptic Compounding Business Strategy team including influential testimony at a Provincial Legislative Investigational Committee,
- Twice receipent of the Baxter President's Award winner.

Additional Experience

Patheon	**Associate Director Quality over 3 sites**	**1996-2008**
Germiphene	**R&D Manager**	**1990-1996**