GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Richard Smalley

MSc C.Chem FRSC
Senior Consultant

Recognised Areas of Expertise:

Experienced GxP and Quality consultant providing QP, RPi and RP services, with extensive operational and strategic expertise across pharmaceutical dosage forms, international GxP requirements, unlicensed medicines and medical devices. Skilled in supporting urgent and strategic client needs, including inspection action remediation, significant change management, product quality and facility improvement, auditing, training, supplier management and risk management. Proven global leader and driver of organisational, GMP/GDP, remediation and continuous improvement initiatives. Proficient in recall handling, inspection hosting, gap analysis, improvement programmes and liaison with regulatory bodies, with successful experience managing supply chains, distribution networks and customer relationships. Respected QP Assessor in the UK.

- Highly experienced QP, RPi and RP supporting global IMP and commercial products.
- Strong leadership, strategic improvement, communication and interpersonal skills.
- Considerable audit expertise, FDA/EU cGMP knowledge and risk management capability.
- Skilled in gap analysis, US PAI preparation and remediation implementation.
- Strong problem-solving capability, including making and implementing complex or difficult decisions.
- Experienced in Six Sigma, DoE, TQM and culture change methodologies.
- Strong supplier management, validation, sub-contractor management and commercial awareness.
- Proven ability to motivate, inspire and develop staff at all levels, including turning around poor performance.
- Effective at leading regulatory inspection preparation, QMS improvement, technical transfer, scale-up and efficiency programmes.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Independent Consultant working on behalf of Vital Boost Limited (Pharmaceutical Consulting)

Career History:

- **June 2014 – Present: Vital Boost Limited (Pharmaceutical Consulting) – Consultant**
  Consultant and/or contract Qualified Person to numerous clients (UK, EU, US, Australia, Japan):
  - VP / Quality Director level strategic advice; assessing culture, performance, performing supplier audits and mock GMP inspections.
  - Quality Management System and facility design improvement.
  - Supporting preparation for regulatory inspections.
  - Jointly hosting regulatory inspections and responding to inspection reports.
  - Supporting license submissions/resubmissions.
  - QP services
  - GMP training (general and specific, focused courses).
  - Risk management implementation and lifecycle improvement.
  - Oversight in overseas plants; person-in-plant activities.
  - Supporting significant expansion and redesign of a biologics manufacturing site.
  - Qualified Person for several first-in-class Gene Therapy products during IMP then commercial supply.

- **June 2013 – July 2014: Hospira - EMEA Commercial Quality Director**
  - Reporting to VP Global Quality and the President of EMEA region.
  - Responsible for the Europe, Middle East and Africa Commercial Quality team, covering pharmaceutical, medical device, compliance and supplier quality teams in the regional headquarter offices (UK) and supply chain regional headquarter offices (Netherlands), plus quality staff in 8 affiliate/country offices and in 2 aseptic compounding units in London. Achievements include:
    - Successfully leading remedial activities to regain CE mark and ISO13485 certification. Hosting EU and supporting US inspections.
    - Driving compliance and performance improvement across the region, liaising with US and Asian colleagues and building an effective and resilient organisation to meet future needs

- Core member of head office relocation steering team (including a major relicensing project for 70 products)
- Driving and coordinating the relocation of the Device EU legal entity from Eire to UK (including weekly telecons with 3 agencies and a major relabelling project)
- Supporting a significant initiative for global expansion and new product launches (Biosimilars)
- Leading a number of smaller projects within Quality (Artwork Management system, outsourcing, batch release efficiency improvement, risk management, FMD, LMS)
- Leading organisation redesign for the region. The team was demotivated, lacking direction and efficiency on my arrival; minor changes but greater support, more effective leadership (culture change) and the identification / handling of the long-term priorities was key to turning the team around.

- **September 2010 – June 2013: Aptuit – Site Quality Director**
  - Reporting to the Executive VP Quality.
  - Responsible for all aspects of Quality for the development, manufacture & testing of aseptically prepared sterile investigational medicinal products for use in global Clinical Trials.
  - Active on MIA (IMP) as Qualified Person, driving remediation, thorough investigations, deviations and effective CAPA.
  - Developing and improving compliance of QMS in line with ICH Q8, 9 and 10.
  - Establishing strong relationships with senior customer representatives. Improving supplier performance.
  - Driving facility improvements – cleanroom redesign/refurbishment, bringing sterility testing inhouse, implementing RABS etc.
  - Hosting and responding to client / regulatory audits and inspections (including HSE for potent products and Home Office for Controlled Drugs).

- **May 2008 – September 2010: UCB Pharma - Associate Director, Global Quality Assurance**
  - Leading a global team of managers and specialists for the Cimzia biologic product (pegylated Fab' fragment of a humanised TNF inhibitor monoclonal antibody) as manager of Vendors & Projects QA group based in Belgium.
  - Ensuring compliance and quality throughout the supply chain from Master Cell Bank through contract biologics API manufacture, contract laboratory analysis, contract filling of PFS and packaging, assembly of pre-filled syringes, certification/release and cold chain distribution.

- Supporting global licensing, effective progression of projects, licence variations and process optimisation. Coordinating Risk Management strategy development within the Global Quality Assurance function.

- **September 2000 – May 2008: 3M Health Care**
- **November 2006 – May 2008: Global Vendor Assurance and Head of Corporate Compliance**
  - As below with responsibility for corporate and supplier auditing on 5 continents plus Vendor Assurance at 6 pharmaceutical business sites, including budgetary control for these.
  - Providing proactive leadership in strategy development and implementation. Negotiation with directors of supplier organisations and contract customers.
  - Active Qualified Person in UK.

- **January 2003 – November 2006: European Vendor Assurance Manager**
  - Development of global vendor quality strategies with sites in EU, Americas and Australia.
  - Co-ordination and performance of audits at global suppliers and contract manufacturers (parenterals, packaging, liquids) through audit teams and as a specialist / lead auditor.
  - Management / development of corporate supplier complaint and distribution systems.
  - Leading implementation of global Vendor monitoring systems and improvement methods (through implementation of TQRDC).
  - Responsible for management of teams based on 3 sites.; hosting inspections.
  - Active QP from mid–2005 for respiratory/pMDI, tablets, c/r capsules, liquids, creams, parenterals and transdermal products.

- **September 2000 – January 2003: Group Leader, Quality Engineering**
  - Group Leader responsible for 7 graduate level staff and all Quality Assurance activities other than document control.
  - All aspects of compliance managed, e.g. production support, unplanned and planned deviations, internal audits, QA management of development projects, customer complaints, supplier complaints, validation document review, recall investigation and responses.
  - Trainee QP

- **August 1998 – September 2000: Bovis LendLease Pharma (Tanvec) - Validation and Quality Consultancy**
    - Generating VMP, URS, DQ, IQ, OQ and PQ documents and executing on site at Pharmacia (Sweden), Wyeth (Eire), Medeva, DePuy etc.
    - Quality consultancy – responding to client requests, supporting projects, problem solving e.g. purified water systems, cleanroom design, high-speed packaging lines.
    - Providing specialised GMP training to groups of upto 70 delegates.
    - Performing audits and gap analyses for pharmaceutical clients (dosage forms, packaging, biopharmaceutical, medical devices & API).

- **1997 – 1998: Croda Chemicals - Quality Manager (API & Excipients)**
    - Driving cultural and organisational change with successful implementation of GMP programmes i.e. complete rewriting of Quality System, training of all staff, implementation of validation for critical processes & new equipment.
    - Close liaison with suppliers & customers. Hosting audits.
    - Operational management as a member of the senior management team.

- **1995 – 1997: CP Pharmaceuticals - Senior Quality Assurance Officer**
    - Responsible for batch review of liquids, creams / ointments, support to production departments, Quality lead on both good distribution practice and the complaints handling systems.
    - Supported validation activities on site plus adhoc support to sterile product and solid dose manufacturing departments.

- **1994 – 1995: Astra-Zeneca (Macclesfield) - Pre-PAI Preparation Team, Contractor/Consultant**
    - Successful pre-PAI audits and preparations leading to launch 5 fast-track products in US and EU (Casodex, Arimedex, Seroquel, Tomudex, Zoladex)

- **1989 – 1993: Monsanto – Quality Manager API**
    - Quality management and improvements to existing processes through real-time SPC and design of experiments. Implementation of an effective performance management program for several key customers. Process, product and cost improvement projects. Successful hosting of FDA inspection. Auditing of suppliers and supporting internal audits.

- **1987 – 1989: Wellcome Foundation – Supervisor, Quality Control and Process Laboratories**
    - Sampling and testing of over 650 raw materials (API, excipients and solvents), cleaning validation and analytical method development. Testing of pharmaceutical finished products.

Education:

- 2005-2007: MSc in Pharmaceutical Quality & GMP (Distinction)
  Strathclyde University

Continuing Education & Job-Related Training:

- JPAG Assuring the Quality of aseptic medicines (organiser and chair) (2021); MHRA GMP and GDP Seminars (2020, 2021, 2022)
- JPB QP Assessor Training day (2020, 2021, 2022, 2023, 2024, 2025, 2026)
- PHSS/PQG Welsh QP Forum (2020, 2023); MHRA GMP and GDP Seminars (2019)
- JPB QP Assessor Training day (2019); PHSS/PQG Welsh QP Forum (2019)
- JPAG Assuring the Quality of aseptic medicines (organiser and chair) (2019)
- RPS Joint QP Symposium (2019)
- MHRA GMDP Seminar (2018); PHSS Annual Meeting / ATMP Seminar (2018)
- PHSS/PQG Welsh QP Forum (2018); PHSS Annex 1 Draft Seminar (2018)
- JPAG Cleaning Validation Seminar (2018)
- MHRA GMDP Seminar (2017); PHSS Sterile Products Seminar (2017); MHRA GMDP Seminar (2016)
- JPAG GDP Seminar (2016); MHRA GMP Seminar (2015); RQA Smart Quality Symposium (2015)
- JPAG GMP Seminar (2015); MHRA GMP Seminar (2014)
- NSF Alumni (2014, 2021, 2026); Medical Device Directive (QP module 2014)
- ISO13485 internal course (2013); QP Symposia (2013)
- PDA/PICS Workshop (2012)
- BioPharmaceutical Summer School (2010)
- DBA QP Modules 1-12 (2002-2004)
- IQA module A1 (12 months, 1993)
- ISO9001 Lead Assessor (1991); Design of Experiments (1990)
- Total Quality Management Programme (6 weeks, 1990)

Professional Memberships:

- Eligible Qualified Person under the provisions of Directives 2001/83/EC and 2001/82/EC
- Chartered Chemist and Fellow of the Royal Society of Chemistry
- Chartered Quality Professional and Member of the Chartered Quality Institute; Member of the Research Quality Association; Member of Pharmaceutical and Healthcare Sciences Society; IRCA Certified Lead Assessor; Six Sigma (6 σ) Green Belt - trained at 3M; NEBOSH Diploma

Published Articles & Presentations:

- Industrial Pharmacy, Issue 21, March 2009 "Impact of ICH Q8, 9 & 10 on the Qualified Person"
- GMP Review, Volume 8, no 2, July 2009 "Quality Risk Management for Suppliers"
- Presented in UK (2008 QP Symposium, 2014 at JPAG), in Europe (IPEC Conference 2008), Singapore (Cold Chain Asia 2009) and US (PDA North East Chapter 2012)
- Coordinating / chairing JPAG Aseptic Processing Seminar (May 2019, July 2021)
- Presenting at JPAG API/Excipient meeting in March 2024
- Co-host at 2024 QP Symposium, London
- Chair for 2025 Trainee QP Conference
- QP Forum with MHRA at Making Pharmaceuticals, Coventry May 2026