GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Steven Nolan

MChem, Chemistry
Qualified Person and Auditor,
GxPAssure

Recognised Areas of Expertise:

- Experienced Quality professional within the pharmaceutical industry, with a strong background across both Quality Assurance and Quality Control. Holds a proven track record in a range of technical and managerial roles, including serving as the most senior Quality authority within organisations.
- GMP, GLP, GCP and ISO Auditing across multiple product types to EU GMP, CFR 210/211, ISO 9001, 17025 and 13485.
- Eligible to act as a Qualified Person (QP) under Article 49 of Directive 2001/83/EC and Article 53 of Directive 2001/82/EC.
- Quality leadership for test laboratories implementing QMS for ISO 17025 and GLP
- Extensive experience in defining, implementing, maintaining and improving Pharmaceutical Quality Management Systems at both site and corporate level. Expertise spans research and development environments, commercial manufacturing, clinical manufacturing, and the production of unlicensed medicines.
- Technical capability includes the manufacture, testing and release of a wide range of dosage forms, including sterile and aseptic products, small-volume parenterals, solid dose forms, antibiotics, inhalation products (aerosol and dry powder), radiopharmaceuticals, liquids, creams and other formulations across development, clinical and commercial stages.
- Demonstrated experience in engaging with global regulatory authorities, leading site inspections and audits, and successfully driving remediation programmes across multiple organisations. A highly experienced GMP auditor with a strong history of auditing diverse actors within the pharmaceutical supply chain.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Director working for United QP Consulting Limited

Career History:

- **November 2022 – Present: United QP Consulting Ltd - Director**
  - Auditing for various consultancy organisations – GMP, GCP, GLP, ISO
  - QA consultancy for Specials manufacturer on risk management and future business expansion
  - Contract QP and QA support at Wockhardt UK working with sterile injectables and biologics
  - Contract Quality Head for Extractus test laboratory implementing QMS for ISO 17025 and GLP
  - Quality Consultancy for WDA holder entering MS specials and CBMP importing Head of Quality

- **February 2022 – November 2022: Hall Analytic / Element Materials - Technology Quality Director**

- **June 2021 – February 2022: M&A Pharmachem - Head of Quality Head of Quality**
- **June 2019 – June 2021: Pharmaserve (North West) Limited – Head of Quality**
  - Responsibility for the Quality Assurance Department, the Quality Control Department and accountability for the suitability of the Quality Management System in supporting the manufacture of pharmaceutical products across site.
  - The role was required to completely review, redesign, implementation and maintenance of the site PQS.
  - Also acting as QP releasing commercial and clinical materials. With the responsibility for supporting customers in setting up of clinical trials in UK.

- **July 2018 – June 2019: Recipharm, Ashton – Qualiity Manager**
  - With responsibility to manage the Quality function at the site, reporting to, and deputising for, the Head of Quality.
  - This included responsibility for the management of the QC department, consisting of Raw Materials, Finished Product, Stability and Microbiology Laboratories, and the QA department, in support of the site manufacturing processes.
  - This role required the continual review and promotion of improvement of operating standards and processes across the Ashton site.

- **March 2017 – July 2018: Catalent, Bolton - Systems Manager and Qualified Person**
  - As Qualified Person reviewing and certified batch assembly prior to release to market or sponsor/clinical trials.
  - As direct Quality representative for key customer accounts and direct Quality contact with other functions, including production, print room and project management.
  - As Systems Manager with responsibility for the Validation system at site, including review and improvement in process effectiveness.
  - With responsibility for the Incoming Goods process.
  - Also performed audits where necessary to support QP and 3rd

- Country declarations for client MAA/CTA requirements and advise on the governance of client supply chains as required and establishment and management of clinical trials in UK/EU.

- **March 2015 – March 2017: Sanofi, Holmes Chapel - Qualified Person**
  - As Qualified Person with responsibility for certifying finished product prior to release to market.
  - Acting as responsible person in relations to a significant client and provided QA oversight for the manufacture, testing, release and packaging of this key aerosol product.
  - Also provided QA oversight in the development and registration of a new dry powder inhalation product.
  - Providing Quality and Compliance leadership to Site Operations to ensure that all site and global Quality processes operate to the highest standards of compliance.

- **February 2014 – March 2015: GSK Global Manufacturing and Supply, Ulverston - Quality Assurance Manager and Qualified Person**
  - As QA Manager with responsibility for key Quality systems and supported the design and implementation of a new deviation system at both site and corporate level.
  - Acting as deputy for the Site Quality Director reporting to key executive groups
  - Also act as QP certifying bulk finished product batches of sterile antibiotics
  - Managing a number of key teams (QA, Regulatory Affairs, QC) with a number of direct reports in the QA leadership team.
  - With responsibility for defining capability, identifying gaps in skill levels and mitigating through reorganization and growth of these teams.

- **September 2010 – February 2014 WMIC, University of Manchester - Qualified Person and Quality Assurance Manager**
  - As QA Manager at the WMIC Steve was responsible for the application of the Quality Management System, with scope to including all aspects of activities within a multidisciplinary centre (including GMP manufacture, Clinical administration and scanning, Pre-clinical research, Data manipulation and storage and Project/Study Management). Steve also acted as both QP and releasing officer at the WMIC. The role involved supporting in the setting up and management of research and clinical studies.

- **August 2008 – September 2010: WMIC, University of Manchester - QC Team Leader**

- **April 2007 – August 2008: WMIC, University of Manchester - Senior QC Analyst**

- **November 2005 – April 2007: Wolfson Molecular Imaging Centre (WMIC), University of Manchester - Analytical Chemistry Technician**

- **May 2003 – Nov 2005: North West, Stepping Hill Hospital - Pharmaceutical Scientist Quality Control**

Education

- 2012: Eligible to act as QP under provisions of Article 49 of directive 2001/83/EC and Article 53 of directive 2001/82/EC and HMR
- Qualified Pharmaceutical Auditor/Lead Auditor experienced in auditing against ISO guidelines, GMP, GLP, GCP and global regulations
- Member of the MC1 Expert Advisory Group for the British Pharmacopoeia providing advice on new and revised/updated drug product monographs
- QP assessor for the Royal Society of Chemistry. Steve reviews and approves third party training courses for the Royal Society of Chemistry accreditation programme