CURRICULUM VITAE

Philip Rose

BSc (Hons) Chemistry
Pharmaceutical Industry Consultant

Philip Rose is an experienced quality professional and Qualified Person (QP) with over 20 years experience within the pharmaceutical industry. He has unique expertise gained from both his time as an MHRA Inspector and also within industry in a wide range of areas including GMP sterile manufacture, biologics, solid dose and ATMP manufacture, non-sterile manufacture, inspecting and auditing nationally and internationally, training, presenting and mentoring. Philip is very able to find solutions to complex situations and has an in depth and current knowledge of regulatory guidance and the interpretation of it.

Recognised Areas of Expertise

- Manufacture of biologicals, steriles and non-steriles
- Good Manufacturing and Distribution Practice
- UK specials
- Inspection readiness and remediation
- Regulatory compliance
- Global auditing

Involvement with Professional Associations/Societies

- Royal Society of Chemistry – Member.
- Qualified Person (Permanent Provisions)
- MHRA Compliance Monitor

Current Employment

- Independent Consultant working on behalf of ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry.

Career History

June 2022 to August 2023 - NSF HEALTH SCIENCES
EXECUTIVE DIRECTOR

- Managed a portfolio of clients with their requirements in consultancy, auditing and training.
- Direct interaction with clients from initial contact to delivery of bespoke solutions to their requirements.
- Subject matter expert in sterile medicinal, biological medicinal and advanced therapy medicinal products (ATMPs).
- Delivered public and in-house training to clients.
- Delivered in-person, on-site consultancy for both on-going compliance and remediation activities, including CMT and IAG cases.
- UK Member of the Senior Leadership Team.

June 2021 to June 2022 -MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)
LEAD SENIOR GMDP INSPECTOR

- As below for GMDP and Senior GMDP Inspector, plus:
- Lead inspector for the most complex regulatory inspections nationally and internationally
- Led international joint inspections overseas including EMA and USFDA
- Deputy to Expert Inspector on decisions and policy relating to GMP
- Member of the Compliance Management Team
- Member of the Innovation office Inspectorate advice team advising innovative companies on regulatory queries
- Member of a number of scientific advice meetings
- Mentor to junior inspectors
- Hostile Environment Awareness Training (HEAT) trained to advanced level

Mar 2019 to June 2021 - MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)
SENIOR GMDP INSPECTOR

- Key member of MHRA Vaccines Task Force heavily involved in delivering vaccines to the UK and other populations
- GMP Inspections of Biologic, ATMP, Sterile and Non-Sterile pharmaceutical manufacturers for supply to UK and EU markets globally
- Inspectorate Lead for Biologics Inspection Group
- Inspectorate Deputy for Sterile Inspection Group
- Part of the drafting group for PIC/s Annex 2a
- Member of the MHRA Cross-contamination Inspection Group
- Delivered a large number of presentations at Industry conferences in addition to MHRA Symposia
- Trained third country regulators in vaccine manufacturing

Jan 2015 to Mar 2019 - MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)
GMDP INSPECTOR

- GMP Inspections of Biologic, ATMP, Sterile and Non-Sterile pharmaceutical manufacturers for supply to UK and EU markets globally
- Inspectorate Lead for MHRA Steriles Inspection Group
- Member of the MHRA Cross-contamination Inspection Group
- Trained 50 EU and international regulators on Inspecting facilities for cross contamination aspects

March 2013 – Jan 2015 - BTG PROTHERICS, FFOSTRASOL
Quality Manager / Qualified Person

- Qualified Person (Permanent Provisions) named on MIA, MIA(IMP) and Specials licences.
- Responsible for two critical care biologic products.
- Management of site Quality Management System.
- Lead Auditor
- Improvements implemented to well established systems
- Responsible for Quality communication with the regulators in response to GMP review on site
- Led the inter-site QP Forum
- Led, mentored and developed the Quality department
- Review and approval of Quality documentation
- Responsible for department metrics

November 2012 – March 2013 - ECOLAB, BAGLAN, NEATH
Head of Quality, Healthcare

- Responsible for complete quality function on sterile and non-sterile manufacturing site
- Head of Quality Assurance, Quality Control, Validation and Microbiology
- Reviewed existing quality system
- Implementation plan of quality improvements

November 2007 – November 2012 - PATHEON UK LTD, SWINDON
Data Verification Team Leader, Pharmaceutical Development Services

July 2001 – July 2005 - CARDINAL HEALTH (FORMALLY RP SCHERER), SWINDON
New Product Development Scientist II

Qualifications

1998 - 2001: UNIVERSITY OF KENT AT CANTERBURY
BSc (Hons) Chemistry