CURRICULUM VITAE

Vicki Pike

BSc (Hons) MRPharmS, Qualified Person

EPIC Operations Manager
and Pharmaceutical Industry Consultant

Vicki has over 25 years experience working in the pharmaceutical industry, including 7 years working as GMDP Inspector for the MHRA. Vicki was accredited to perform a wide range of inspections of different dosage forms and processes including: steriles, non-steriles, specials (unlicensed medicines), medical gases, IMPs, herbals, importation and wholesale dealing.

Prior to joining the MHRA, Vicki worked for AstraZeneca at their UK manufacturing site, predominately in Quality roles, and became eligible as a QP in 2006. After leaving MHRA she joined GlaxoSmithKline, where she worked as a corporate auditor for 8 years, and latterly led a remediation project at a European manufacturing site.

Vicki is a pharmacist by training and puts patient impact at the forefront of her decision making. Vicki is passionate about sharing her knowledge, especially when coaching and training others.

Recognised Areas of Expertise

- A highly experienced Quality professional with over 25 years spent working in the Pharmaceutical Industry
- 7 years within the UK Regulator – MHRA, as a GMP / GDP Inspector
- Eligible to act as a QP since 2006 under Directives 2001/83/EC and 2001/82/EC.
- Extensive experience as an auditor with expertise in a wide range of dosage forms including:
    - active substances
    - steriles - aseptic and terminally sterilised, includes small and large volume parenterals, powders, lyophilised products and long acting depot
    - non-steriles - includes tablets, hard and soft gelatine capsules, creams, ointments, liquids, pMDI, dry powder inhalers, and nasal sprays
- Excellent knowledge of UK, European, US and other International legislation relating to GMP and GDP requirements.

Current Employment Nov 2024 - present

- Operations Manager for ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry.

Career History

Jan 2024 – Oct 2024

GlaxoSmithKline, Priory Street, Ware, Hertfordshire, SG12 0DJ

Remediation Director

- **Main activities & responsibilities**
  - Ensured an integrated Remediation Plan to address each of the identified deficiencies was developed, tracked and maintained
  - Ensured sufficient resources were recruited to deliver the plan
  - Management of Third Party Consultants on site, ensuring their requests were met and concerns addressed
  - Facilitated governance meetings at site and central function levels
  - Identified, escalated and mitigated risks and issues
  - Supported development of corrective action plans
  - Coached site staff in Quality improvement areas and Quality culture
  - Verified CAPA and regulatory commitments made by the site

March 2022 - Jan 2024

GlaxoSmithKline, Priory Street, Ware, Hertfordshire, SG12 0DJ

Quality Director

- **Main activities & responsibilities**
  - Management and leadership of the Product Incident and Recall processes, including documentation, training, data oversight and reporting
  - System owner for PRS (Product Incident and Recall System) including accountability for system performance monitoring, system improvement, and guidance on use and maintenance
  - Utilised Product Incident Data to provide analysis and reports on performance of the process and the trends of data contained within to identify risk and/or improvement areas
  - Management and leadership of the Pharma Quality Alert/Bulletin Process
  - Leading the team responsible for providing quality oversight to the Artwork and Packaging Service, including serialisation

August 2014 – February 2022

GlaxoSmithKline, Priory Street, Ware, Hertfordshire, SG12 0DJ

Quality Audit Manager

- **Main activities & responsibilities**
  - Performed and managed GMP/GDP compliance audits of GSK and Third Party manufacturing sites, Logistic Service Providers and Marketing Companies
  - Identified any gaps to GSK's Quality Management System and applicable cGMP and GDP requirements
  - Performed 'for cause' audits at specific sites as required
  - Coached and developed others in Auditing, both within immediate team and across GSK

June 2007 – July 2014

Medicines and Healthcare products Regulatory Agency (MHRA)

151 Buckingham Palace Road, Victoria, London. SW1W 9SZ

Good Manufacturing and Distribution Practice (GMDP) Inspector

- **Main activities & Responsibilities**
  - Inspecting pharmaceutical manufacturers, importers and distributors in the UK and overseas to ensure compliance with EU GMP and GDP
  - Accredited to perform a wide range of regulatory inspections including:
    - Wholesale dealing
    - Importation
    - Non-sterile manufacture
    - Sterile manufacture
    - Specials (unlicensed medicines)
    - Assembly only (included Parallel Imports)
    - Medical Gases
    - Investigational Medicinal Products
    - Herbals Medicines
  - Mentored two new starters through their induction period and continued to support them once accredited
  - MHRA lead on Medical Gases. Chaired joint meetings between the MHRA and the British Compressed Gas Association to improve collaboration
  - Conducted joint inspections with several other Regulatory Agencies including FDA (USA), SAHPRA (South Africa), HSA (Singapore), ANVISA (Brazil), HPRA (Ireland), ANSM (France), IGZ (The Netherlands) and World Health Organisation (WHO). Shared knowledge and gained understanding of other Regulators interpretations of GMP
  - Wrote technical guides for use by the inspectorate covering non-sterile manufacture and herbal product manufacture
  - Wrote and delivered presentations at the following MHRA GMP Symposia:
    - 2009 – Deficiencies arising from MHRA Inspections
    - 2011 – Safety Features and Compliance with the MA

September 1998 – June 2007

AstraZeneca, Silk Road Business Park, Macclesfield, Cheshire. SK10 2NA

QA Advisor / Eligible QP July 2004 – June 2007

First Line (Production) Manager March 2003 – July 2004

Quality Assurance Officer September 1998 – March 2003

- **Main activities & Responsibilities**
  - Performed batch release activities for finished product dosage forms including tablets, capsules, nasal spray and aseptic depot
  - Operational management of tablet packaging lines and teams
  - Providing quality assurance advice and support to all production areas across site including oral solid dose, sterile products and active pharmaceutical ingredients. Perform investigations into critical incidents including recalls
  - Eligible to act as a QP in July 2006

July 1996 – August 1998

Aberdeen Royal Infirmary, Pharmacy Department, Foresterhill. Aberdeen

Basic Grade Pharmacist August 1997 – August 1998

Pre-Registration Pharmacist July 1996- July 1997

- **Main activities & Responsibilities**
    - Providing clinical pharmacy services to hospital wards and out of hours/on call dispensary service

Education & Qualifications

- **BSc (Hons) First Class Pharmacy** - September 1992 - June 1996

  Robert Gordon University, School of Pharmacy, Schoolhill, Aberdeen.
- **Eligible Qualified Person** - July 2006
- Registered with the **General Pharmaceutical Council**
- Member of the **Royal Pharmaceutical Society**