CURRICULUM VITAE

Kathleen Williams

MSc, CChem

Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- Former MHRA GCP Senior Inspector
- Audits in GCP, GPV and clinical/analytical laboratory areas
- For-cause and due diligence audits
- Worked at strategic level developing risk based strategies for QA Led initiatives and audit programmes

Current Employment

- Independent consultant working on behalf of ExPharmaceutical Inspectors Consortium

Involvement with Professional Associations/Societies

- Chartered Chemist (CChem) and Member of the Royal Society of Chemistry
- RQA member since 2002.
- RQA GCP Committee member since June 2011.
- RQA Regulatory Affairs Working Party Member since Jan 2015

Career History

- Dec 2013 to date: Director and QA Consultant
- Jan 2010 to November 2013: Lead QA Specialist (QA, GCP, GPV and GLP compliance), LEO Pharma
    - Provide expertise and advice on matters related to GCP and GPV
    - Participate in QA led strategic initiatives and projects where relevant

- Conduct audits in line with QA audit plans and SOPs
- Coordinate/participate and assist inspectors during inspections of LEO Pharma GLP, GPV ,GCP and MAH activities
- Strategy development and project implementation as well as planning of QA audit activity
- Line Management of five personnel within the department

- Dec 2007 to Dec 2009: Senior Manager, QA, Mitsubishi Pharma Europe
  - Head of department responsible for planning, resourcing and management of QA audit activity for MPE managed studies
  - Provide QA advice on GXP matters to MPE personnel
  - Provide GXP training to MPE Personnel
  - Provide Annual Budget estimates for QA Department
  - Provide QA review and approval of MPE SOPs and WIs
  - Development and management of CAPA system
  - Conduct audits in line with QA audit plans, SOPs and WIs
- Feb 2004 to Dec 2007: Inspector/Senior GCP Inspector, MHRA, UK
  - Contributed to the development of a national programme for GCP Inspections
  - Plan and conduct GCP Inspections
  - Provide advice on GCP and GCP Inspection issues
  - Contribute to development and maintenance of SOP system
  - Contribute to development of EMEA SOPs
  - Attendance at EMEA inspectors meetings
  - Plan and conduct EMEA GCP Inspections
  - Attendance at GCP Consultative Committee Meetings
  - Supporting role in liaison with NRES
  - Development and delivery of GCP Inspection conferences
  - Mentoring & Training of GCP Inspectors
  - Management of GCP Inspectorate referrals process (e.g. whistleblowers)
- Jan 2002 to Jan 2004: Auditor/Senior Clinical Quality Assurance Auditor, Pfizer UK
  - Conduct of GCP Investigator site audits, vendor audits (CROs & Laboratories), Internal system audits, Local area offices (Affiliates) and regulatory submission document audits
  - Lead clinical auditor for two clinical research projects
- Nov 1999 to Nov 2001: QA Compliance Auditor, GSK, UK
  - Conduct of cGMP audits of UK Manufacturing Product Supply Sites
  - Responsible for development, management and resourcing of local site audit schedule
  - Responsible for training & mentoring of internal auditors on site
- Oct 1996 to Nov 1999: Analytical Technologist, New Products Laboratory, Glaxo Welcome, UK
  - Analytical method validation, cleaning validation, stability testing, process validation testing

    - Responsible for set up and delivery of laboratory compliance self-inspection programme
- Jan 1995 to Jun 1996: Applications Specialist, Chemlab Instruments, UK
    - Method development for Flow Injection Analysers