GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

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Dr. Kath Williams

PhD in Analytical Chemistry &
MSc in Analytical Sciences
Senior Consultant, GxPAssure

Recognised Areas of Expertise:

A highly experienced Quality Assurance professional offering consulting and auditing services with over 25 years' experience across the pharmaceutical and pharmaceutical research sectors, specialising in GCP, GVP, GLP, and clinical/analytical laboratory quality systems. A former MHRA Senior GCP Inspector, bringing deep regulatory insight and a proven record of delivering robust audit programmes, strategic QA initiatives, and compliance frameworks for global organisations, SMEs, and specialist service providers.

Experienced in conducting a wide spectrum of audits—including for-cause, due diligence, investigator site, Phase I, vendor/CRO, niche technology providers, and data integrity assessments—supported by strong analytical capability and decisive problem-solving skills. Demonstrated success in designing risk-based audit strategies, leading QA departments, managing global inspection readiness, and coaching auditors at varying levels of expertise.

Recognised as an engaging trainer and subject-matter expert in GCP and GVP, with substantial experience representing organisations during MHRA, EMA, and other regulatory authority inspections. Chartered Chemist (CChem MRSC) with a PhD in Analytical Chemistry and extensive professional development spanning regulatory updates, data integrity, and GxP compliance.

Professional Memberships;

- Chartered Chemist (CChem), Member of the Royal Society of Chemistry (MRSC)
- Member of the Research Quality Association (RQA) since 2002
- Former Chair of the RQA Board

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Director and QA Consultant, KEW Quality Consulting Ltd

Career History:

- **December 2013 - Present: KEW Quality Consulting Ltd – Director and QA Consultant**
  - Consulting and auditing services to clients within the pharmaceutical industry and pharmaceutical research environment (GCP and PV Systems, GCP Investigator Sites, GCP Clinical and Analytical Laboratories, Phase I Units, Vendors / CROs, Marketing Partners, Local Operating Companies/Affiliates)
  - Niche service provider audits (IWRS, ECG reader etc.)
  - Specialist auditing services (For-Cause, Due Diligence Activities, Data Integrity)
  - GCP Gap Analysis and CAPA development initiatives
  - Assisting clients with QA led project to develop training and mentoring programs for GCP and GVP auditors
  - Coordinate/participate and assist clients during inspections of GVP & GCP and MAH activities
  - GCP and GVP Mock Inspections
  - Excellent trainer with engaging presentation skills
  - Strong analytical thinking and proven problem-solving abilities
  - Certified GDPR foundation and Practitioner

- **January 2010 – November 2013:LEO Pharma – Lead QA Specialist**
  - Development and delivery of QA auditing risk-based strategy for GCP, GLP, GVP audits across the LEO Global organisation
  - Line management of five personnel within the department
  - Provided expertise and advice to business partners on GxP related matters
  - Conducted GCP and GVP audits in accordance with QA audit plans

- **December 2007 – December 2009: Mitsubishi Pharma Europe – Senior Manager QA**
  - Head of department responsible for planning, resourcing and management of QA audit activity
  - Provide annual budget estimates for QA Department to global HQ
  - Line Management of QA department (three personnel)
  - Successful development and implementation of CAPA system
  - Conduct of GCP and GVP audits in accordance with QA audit plans

- **February 2004 – December 2007: MHRA – Inspector / Senior Inspector**
    - Development and management of GCP Inspectorate referrals process (Serious Breaches)
    - Contributed to the development of national GCP Inspection program
    - Conducted GCP inspections for MHRA and EMA
    - Attended GCP EMA inspectors meetings
    - Development and delivery of GCP Inspection Conferences

- **January 2002 – January 2004: Pfizer – Auditor / Senior Clinical QA Auditor**
    - Conduct of GCP audits and lead QA support for two clinical projects

- **November 1999 – November 2001: Glaxo Smith Kline – QA Compliance Auditor**
    - Conduct of cGMP audits of UK Manufacturing Product Supply sites

- **October 1996 – November 1999: Glaxo Welcome – Analytical Technologist**
    - Analytical Method Validation, Cleaning Validation, Stability Testing, Process Validation Testing

Education:

- 1990 – 1994: PhD in Analytical Chemistry – University of Hull
- 1990 – 1994: MSc in Analytical Sciences - University of Hull
- 1987 – 1990: Graduate of the Royal Society of Chemistry part II (First class)
- 1987 – 1990: HND in Physical Sciences (Chemistry)

Continuous Professional Development

- February 2025: MHRA GCP and Laboratory Symposium London
- February 2025: GCP is Changing….Whats new in E6(R3) (webinar – Brookwood) Remote
- February 2024: MHRA/FDA/HC GCP and PV Symposium London
- March 2022: MHRA PV Symposium Remote
- March 2022: MHRA GCP Symposium Remote
- January 2022: Eu Clinical Trial Regulations (on-line course) – Brookwood Remote
- June 2020: FDA Bioanalysis Symposium Remote
- February 2020: MHRA GCP and PV Symposium London
- February 2020: MHRA GLP Symposium London
- September 2018: MHRA GCP Symposium Leeds
- June 2018: Certified GDPR Foundation and Practitioner London

- May 2018: MHRA PV Symposium London
- March 2018: Course Tutor RQA Seminar on Data Integrity (intermediate)
- October 2017: Data Integrity, Critical Thinking (Advanced) Green Mountain QA, Dublin
- March 2017: Course Principal RQA Seminar on Data Integrity (introduction) London
- September 2016: MHRA GCP Symposium Birmingham
- September 2016: Course Principal RQA Seminar on Data Integrity, Heathrow
- May 2015: Course Tutor RQA Seminar on Investigator Initiated Studies, Windsor
- April 2015: Advanced Data Integrity (train the trainer) Course Green Mountain QA, Dublin
- December 2014: QA Data Integrity Auditing Course Green Mountain QA, Dublin
- November 2014: Data Mining Workshop RQA pre-conference training, Brighton
- September 2012: EU Pharmacovigilance Training (GVP Modules) VigiReg Consulting Ltd
- May 2012: Quality Metrics Corporate Workshop LEO Pharma in-house training
- January 2012: LEAN Quality Assurance LEO Pharma in-house training
- January 2012: Drug Safety Training LEO Pharma on-line training
- January 2011: Drug Safety Training LEO Pharma on-line training
- January 2010: Drug Safety Training LEO Pharma on-line training
- March 2010: New Starter One day Induction (products/safety) LEO Pharma face to face training
- September 2005: ISO 9000 lead auditor examination (IRCA)
- 2009 – 2010: RQA Systems Audit Course (course Tutor)
- November 2011: RQA Annual Conference Bristol