CURRICULUM VITAE

Mark Poulton

BSc (Hons) Applied Biology
Senior Consultant, GxPAssure

Recognised Areas of Expertise:

A dedicated and adaptable professional with extensive expertise in Clinical Quality Management and Clinical Project Management, committed to ensuring the highest levels of compliance, operational efficiency, and delivery excellence. Experienced in leading quality initiatives, managing complex global projects, and supporting organisational objectives through strong analytical and problem-solving capabilities.

Recognised for exceptional communication and presentation skills, with the ability to translate complex concepts into clear, actionable insights for diverse stakeholders. A confident and supportive team manager, fostering collaboration, motivating colleagues, and promoting a positive team culture. Known for strong interpersonal skills, reliability, and a proactive work ethic. Highly proficient in utilising information technology to streamline processes and enhance productivity across clinical and quality operations

- Clinical Quality Management
- Clinical Project Management
- Communication & Presentation
- Problem Solving & Risk Identification
- Team Management & Leadership
- Interpersonal Skills & Stakeholder Engagement
- Quality Systems & Regulatory Compliance
- Information Technology to Enhance Productivity

With multiple industry publications to my name, I have contributed original research and insights to respected journals and international conferences, including:

- Archives of Virology (1983): Some characteristics of Mycoplasma virus
- Journal of Antibiotics (1989): A Novel Series of Milbemycin Antibiotics from Streptomyces Strain E225 I. Discovery, Fermentation and Anthelmintic Activity

- Journal of Antibiotics (1990): A Novel Series of Milbemycin Antibiotics from Streptomyces Strain E225 II. Isolation, Characterisation, Structure Elucidation & Solution Conformations
- VIII International Conference on AIDS, Amsterdam (1992): Mode of Action of BRL 47923, A Potent and Selective Inhibitor of HIV Replication

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Founder and Executive Director of Poulton Quality Solutions Ltd

Career History:

- **January 2019 to Present: Poulton Quality Solutions Ltd – Founder and Executive Director**

  A quality Consultancy providing Global Clinical QA services to companies and organisations requiring expertise in all areas of Clinical Quality. The company can provide the following services;

  - CRO Systems review
  - Investigator Site and Phase I Unit assessments
  - TMF (paper & electronic) evaluation
  - Laboratory (Local, Central, Specialist, Bioanalytical) oversight
  - Bioequivalence studies
  - CSV, IRT, EDC, ePRO assessments
  - Document management and evaluation (Protocol, PIS/ICF, CRF, IB, CSR, DSUR)
  - GLP & GMP auditing
  - GCP training (ICH GCP, CT Regulations, Inspection Preparation, CAPA & RCA)
  - Inspection support (Mock EMA/MHRA/FDA Inspections, facilitation, response preparation)
  - General Clinical QA Consultancy

- **May 2017 to December 2018: Clovis Oncology – Senior Manager GCP QA**
  - Redeveloping GCP QA QMS to fit with current requirements
  - Development of audit schedule
  - Planning, performing and reporting audits according to schedule requirements
  - Management of GCP QA documentation
  - Management of GCP QA consultants

- Provision of adequate responses to inspection reports
- Provision of GCP training to all staff on an annual basis
- Oversight of clinical quality and provision of advice and training as necessary

- **November 2016 to May 2017: Clinical Consultants Ltd – Principal QA Consultant**
  - Delivery of audits (ISAs, Systems, Safety, TMF, Documentation)
  - QA consultancy and QMS improvement recommendations
  - Speaking engagements and training presentations on GCP
  - Internal QMS review and enhancement proposals

- **October 2011 to November 2016: ADAMAS Consulting, Executive Principal Consulting**
  - Delivery of projects in compliance with agreed proposals and budgetary constraints.
  - Performing the role of Project Lead, Lead Auditor or co-Auditor
  - Delivery of consultancy services and training services
  - Project management, including project plan preparation and archiving of project documents.
  - Audit management, preparation, conduct, reporting, follow up and archiving of audit documents.
  - Delivery of consultancy services (e.g. SOP development, quality system advice, general advice on regulatory compliance issues)
  - Perform GCP audits (system, ISA, ERC, Laboratory, IRT, data management, database, EDC, Biostatistics, Medical Writing, Document Audits (Protocol, IB, ICF / PIS, CRF, CSR), TMF, CSV)
  - Perform GLP and GMP audits

- **August 2006 to September 2011: Medicines & Healthcare Products Regulatory Agency – GCP Inspector**
  - Responsible for planning, performing, reporting and closing GCP inspections according to UK law
  - Involved in commercial, non-commercial, investigator sites, please 1 GCP inspections
  - Management of GCP Consultative Committee
  - Member of training team managing all aspects of GCP inspector training.
  - Management of MHRA Symposia and presentations on behalf of MHRA at various meetings.

- **February 2001 to July 2006: Takeda Eurpoe R&D Centre Ltd – Programme Manager, Clinical Project Scientist**
  - Line management of study managers
  - Clinical Member of Regulatory Inspection Planning Team

- Management of;
  - EU arm of global Phase III safety study for lpid lowering agent
  - Global Phase III programme in ladies health, involving phase 1 and phase III studies
  - Co-sponsored large global Diabetes complications outcomes study
  - European development plan and clinical trials of novel oncology agent and liaison with Japan and USA regarding development progress
  - Development planning for new agent for prostate cancer and initiating those studies post company approval
  - Responsible for planning and managing First-In-Man studies of new CNS agent
  - Development of EU Advisory Board for CNS product development

- **March 1999 to February 2001: Du Pont Pharmaceuticals Ltd, Stevenage – Senior Clinical Research Scientist, Europe**
  - Responsible for initiating and managing European arm of Phase III cardiovascular programme.
  - Management of UK centres and CRO involved in Phase II RA study
  - Assistance with monitoring UK Phase 1 studies
  - Development of European processes for clinical studies
  - Investigation of clinical trials management systems for use by company on a global scale.

- **December 1998 to March 1999: Axess Ltd (on contract at Lorex Synthelabo, Maidenhead) – Clinical Research Associate, Medical Department**
  - Responsible for all Phase 1 clinical studies performed in the UK
  - Initiated and monitored a urology Phase 1 (population pk) study and a hospital-based Phase IV anti-inflammatory study.
  - Manged and monitored a cardiac safety assessment Phase 1 study

- **May 1997 to November 1998: NeXstar Pharmaceuticals, The Quorum, Cambridge – Clinical Research Associate, Medical Department**
  - Management and monitoring of NeXstar sponsored clinical trials in UK in anti-infectives (anti-fungal), haematology and oncology therapeutic areas.
  - Provide assistance to investigators conducting their own research trials
  - Provide expertise in global clinical research
  - Development of global SOPs and processes associated with GCP
  - Development of internal processes and communication lines to improve efficacy of global clinical research.

- **January 1994 to May 1997: Smith Kline Beecham Pharmaceuticals, Harlow – Clinical Investigation Scientist (Antiviral)**
    - Management of a number of worldwide clinical trials involving Europe, US and the far east.
    - Responsible and accountable for all aspects of clinical trials from inception to report.
    - Development of clinical trial protocols and CRFs
    - Tracking study progress and meeting timelines
    - Reduction of overall study timelines
    - Liaison with country medical departments regarding protocol design and study logistics and timelines.
    - Budget management
    - Clinical report writing
    - Preparing presentations for internal and external meetings

- **January 1993 to December 1993: Smith Kline Beecham Pharmaceuticals, Brockham Park – Research Biochemist**
    - Method development for elimination of known compounds in natural product screens
    - Development of antiviral compounds, concerned with mode of action elucidation

- **June 1991 to October 1992: Smith Kline Beecham Pharmaceuticals, Great Burgh – Research Biochemist (Higher Scientific Officer)**
    - Studied the intracellular metabolism of antiviral compound
    - Investigated dermal models to measure skin penetration and metabolism of antiviral compounds.

- **April 1984 to May 1991: Smith Kline Beecham Pharmaceuticals, Walton Oaks – Research Biochemist (Scientific/Higher Scientific Officer)**
    - Managed a small team responsible for the development and implementation of high throughput screens for the detection of metabolites acting on neuroreceptors.
    - Managed neurochemical screens for natural product discovery involving 240 culture samples per screen per week and isolated a number of microbial metabolites with activity in these screens, including a novel series of milbemycin antibiotics.
    - Responsible for the provision of computer programmes and databases for storage, analysis and retrieval of laboratory acquired data.

- **November 1978 to May 1984: Smith Kline Beecham Pharmaceuticals, Brockham Park – Technician / Senior Technician / Scientific Officer**
    - Screened more than 500 compounds against a variety of mycoplasma species

- Performed in vitro metabolism studies on compounds using bioanalysis to determine metabolism in a number of tissues.
- Completed a feasibility study on the potential of natural products as novel antimycoplasma agents.
- Discovered a novel virus infecting mycoplasma hyorhinis

- **August 1976 to November 1978: Smith Kline Beecham Pharmaceuticals, Worthing – Junior Technician**
  - Responsible for bioassay and electrophoresis of antibiotic and vitamin preparations.

Education:

- 1980 - 1983: BSc (Hons) Applied Biology – North East London Polytechnic
- 1978 – 1980: HNC Applied Biology – North East Surrey College of Technology
- 1976 – 1978: ONC Biology Sciences – Brighton Technical College
- 1971 – 1976: 6 GCE 'O' lovels – Tideway Comprehensive School
- Professional Membership to RQA (Research Quality Association