CURRICULUM VITAE

Mark Poulton

BSc (Hons)
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- Clinical Quality Management
- Clinical Project Management
- Communication & Presentation Skills
- Problem Solving
- Team Management
- Strong Interpersonal Skills
- Dedicated Team Worker
- Information Technology

Involvement with Professional Associations/Societies

- RQA (Research Quality Association)

Current Employment

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

Career History

Jan 19 to date
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
- Investigator Sites
- Phase One Units
- Trial Master File (TMF), paper and electronic
- Laboratory: Local, Central, Specialist and Bioanalytical
- Bioequivalence studies and services
- Computer System Validation (CSV)
- Interactive Response Technologies (IRT)
- Electronic Data Capture (EDC)
- Electronic Patient Reported Outcomes (ePRO)
- Document Management Systems
- Internal Systems
- Documentation:
    - Protocol
    - Patient Information Sheet / Informed Consent Form (PIS / ICF)
    - Case Report Form (CRF)
    - Investigator Brochure (IB)
    - Clinical Study Report (CSR)
    - Development Safety Update Report (DSUR)
- GLP auditing of GLP laboratories
- GMP auditing of oral solid dosage forms
- Training:
    - ICH GCP
    - Clinical Trial Regulations
    - Inspection Preparation
    - CAPAs and Root Cause Analysis
- Inspection Training and Support:
    - Mock EMA, MHRA or FDA GCP Inspection
    - Facilitation during an Inspection
    - Assistance in Inspection response preparation
- Clinical QA Consultancy

May 17 to Dec 18
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.

Nov 16 to May 17
Quality, Regulatory, Clinical Consultants Ltd, Principal QA Consultant.

- Conducting audits for clients (ISAs, Systems, Safety, Documents, TMF).
- Supporting clients as QA consultants, with feedback provided re quality systems.
- Presentation at company symposia relating to GCP.
- Review of internal QMS and provision of improvement changes.

Oct 11 to Nov-16
ADAMAS Consulting,

Executive Principal Consultant
Principal Consultant & Operations Support (Sep-14 to Sep-15)
Principal Consultant (Jan 14 to Aug-14)
Senior Consultant (Sep12 to Dec-13)
Consultant (Oct 11 to Sep 12)

- 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 (e.g., SOP development, quality system advice, general advice on regulatory compliance issues) services.
- 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.

Aug 06 to Sept 11
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, Phase 1 GCP Inspections.
- Management of GCP Consultative Committee.
- Member of Training Team managing all aspects GCP Inspector training.
- Management of MHRA Symposia and presentations on behalf of MHRA at various meetings.

Feb 01 to July 06
Takeda Europe 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 a lipid lowering agent.
- Global Phase III programme in ladies health, involving phase I 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.

Mar 1999 to Feb 01
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 I studies.
- Development of European processes for clinical studies.
- Investigation of clinical trials management systems for use by company on a global scale.

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

May 1997 to Nov 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.

1976 to May 1997
SmithKline Beecham Pharmaceuticals *(formerly Beecham Pharmaceuticals Research Division).*

Jan. 1994 to May 1997
Anti-infective Therapeutic Unit, Harlow, Clinical Investigation Scientist (Antivirals)
- Management of a number of world-wide 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.

Jan. 1993 to Dec. 1993
Microbial Biochemistry Department, Brockham Park, Research Biochemist.
- Method development for elimination of known compounds in natural product screens.
- Development of antiviral compound, concerned with mode of action elucidation.

Jun. 1991 to Oct. 1992
Antiviral Chemotherapy Programme, Great Burgh. Research Biochemist (Higher Scientific Officer).
- Studied the intracellular metabolism of antiviral compounds.
- Investigated dermal models to measure skin penetration and metabolism of antiviral compounds.

Apr. 1984 to May 1991
Veterinary Microbial Metabolites Project, 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.

Nov. 1978 to May 1984
Pseudomonic Acid Project, 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*.

Aug. 1976 to Nov. 1978
Microbiological Assay Services Unit, Worthing, Junior Technician.
- Responsible for bioassay and electrophoresis of antibiotic and vitamin preparations.

Publications

- Archives of Virology (1983) 77:81-85 'Some Characteristics of Mycoplasmavirus Hr1, Isolated from and infecting *Mycoplasma hyorhinis*.'
- J. Antibiotics (1989) 42(11):1593-1598 'A Novel Series of Milbemycin Antibiotics from Streptomyces strain E225 I. Discovery, Fermentation and Anthelmintic Activity.'
- J. Antibiotics (1990) 43(9): 1069-1076 'A Novel Series of Milbemycin Antibiotics from Streptomyces strain E225 II. Isolation, Characterisation, Structure Elucidation & Solution Conformations.'
- Abstracts of the VIII International Conference on AIDS, Amsterdam, 19 - 24th July 1992 Abstract No. PoA2311 'Mode of Action of BRL 47923, A Potent and Selective Inhibitor of HIV Replication.'

Education

Date	Qualifications	Establishment
1980-1983	BSc(Hons) Applied Biology	North East London Polytechnic
1978-1980	HNC Applied Biology	North East Surrey College of Technology
1976-1978	ONC Biological Sciences	Brighton Technical College
1971-1976	6 GCE 'O' levels	Tideway Comprehensive School