PROFILE

First class Quality Practitioner skilled in the design and development of Quality Systems complying with both global and local regulations, and specialist advisor to a range of young biopharmaceutical organisations. Integral in defining and enhancing business knowledge and awareness of regulatory expectations and company quality requirements by building solid relationships with key stakeholders. Commercially aware, with a keen eye for detail to improve systems, not just to criticise, able to provide value through the provision of informed, cost effective Quality Solutions, appropriate to the stage of development.

KEYSKILLS & ACHIEVEMENTS

Quality System Design & Implementation

- Rescued previously failing quality system operating in the UK and US for an innovative drug delivery firm. Designed the framework to support operations and established an internal and vendor audit programme.
- Skilfully harmonised operations across multi-cultural sites to ensure a uniform approach to processes and SOPs.
- Designed and implemented quality systems for small start-up operations. Addressed the Critical Success Factors for all disciplines across the development pathways from research through to Phase IV.
- Designed and developed both internal and external audit programmes to support GMP (pharmaceutical and device), GLP and GCP negating the need for three separate systems.

Quality Audits

- Clinical QA skills developed within global environments including the auditing of CROs.
- Experienced auditor of all phases of clinical studies, IMP GMP manufacturers and testing laboratories, and GLP facilities.
- Successfully guided a number of businesses through the entire MHRA inspection process, from initial preparation to formulating inspection report responses.

Project Management

- Managed the project team responsible for the implementation of an electronic SOP system within budget and time.
- Facilitated the closure and transfer of the QA unit and Archives for two businesses in line with transition plan milestones.

PROFESSIONAL EXPERIENCE

2004 - present
Managing Director and Consultant

- has assisted a number of biotechnology companies to set up quality systems, prepared quality manuals and SOPs and reviewed documentation in preparation for IMPD submission.
- Conducted CRO (phase I and full service), clinical site, TMF, device contractor, CMO and clinical packaging and labelling CRO audits.

PowderMed Ltd (wholly owned subsidiary of Pfizer Inc) **2004 - 2008**
An innovative vaccine delivery business
Head of QA (part time)

- Interpretation of regulatory requirements in collaboration with customer departments to ensure appropriate level of compliance to support the current phase of development of the organisation.
- PowderMed operated as a virtual organisation whilst retaining release testing in house. Assured management of the quality status of third party contractors, through a combination of vendor/CRO audits, data review and questionnaires.

Health Decisions Ltd **2004 - 2005**
A Clinical CRO
Head of Quality and Compliance

- Established a UK quality system to support Health Decisions, acted in a consultant capacity conducting CRO, clinical investigator site and internal database audits.

Chiron Vaccines
A global vaccine organisation
Head of R&D Quality (6 months) **2003 - 2003**
Responsible for maintenance of GMP quality standards within Technology Development groups in Germany, Italy and UK.

PowderJect Technologies Ltd **2000 - 2003**
An innovative vaccine and drug delivery organisation
Associate Director, Quality Assurance/Quality Control

- Responsible for assuring compliance at PJ Technologies with the appropriate level of GMP (device and pharmaceutical), GLP and GCP requirements.
- Led all global Clinical QA compliance activities, appointed QA representative on clinical integration team responsible for harmonising processes and SOPs.
- As Global Project Manager established and implemented a new quality system to support international GXP requirements in the US and UK.
- Established an external audit programme to support GMP (device and pharmaceuticals), GLP and GCP compliance. Audited Clinical CROs, packaging and labelling CROs, CMOs, device manufacturers, plastic moulders and irradiation contractors.
- Advisor to other companies within the group on Bioanalytical (Serology) quality related working practices.
- QP responsible for the release of Investigational Medicinal Products in line with GMP requirements.

Abbott Laboratories, MediSense Products **1998 - 2000**
An international pharmaceutical and diagnostic organisation
Quality Records Manager

- Managed a team responsible for the MediSense Final (QP) Release and Documentation systems.
- Member of the core project team appointed to supported the FDA inspection.
- Performed internal quality audits (internal and vendor) to assure compliance with medical device GMP and ISO requirements, also supported bi-annual ISO inspections. Developed and assessed compliance of MediSense clinical trials with EN 540 (ISO 14155).
- Project managed a $100, 000 electronic SOP system implemented in early 2000.

Hoechst Marion Roussel **1992 - 1998**
Quality Assurance Manager

- Developed and implemented procedures for conducting supplier, contract laboratory and vendor audits.
- Personally introduced and implemented GLP in Veterinary business followed by a successful MCA inspection, nine months after initiation. Developed and conducted veterinary GCP audits in the UK.
- Ensured that all pre-clinical and clinical studies were conducted in compliance with GLP, GCP and company policies. Audited and assured compliance within Phase I Clinical unit, and of phase II and III clinical trials.
- Hosted MCA and FDA inspections, (6 in total).
- QP responsible for Clinical Trial Supplies release 1995 - 1998.

Hoechst UK Ltd 1986 - 1992
Quality Assurance Officer 1989 - 1992
Technical Officer 1986 - 1989
Tenovus Cancer Research 1985 - 1986
Research Technician

PROFESSIONAL MEMBERSHIPS & EDUCATION

Professional Bodies

ISO Lead Auditor **2007**

MiBiol, CBiol **2006**

Fellow of Research Quality Assurance (BARQA) **2001**

- Member since 1989
- Past Member of GLP committee (3 years as secretary) and Education & Training Committee
- Past Chairman of Publications Committee and BARQA Board member
- Current member of Committee and Newsletter Co-Editor
- Course presenter on BARQA diploma and RQA short courses

Registered QA Professional GLP (US SQA) **1997**

Education

University of Hertfordshire:

BSc Hons in Physiology/Pharmacology

1990

Diploma of Higher Education **1988**

South Glamorgan Institute of Higher Education:

HND in Applied Biology (Physiology/Microbiology) **1984**
