CURRICULUM VITAE

Louise Mawer

BSc (Hons), PG Dip
Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- Experience in GMP, GLP, GVP and GCP working environments
- GxP Auditing and Training Services (GCP, GLP & GVP)

Current Employment

- Independent consultant working on behalf of EPIC Auditors Limited

Involvement with Professional Associations/Societies

- Member of The Research Quality Association (formerly the British Association of Research Quality Assurance, BARQA).

Career History

- June 2016 – December 2016 Quality Consultant and Trainer (Contract – 0.5FTE) Genomics England, Queen Mary University of London
  - Support to Director of Data Quality & Quality Assurance Manager
  - Quality Assurance Strategy Development
  - Training in Quality Management Systems
  - Support to the development of Genomics England Data Management Quality Systems

- December 2013 – June 2016 Program Manager (Contract – 0.5FTE) Janssen PRD, High Wycombe
  - Planning, performing and reporting of audits for Janssen PRD QA
  - GCP: CRO facility & QMS audits, data & study audits (including reports), supporting systems including CSV and e-data considerations. Investigator site audits
  - GVP: Local Operating Companies / Affiliates, CRO, PV Partners, internal systems
  - Maintenance of relevant records and archive files in support of the above
  - Provide GCP & GVP guidance, training, knowledge and support

- Support regulatory inspection when requested

- March 2011 – December 2013: Principal QA Specialist LEO Laboratories Ltd
  - Planning, performing and reporting of audits for GCP, GLP and GVP within LEO Pharma Group, including study-specific, system, process and facility audits both internally and externally
  - GLP/GCP: CRO facility and QMS audits, data and study audits (including reports), supporting systems including CSV and e-data considerations, bioanalytical & safety laboratories. Investigator site audits (GCP)
  - GVP: Affiliate, CRO, PV Partners, internal systems (database/signal detection/EMA module compliance etc)
  - Maintenance of relevant records and archive files in support of the above
  - Support regulatory inspection when requested
  - Provide guidance, training, knowledge and support to the development of LEO Policies, Procedures and Guidance in the areas of GCP, GLP and GPvP (GVP)
  - Support and input to departmental strategy

- February 2006 – March 2011: Senior GCP Inspector & GLP Inspector – Medicines & Healthcare Products Regulatory Agency. This role involved extensive strategic support and input at the UK national level, and within Europe. Influence and participation at the third country level was also encouraged and supported.
  - Support, guide and advise internally and externally for implementation of pragmatic, effective GCP systems and procedures to facilitate compliance at the operational level resulting in a safe research environment for current and future study subjects, with accurate, timely, concise documentation and reported/published research data
  - Draft, comment, amend and revise national and international guidance documents, legislation and procedures as requested
  - Contribute to further development of the national programme for GCP Inspections
  - Organise and conduct GCP Inspections within the UK and overseas alone or in a team. [Included responsibility for more complex inspections (such as those investigating Serious Breaches, potential fraud, and specific license-related issues), and those of a politically sensitive nature]
  - Contribute to the development of departmental SOPs, those in support of the National Health Service Research Support Services and EMA inspection procedures
  - Contribute to the development of EMA GCP inspection systems and processes: particular responsibility for risk-based inspection developments and liaison for clinical laboratories and bioequivalence studies
  - Conduct GLP Inspections within the UK and provide GLP support as requested (GLPMA accredited Inspector)
  - Represent the Agency within and outside the UK through contributions to training programmes, symposia and conferences; in particular development and roll-out of the GCP Non-commercial Symposia and MHRA involvement in international groups such as EMA and Canadian Validation Group (CVG)
  - Specific responsibilities and lead in the area of non-commercial organisations and bioequivalence inspections, key support in the Phase I accreditation programme, and clinical laboratories

- December 2003 – February 2006: GCP Inspector – Medicines & Healthcare products Regulatory Agency
    - Significant responsibility and involvement for initial consolidation of information upon which the 2004 Statutory GCP Inspection Programme was based; drafting proposals for management comment, review, and scheduling. Subsequently I led a similar project developing inspection processes and procedures for roll-out in the non-commercial setting
    - Responsibility for the drafting and development of systems and processes to facilitate exchange of information with the Central Office for Research Ethics Committees (COREC), and subsequent development of the Memorandum of Understanding (currently in place with the National Research Ethics Service (NRES), the Gene Therapy Advisory Committee (GTAC) and the Appointing Authority for Phase I Ethics Committees (AAPEC))
    - Active participant at the EMA Inspectors Working Group for GCP and both the Quality Risk Management sub-group (a joint meeting at the European level between licensing assessors, Clinical Trials Units and Inspectors), and Advanced Therapies GCP sub-group
    - Contributor to the development of systems and procedures for bioequivalence studies in a CMDh-GCP Inspectors sub-group (CMDH – The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human).
    - Participant in joint meetings and inspections between Inspectorates (including the FDA) in relation to risk-adapted proposals and information sharing
    - Cross-trained in GLP and contributed to a number of triggered inspections in both the GLP and GCP setting, particularly where laboratory and clinical experience was an asset
    - Supported the training of a number of laboratory staff in clinical laboratories and provided GCP guidance, advice and editorial review for the development of the Clinical Laboratories Guidances by MHRA and EMA
    - Working with Enforcement and Inspectorate colleagues I participated in investigations for GCP, GVP and GLP; preparing materials for court inlcuding Expert Wirness statements.

- April 2001 – November 2003: Senior Quality Associate (GLP/GCP) – Celltech R&D
    - Study-specific and system inspections as required by Celltech quality audit programmes, including accurate and timely protocol, data and report audits (GLP/GCP)
    - Planning, conduct and performance of in-house and Contract Research Organisation (CRO) facility inspections for GLP and GCP compliance. CRO contact & liaison officer
    - Quality representative on Project Development Core and Satellite teams
    - Training & provision advice for GLP and GCP
    - Development of systems for benchmarking, metric recording, evaluating and reporting quality measures

- 1998 – 2001: Senior Quality Assurance Officer (GLP) – Covance Laboratories Limited
    - Accurate and timely protocol and report audits, procedural audit schedule management for pre-clinical work (GLP)
    - Site-wide procedure and facility inspections in accordance with GLP and ISO standards. Assessment of suppliers and sub-contractors

- Quality system responsibilities (SOP/Form review)
- Liaison and training officer providing internal and external guidance and advice

- 1995 – 1998: Quality Assurance Associate (GCP) – Leicester Clinical Research Centre
  - Review of Phase I trial protocols, data and operational activities for compliance with national and international GCP standards. Comprehensive study-specific and process-based audits. Document control, management and site Archivist. Chair of LCRC Safety Committee.

- 1992 – 1995: Senior Pharmaceutical Technician (Research Formulation Role) – Metered Dose Inhalation (MDI) Development, Fisons R&D
  - Development and Formulation of non-CFC metered dose inhalers (MDIs) including stability testing, suspension characterisation and performance evaluation. Pre-formulation and additive solubility studies. Batch record and report generation in support of bench and pilot-scale product manufacture.

- 1990 – 1991: Industrial Trainee (GMP/Research Formulation Role) – Pharmaceutical Formulation Development (PFD) Department, Glaxo Group Research
  - Development of hard gelatin capsule formulation for a new chemical entity including bench and pilot-scale product manufacture to GMP standards. Powder blend particle size analysis and powder flow characterisation. Small scale solution and suspension manufacture for method development and stability evaluation purposes.