



CURRICULUM VITAE

Louise Mawer

BSc (Hons)
Senior Consultant



Recognised Areas of Expertise:

- Provision of GXP auditing and training services (GCP, GLP & GVP)
- Mock Inspections, strategy advice & gap analyses (GCP/GVP)
- GXP training for auditors & those involved in pharmaceutical submissions
- Training in data integrity, record-keeping practices and electronic record management for those in research & at the research/development interface
- On-the-Jobcoaching & mentoring
- Global audits of Clinical Trials/GCP services & activities –
 - all Phases Including Phase I
 - clinical laboratories
 - systems & process audits
 - study-specific
 - vendor/Contract Research Organisation (CRO) assessments
 - routine & for-cause
 - conduct of audits for commercial, non-commercial & academic Sponsors
- Inspection preparation services for GCP & GVP including investigator sites
- GLP Study, system/process & facility audits. Support to & audits of GLP Quality Assurance. Vendor/CRO assessments
- Pharmacovigilance audits (primary reference framework European Good Pharmacovigilance Practice (GVP) Guidelines & associated regulations/directives): system & process audits, vendors/CROs, affiliates, partners, and Marketing Authorisation Holder audits
- Work with Organisations at the Research/Development interface for Quality Management Systems development



Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Director of independent GMP consultancy providing services for multiple pharmaceutical companies

Career History:

- **March 2011 – December 2013: LEO Laboratories**
 - 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 & OMS audits, data & study audits (including reports), supporting systems including CSV and a-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
 - Regulatory inspection support
 - 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: Medicines & Healthcare Products regulatory Agency (MHRA)**
 - **Senior GcP inspector**
 - Support, guide & advise the implementation of pragmatic, effective GCP systems & procedures resulting in a safe research environment for current & future study subjects, with accurate, timely, concise documentation & reported/published research data
 - Author, comment, amend & revise national & international guidance, legislation & procedures as requested
 - Contribute to development of the national programme for GCP Inspections
 - Organise & conduct GCP Inspections within the UK & overseas alone or in a team. [Included responsibility for more complex inspections (such as those investigating Serious Breaches or potential fraud, and specific license-related issues), & those of apolitically sensitive nature)
 - Contribute to the development of EMA GCP inspection systems & processes: responsibility for risk-based inspection developments I (MHRA publication), liaison for clinical laboratories & bioequivalence studies

- MHRA representative for various UK contributions to training programmes, symposia and conferences; development & roll-out of the GCP Non-commercial Symposia and MHRA involvement in international groups such as EMA and Canadian Validation Group (CVG) (now Workshops in Recent Issues in Bioanalysis, WRIB), Clinical Trial Transformation Initiative (CTTI) & collaboration with FDA (GCP Inspections, Bioanalysis and EMNMHRA inspection work-sharing initiative)
 - Contribute to the development of departmental SOPs, National Health Service Research Support Services SOPs & EMA inspection procedures
 - Inspectorate Lead for non-commercial organisations & bioequivalence inspection strategies, Lead Inspector - Phase I accreditation programme, clinical laboratories, GCP Sponsors, CROs etc.
 - MHRA GLP Monitoring Authority Inspector: conduct GLP Inspections within the UK & provide GLP support as requested
- **December 2003 – February 2006: Medicines & Healthcare Products regulatory Agency (MHRA)**
 - **GcP inspector**
 - Responsible for the development of the 2004 Statutory GCP Inspection Programme in collaboration with the GCP Expert Inspector
 - Lead for the Non-commercial GCP Inspection Programme
 - GCP Inspectorate Liaison with Central Office for Research Ethics Committees (COREC - now the National Research Ethics Service, NRES)
 - MHRA Representative at the EMA Inspectors Working Group for GCP
 - MHRA Representative at the Quality Risk Management sub-group (a joint meeting at the European level between licensing assessors, Clinical Trials Units & Inspectors), & Advanced Therapies GCP sub-group (including development of the initial EMA GCP Guidance for ATMP)
 - Contributor to the development of systems and procedures for review & audit of bioequivalence studies in a CMDh-GCP Inspectors sub-group (CMDh - The Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human) including assessors' guidance for triggers for inspection
 - Participant in joint meetings & inspections between Inspectorates (including the FDA) in relation to risk-adapted proposals and information sharing
 - Active in triggered inspections & Enforcement Investigations for GCP, GVP and GLP settings
 - GCP guidance, advice, and editorial review for the development of the Clinical Laboratories Guidance by MHRA & EMA
 - Trained as an Expert Witness, Phase I Accrediting Inspector & investigational Medicinal Products Inspections

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

- **1998–2001: Covance Laboratories**
 - Accurate & timely protocol and report audits, procedural audit schedule management for pre-clinical work (GLP)
 - Site-wide procedure & facility inspections in accordance with GLP & ISO standards
 - Assessment of suppliers & sub-contractors
 - Quality system responsibilities (SOP/Form review)
 - Liaison and training officer providing internal & external guidance and advice

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

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

- **1990 – 1991: Glaxo Group**
 - Fast-track 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 & powder flow characterisation. Small scale solution and suspension manufacture for method development & stability evaluation purposes.

Education:

- Post Graduate Diploma in Research Quality Assurance, Anglia Polytechnic University, 2002 to 2003
- BSc Honours, Upper Second Class (Associated with Biology), The Open University, 1995 to 1999
- BTEC HND Science (Medicinal & Cosmetic Products), Leicester Polytechnic, 1989 to 1992
- A-level Biology, Chemistry & Mathematics, Crossley Heath School, 1986 to 1989
- 70-levels including Mathematics, English & French, Crossley & Porter Grammar School, 1981 to 1986

Recent Training Courses, Meetings & Symposia:

- Artificial Intelligence in Drug & Biological Drug Development Duke University, Remote Workshop, 06Aug24
- 2024 State of Real World Evidence Policy Duke University/FDA, Remote Workshop, 25Jul24
- Outcome Reporting Bias & SAPs in Clinical Trials TMRP, Webinar, 03Jul24
- I think, Therefore I do Clinical Trials* (inc. EMA Serious Breach Update) EFGCP, Ghent 01Jul24
- From Theory to Practice: Real-World RBQM Workshop Cyntegrity, Webinar, 26Jun24
- COER Bioanalytical & Bioequivalence Inspections Workshop FDA SBIA, Remote Workshop, 13Jun24
- Future of Analytical Procedures, ICH Q2(R2) ISPE, Webinar, 03Apr24
- Drug Safety Webinar FDA SBIA, Webinar, 07Mar24
- Artificial Intelligence in Drug and Biological Product Development FDA, Remote Workshop, 03Jul24
- Pharmacovigilance Symposium MHRA, London, 28Feb24
- Regulatory GCP Symposium, FDA-MHRA-Health Canada FDA SBIA, Remote Symposium, 13-15Feb23
- Practical Applications of ICH E6(R3) Clinical leader, Webinar, 14Dec23
- Decentralised Trials: lessons learned HRB TMRN, Webinar, 07Dec23
- Mastering GMDP Compliance & Inspection Readiness EPIC Auditors, Virtual Symposium, 05Dec23
- Challenges in Global Literature Monitoring PrimeVigilance, Webinar, 16Nov23
- Ensuring Data Integrity: Trends, Challenges & Best Practices ISPE, Webinar, 20Sep23
- Correcting the Scholarly Record UKRIO, Webinar, 20Sep23
- Digital Data Flow Project Phase 3 CDISC, Webinar, 14Sep23
- Virtual audits in a digitally evolving World RSSL, Webinar, 06Sep23
- ACTEUICHE6(R3) Multi-stakeholder Workshop EMA, Remote Public Consultation, 29Aug23
- Grand Rounds: Harmonising GCP Guidelines ICH E6(R3) Duke University, Webinar, 18Aug23
- ICH GCP Stakeholder Meeting (Full day) MHRA, London, 18Jul23
- Strategies for implementing eConsent Drug Target Review, 12Jul23
- EMA CTIS Year 2 Webinar EMA, Webinar, 04Jul23
- Impact of EU Medical Device Regulations TOPRA, Webinar, 29Jun23
- Exploring the role of Local Persons for Pharmacovigilance PrimeVigilance, Webinar, 04May23
- Quality Tolerance Limits Cyntegrity, Webinar, 22Mar23
- Quality Group Meeting (Including ICH M10 training) Consulting Quality Group Remote Meeting, 04Nov22
- Pharmacovigilance Inspections & Audits PrimeVigilance, Webinar, 28Jul22
- Whole Genome Sequencing eLearning via Genomics England Health Education England, eLearn, 12Jul22
- Safety Perspective on the new EU Clinical Trials Regulation PrimeVigilance, Webinar, 14Mar22

T: +44 (0)7414 927035

E: Info@GxPAssure.com

W: www.GxPAssure.com



GXP Assure
Supporting GxP Compliance Worldwide

- MHRA Pharmacovigilance Symposium
- MHRA Good Clinical Practice Symposium
- GDPR Refresher Training

MHRA, Webinar, 10-11 Mar 22
MHRA, Webinar, 07-09 Mar 22
Griffin House Consultancy, 30 Jan 22

Personal:

- Chair of the European Forum for Good Clinical Practice (EFGCP) Auditors' Working Party and EFGCP Board Member (2019 onwards). Tutor on EFGCP Auditors' Training Course
- Member of The Research Quality Association, RQA, RQA Northern Regional Forum Faculty, Research Practice Group Member & participant in the Non-interventional Study Special Interest Group (NISSIG)
- ISPE Member & Mentor
- Member of CDISC TMF Reference Model Group (Risk-based Approach White Paper Co-author)
- DIA TMF Course Tutor
- Fleming Events Course Tutor for GCP/GLP laboratories and Toxicology Development Plan