



CURRICULUM VITAE

Jennifer Martin

BSc (hon), Chemistry
Senior Consultant, GxPAssure



Recognised Areas of Expertise:

Regulatory Intelligence & Compliance

- Oversight of regulatory intelligence activities, assessing business impact and driving implementation of regulatory updates and process improvements.
- Experienced in SOP review, compliance alignment, and cross-functional regulatory collaboration.

Quality Management, QIs & CAPA

- Skilled in managing Quality Issues (QIs), Corrective and Preventive Action (CAPA) plans, and leading serious breach determinations.
- Acts as a GxP Subject Matter Expert, providing quality and compliance guidance to study teams and functional departments.

Audit & Inspection Leadership

- Extensive experience contributing to and overseeing internal and external audits and regulatory inspections.
- Strong background in managing QA relationships with vendors and sponsor QA, including Quality Agreement oversight.

Regulatory Policy, Guidance & Innovation

- Contributed to major MHRA initiatives including ILAP, the Medicines and Medical Devices Act 2021, and post-EU exit clinical trial legislation.
- Provided regulatory advice on innovative trial designs, decentralised models, and emerging technologies.
- Authored and edited multiple chapters of the MHRA GCP Guide and contributed to EU-level guidance.



GCP Operations Management

- Managed teams of GCP Inspectors and led the risk-based inspection programme at the MHRA.
- Experience in team mentoring, coaching, performance management, and professional development.
- Successfully led teams through the COVID-19 pandemic, ensuring wellbeing while implementing remote inspection models.

Cross-Functional GxP Expertise

- Expert in GCP with a strong working knowledge across GMP, PV, and GLP in relation to clinical trial settings, enabling holistic interpretation of GxP requirements.
- Adept at applying pragmatic, proportionate approaches to compliance across diverse trial models.

Clinical Trial Delivery & Operations

- Comprehensive understanding of clinical trials across all phases, therapeutic areas, and both medicines and medical devices.
- Experience as Study Delivery Lead and Lead CRA overseeing protocol development, trial execution, and clinical reporting.
- Proven ability to deliver studies on time, within budget, and to required quality standards.

Stakeholder Engagement & Influencing

- Skilled in collaborating with regulators, key opinion leaders, HRA, and cross-industry stakeholders.
- Strong interpersonal skills, applying discretion, tact, and persuasion to achieve compliance and positive outcomes.

Strategic Thinking & Problem Solving

- Frequently allocated complex and high-risk assignments due to strong analytical capability and technical expertise.
- Proactive in identifying opportunities for quality improvement and supporting organisations through compliance challenges.

Global Experience & Adaptability

- Significant national and international experience across regulatory, QA, and operational roles.
- Ability to rapidly understand new regulatory frameworks, organisational structures, and operational systems.

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Director, Kingfisher Quality Consultancy Ltd

Career History:

- **July 2025 – present: Kingfisher Quality Consultancy Ltd – Director**
 - Independent GCP Quality Consultant specializing in EU/UK regulations, guidance and intelligence. Providing auditing; mock inspections; regulatory intelligence and interpretation; training, gap analysis and process improvement; Quality issue investigation, root cause analysis and CAPA management
- **January 2022 - May 2025: Worldwide Clinical Trials - Director Therapeutic Area Quality Lead, Jan 2022 - Jan 2023; Director Regulatory Compliance Quality Operations; Feb 2023 - Nov 2024; Director Regulatory Intelligence, Dec 2024 - May 2025**
 - Provide regulatory intelligence/surveillance for GxP requirements globally. Identify new and updated GxP related regulations and guidance. Directing on quality impact to the business and partner with functional areas to ensure compliance requirements for Worldwide systems, processes and training
 - Oversight of GxP Quality Issues (QIs) and Corrective and Preventive Action (CAPA) Plans including serious breach determination
 - GxP Subject Matter Expert providing consultancy to functional areas and project teams and input to process improvements and SOP collaborative reviews for compliance
 - Facilitate and oversee audits and inspections
 - Manage Quality Agreements and relationships with vendors and sponsors QA
- **March 2006 to January 2022: MHRA - Lead Senior GCP Inspector promoted to GCP Operations Manager**
 - Manage a team of GCP inspectors.
 - Put together the GCP risk-based inspection programme and oversee processes improvement
 - Prepare, plan and report GCP inspections to MHRA and/or EMA SOPs, as applicable
 - Non-inspection activities – Provide GCP input to regulatory advice and innovation office meetings, triage of GCP whistle-blowers and serious breaches; answer GCP queries; oversee and contribute to MHRA agency and GCP team projects, liaising with internal and external stakeholders (including other regulatory agencies)

- Input into new clinical trials legislation and guidance, GCP risk adaption, the GCP guide
- Organising, facilitating and presenting at internal and external conferences and symposia
- **March 2004 to March 2006: AstraZeneca - Study Delivery Leader**
 - Led and managed an empowered multi-disciplinary team
 - Project managed clinical trials from concept to archiving to time, quality and budget. Ensuring trials were set-up and conducted according to the country regulations, ICH GCP and quality system
 - Responsible for the trial risk management plan, the preparation and delivery of study documentation (including, protocols, amendments, CRFs, etc.) and facilitate audits and inspections
 - Developed and managed project plans/schedules, budgets and contracts, including negotiating and liaising with investigators, collaborative groups, CROs and external providers
 - Built relationships and developed people (including training, mentoring and coaching)
- **March 1997 to March 2004: Inveresk Research - CRA promoted to Senior CRA**
 - Lead CRA in multi-centre trials in the UK and globally (including Status reporting and tracking)
 - Primary contact with clients, investigator sites and other relevant departments (for example, QA, data management, statistics medical writing and clinical laboratories)
 - Managing and monitoring all clinical trials phases to ICH GCP and regulations, including all types of site visits, regulatory and ethics submissions, creating trial documents (e.g. protocol, information sheet, case report form, clinical report) and facilitating investigator meetings, audits and inspections
- **October 1993 to March 1997: Inveresk Research, Toxicology Support - Senior Research Scientist**
 - Method validation and routine analysis of samples from toxicology studies, including formulating procedures and writing study reports to GLP and ISO 9001 standards

Education:

- 1989 – 1993: University of Edinburgh, BSc (hon), Chemistry
- 1983 – 1989: Queen Anne High School, Dunfermline, Certificate of 6th Year Studies, Chemistry (C), Higher, Chemistry (A); Biology (A); Physics (C); English (C); Maths (C); History (C)

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