CURRICULUM VITAE

Michelle Yeomans

MSc
EPIC Operations Manager
and Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- Accomplished quality professional with over 36 years' experience working within Good Manufacturing (GMP), Good Clinical Practice (GCP) and Good Distribution Practice (GDP) environments both in industry and for the UK medicines regulator (MHRA).
- 17 years at the MHRA contributing to the development of a national programme for GCP statutory inspections and the development of EMA GCP inspection procedures, the development of regulations and European guidelines relating to GMP for investigational medicine products (IMPs), and management oversight of the licensing and inspection of pharmaceutical manufacturers and distributors both in the UK and overseas as Inspectorate GMDP Operations Manager and Unit Manager.
- 19 years working in the pharmaceutical industry, with experience of technical development and quality management roles, developing quality systems in manufacturing and laboratory environments for pharmaceutical and healthcare products, and leading quality management activities within a contract research environment including IMP manufacture and the conduct of clinical trials.
- Excellent managerial and organisational skills. Responsible for strategic direction and operational management of approximately 45 GMP and GDP Inspectors and the GMP/GDP Inspection programme, whilst at MHRA.
- Trained by MHRA to perform GCP and GMP inspection relating to the conduct of clinical trials and manufacture and distribution of IMPs including solid dose, liquid, and aseptically prepared dosage forms.
- Recognised by MHRA as a Transitional Qualified Person for IMPs.

Current Employment

- Operations Manager for ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry.

Career History

GMDP Inspectorate Unit Manager
MHRA Mar 20 – Feb 22

- Overall responsibility for the GMP and GDP Inspectorates leading the Units strategic and operational activities to ensure the safe manufacture and distribution of pharmaceutical products.
- Member of the Inspection, Enforcement and Standards (IE&S) Leadership team involved in setting and reviewing strategic priorities, developing Divisional and Agency priorities and business plans.
- Liaised with other Unit Manager to provide Inspectorate wide support across all GXP disciplines and take forward the Inspectorate strategy.
- Provided expert knowledge on regulations, guidance and the inspection process.
- Managed approximately 45 staff with accountability for the decisions taken by the team – including those made during inspections, international meetings and conferences.
- Influenced at both a national and international level with regard to medicines regulations and inspection issues.
- Undertook high profile presentations on behalf of the Agency and Inspectorate.
- Chaired and participated in project groups involving UK and International Governments, regulators and industry stakeholders.
- Drafted briefings for Ministers and other regulatory bodies, to allow them to make informed decisions.
- Managed non-compliant manufacturers and distributors and the associated risk to public health.

Inspectorate Operations Manager – Business Process Improvement
MHRA Sept 17 – Mar 20

- Secondment to project-based role to lead the GXP Inspectorate inputs to MHRA's operational transformation business process improvement activities.
- Responsible for preparing project mandates including identifying resource requirements, risk/benefit analysis, and financial costings.
- Responsible for successful delivery of improvement projects, leading change and driving innovative improvements to the Inspectorate ways of working whilst maintaining compliance with statutory and regulatory frameworks.

GMDP Operations Manager / Senior GCP Inspector and GMP Inspector
MHRA May 07 – Sept 17

- Managed and supervised a team of GMDP Inspectors in accordance with MHRA policies and procedures including day to day operation of GMP risk-based inspection programme, Hospital Blood Bank compliance assessment process, and associated Inspection Action Group (IAG) and Compliance Management Team (CMT) procedures for managing poor compliance.
- Produced, agreed and delivered the annual inspection plans and budget forecasts for the GMDP Inspectorate.
- Planned and led recruitment campaigns and assessment centres to identify and employ new inspectors.
- Facilitated the training and development of inspectors to maintain and increase the breadth of technical knowledge and inspection capacity within the team.

- Represented MHRA at external stakeholder engagement meetings.
- Provided advice on interpretation of EU GMP requirements and inspection issues in response to stakeholder queries and by hosting the MHRA GMP symposium.
- Achieved authority to perform GMP inspections of MIA(IMP) sites.
- Leader of regulatory change as UK Rapporteur for the revision of EU GMP Annex 13 leading the drafting group to deliver a concept paper and revised draft of Annex 13 for public consultation. Reviewed consultation responses and drafted proposed reply and updated version of the Guideline GMP for IMP on behalf of the EU Commission.
- Senior GCP Inspector responsibilities as below.

GCP Inspector
MHRA Sept 05 – May 07

- Contributed to the development of a national programme for GCP Statutory Inspections.
- Planned, conducted and reported on assigned GCP inspections with authority to inspect Phase II-IV Sponsor/CRO, Phase I/Clinical Pharmacology Units, and Non-commercial Sponsor organisations and clinical trial activities.
- Assessed scientific and technical enquiries received and provided stakeholders with a considered decision.
- Represented MHRA at external stakeholder engagement meetings including MHRA symposium.
- Contributed to the development and maintenance of Inspectorate operating procedures and the development of EMA inspection procedures.
- Trained, supported and assessed new inspectors in specific tasks to enable them to meet the required standards.

Quality Manager and Transitional Qualified Person
Pharmaceutical Profiles LTD Jun 01 – Sept 05

- Responsible for the design and implementation of the pharmaceutical quality system to support the conduct of clinical trials in accordance with GXP regulatory requirements.
- Management of the QA, Pharmaceutical Analysis (QC) and Health & Safety functions.
- Leader of site preparations and regulatory submission of initial MIA(IMP) licence application and subsequent variations.
- Primary contact and host of statutory GCP and GMP regulatory inspections, and Sponsor due diligence audits.
- Established internal audit schedule, trained auditors, and conducted compliance assessments using EU GMP guidelines, EU Clinical Trials Directive 2001/20/EC and UK SI 2004:1031 as audit reference standards.
- Primary QA contact for discussion with Sponsors to design and develop technical agreements and quality plans to ensure individual contract requirements were identified and met.
- Undertook batch certification of IMPs for use in clinical trials in accordance with the legal and professional duties of the Qualified Person by ensuring IMPs were manufactured in compliance with EU GMP, the Product Specification File, and in accordance with the Clinical Trial Authorisation.

Senior Quality Engineer
3M HealthCare LTD Oct 97 – Jun 01

- Leadership and direction to Quality Operation teams in developing management systems to support continuous improvement activities across the product lifecycle at pharmaceutical manufacturing sites in the UK and Europe. Range of products included solid dose, liquid, and metered dose inhalation dosage forms.
- Conducted periodic and rolling quality reviews of authorised medicinal products to identify corrective and preventive action, assess opportunity for continuous improvement and update quality risk management plans.
- Assessed technical information and provided appropriate technical and regulatory information and guidance to Production and Laboratory teams to enable them to make informed decisions.
- Undertook training needs analyses to identify skills gaps, arranging training as required for Production, Laboratory and Quality Operation teams.
- Leader of site audit team required to conduct compliance assessments of vendors, contractors, and site preparation activities for regulatory inspections
- Member of internal audit team, using ISO9001, EU GMP guidelines, and PQG monographs as audit reference standards.
- Completed IRCA approved ISO9001 Lead Assessor/Auditor training and previously registered as IRCA Quality Management System Auditor.

Quality Development Manager
Jordan Personal Care Oct 93 – Oct 97

- Quality Management Representative with responsibility for establishment, maintenance and effective operation of the contract manufacturer's quality management system.
- Manager of QA team and QC laboratory performing raw material and finished product testing. Range of products included non-sterile liquid soaps and gels, and mouthwash and toothpaste personal care products.
- Site contact for discussion with customers to design and develop quality plans to ensure individual contract requirements were identified and met.
- Managed and facilitated the resolution of all customer complaints, and non-conformances.
- Primary host for audits from customers and external bodies. Established the company internal audit schedule and trained audit team.

Process Chemist
Deb LTD Oct 91 – Oct 93

- Supervisory responsibility for effective operation of QC laboratory to ensure raw materials, in-process, and finished product testing conducted in accordance with product specifications. Range of products included liquid and gel hand cleansers, liquid soaps, detergents and disinfectants.
- Provided technical support to manufacturing department by investigating production difficulties, advising and implementing remedial action.
- Completed quality system auditor training and conducted process and procedural audits using BS5750 and EU GMP guideline as audit reference standards.

Owner
Retail saddlery Jun 88 – Oct 91

- Successfully ran own business as an opportunity to pursue a personal interest in horses and horse riding.

Technical Development Technician
Boots Contract Manufacturing Sept 83 – Jun 88

- Completed technical apprenticeship designed to support the development and production of non-sterile pharmaceutical dosage forms from feasibility, scale-up, validation, production and marketed product support.

Qualifications

Masters Degree	Quality Management and Improvement
Post Graduate Diploma	Business Process Improvement and Quality Management
BTEC HNC	Pharmaceutical Science
BTEC ONC	Chemistry