



CURRICULUM VITAE

Peter Coombs

Senior Consultant, GxPAssure



Recognised Areas of Expertise:

Highly dedicated and accomplished professional with extensive expertise in the holding and distribution of medicinal products. Brings unparalleled MHRA inspection experience within the specialised discipline of Good Distribution Practice (GDP).

Offering 31 years of experience in the pharmaceutical industry, including 20 years dedicated to GDP. A highly experienced auditor, with exceptional written and verbal communication skills and over 38 years of experience leading and managing high-performing teams. Strong project management capability, with a proven track record of delivering complex regulatory, operational, and compliance initiatives.

Key Areas of Expertise;

- Expertise in Good Distribution Practice (GDP) compliance
- Inspection preparation and readiness for regulatory audits
- Delivery of regulatory training and education programs
- Leadership in managing complex GDP inspections across the UK
- In-depth knowledge and capabilities of the role and responsibilities of the Responsible Person
- Extensive experience in crisis management
- UK and global supply chain management, including GDP-compliant transportation requirements
- Design and implementation of Quality Management Systems
- Application of Quality Risk Management, with a focus on relative risk within the supply chain
- Assessment of GDP-compliant building structures and environmental control systems
- Structuring GDP-compliant licensing models for complex business operations
- Strong management and leadership capabilities
- Training on GDP regulatory requirements



- Expertise in the provision of medicines within the UK shipping industry and charitable sectors
- Advising industry stakeholders on GDP requirements and contributing to the development of industry guidance
- Consultancy for MHRA GDP inspection preparation and remediation
- Conducting mock regulatory inspections

Current Employment:

- Independent Consultant working on behalf of GxPassure Limited
- Director and Senior Consultant at GDP Pharma Consulting Ltd

Career History:

- **August 2020 to present: GDP Pharma Consulting Ltd - Director and Senior consultant**
 - Providing advice and guidance to pharmaceutical wholesalers in relation to GDP guidance and HMR 2012 regulations.
 - Providing training and support to Responsible Persons, Responsible Persons for Import (RPI's) and Licence Holders.
 - Preparing training packages in relation to various aspects of GDP and delivering them to a varied audience.
 - Providing advice and guidance to clients in relation to remedial actions following an MHRA inspection.
 - Undertaking internal GDP audits and gap analysis on behalf of clients.
 - Driving effective use and implementation of QMS in companies that undertake pharmaceutical wholesaling
 - Eligible named Responsible Person on WDA(H)
- **March 2020 – August 2020: MHRA - COVID Response Operations Manager and GDP Inspector**
 - Development and management of remote Risk Based Inspection Programme for GDP to ensure effective use of available resource and expertise during the pandemic.
 - Management of operational response in managing resource for GDP.
 - Liaison with other government departments to ensure a joined-up approach
 - Maintaining open communications with key stakeholders to ensure overview of industry issues and shortages.
- **2011 – 2020: MHRA - Operations Manager and Senior GDP Inspector**
 - Direct management of GDP inspection team of up to 17 inspectors.
 - Recruitment of new GDP inspectors
 - Delivering training to global audiences

- Advising on GDP requirements to the Maritime and Coastguard Agency
 - Advising on GDP requirements to the Department for International Development
 - Representing GDP at the International Conference of Drug Regulatory Authorities
 - Responsible for introducing a comprehensive risk -based inspection systems into the GDP environment
 - Management of GDP symposium.
 - Acted as an expert witness in GDP during the prosecution of Medicines Act offences.
 - Setting expectations and policy on the distribution of medicines in the maritime sector and within the NHS.
 - Co-led the GDP response to the Covid 19 pandemic including the deployment of extensive crisis management skills.
- **2004 – 2011: MHRA - GDP Inspector**
 - Organised and conducted GDP Inspections in accordance with medicines regulations
 - Worked with other regulators in accordance with the European Commission Compilation of Community Procedures
 - Inspection, review and approval or rejection via regulatory channels of sites and companies applying for Wholesale dealer Authorisations
 - Development of basic risk-based inspection processes
 - Delivered presentations on a variety of GDP related topics at MHRA symposia and to international audiences
 - Worked with other team members to develop the GDP team to be an effective regulatory inspectorate.
- **2001 – 2004: MCA - Prosecutions Manager**
 - Provided legal support in the court environment to barristers prosecuting Medicines Act offences on behalf of the MCA (now MHRA).
 - Manged a team responsible for the highly complex and detailed work of preparing Court papers and supporting documents.
 - Took all decisions during trials on behalf of MCA in relation to the progress of a prosecution and whether to accept any offers made by the defence.
 - Worked closely with MCA Investigators and other law enforcement personnel to ensure effective management of the prosecution case.
 - Liaised constantly with external solicitors in the appointment of suitable barristers and the process of prosecuting a case through the complex and lengthy Courts process

- **1998 – 2001: Medicines of Chinese Origin - Project Lead**
 - Lead and managed a project team over a three-year period to successfully deliver this major project which informed MCA policy in this area.
 - Deployed extensive project management skills to move from a position of a very low information and knowledge base to being recognised authorities on the subject.
 - Development of highly detailed final report with clear recommendations and rationale.
 - Extensive liaison with the UK Chinese community, importers and Chinese medicine practitioners appreciating the cultural sensitivities around this area.
 - Direct liaison with Chinese Government and UK based Chinese officials.
 - Liaison with patients who suffered harm as a consequence of the use of Chinese medicines
 - Setting up a reporting structure within key parts of the NHS so my team could be informed of suspected adverse reactions to Chinese medicines on a nationwide scale.
 - Developed close working relationships and set up structures to share information with Customs and Excise and Port Health Authorities across the UK.
 - Working with laboratories to develop testing protocols and methodologies to consistently analyse suspect medicines for potentially toxic levels of plant, animal or mineral content.

- **1994 – 1998: MCA - Pharmaceutical Investigator**
 - Lead major investigations into criminal activity in relation to Medicines Act and associated offences.
 - Deployed project management skills to manage a wide range of investigations from inception to a successful conclusion.
 - Lead teams during highly stressed activities such as mobile surveillance and raids on properties.
 - Effective liaison with other law enforcement bodies such as the Police and Customs
 - Interviewing suspects under PACE conditions (Police and Criminal Evidence Act)
 - Interviewing potential witnesses
 - Providing evidence in the Court environment.
 - Conducted covert surveillance activities.
 - Police (Blue Light) trained high speed surveillance driver

- **1990 – 1994: NHS - Senior Project Manager**
 - Leading a multi-disciplinary team acting on behalf of the client with responsibility for the oversight and delivery of key areas of a major construction project.
 - Extensive project management skills deployed in delivering a project within tight timescales, with significant financial penalties for failing to achieve key

milestones and in close liaison with a large number of contractors and sub-contractors

- Performing regular on-site audits to ensure work carried out to a satisfactory standard.
- Regular meetings with contractors to address quality issues and identify solutions and to ensure work schedules were maintained in accordance with the contract.
- Making key decisions regarding various elements of the build project in liaison with contractors. Areas covered by my team were elements of building design, IT infrastructure, elements of the mechanical and electrical installation, interior and exterior finishes and post hand over fit out.

- **1985 – 1990: (Various Government Departments) - Facilities and Building Services Manager**

- Responsible for leading a team delivering building management and project management solutions across an estate of approximately 30 buildings in London and the South East.
- Auditing of work undertaken by contractors to ensure compliance with defined standards.
- Regular meetings with contractors to review work undertaken, identify issues and develop resolutions.
- Provision of facilities services across the estate.
- Responsible for compliance with all relevant health and safety requirements.
- Responsible for project managing multi trade contractors to ensure effective delivery of numerous building and facilities projects to ensure minimum disruption to the client.

Education:

- Educated to General Certificate of Education standard or equivalent.
- Successful completion of MHRA GDP Inspector training course and certification.
- ISO 2000 qualified auditor