

## CURRICULUM VITAE

### Peter Coombs

Pharmaceutical Industry Consultant



#### Recognised Areas of Expertise

Dedicated professional, exceptionally experienced in all aspects of the holding and distribution of medicines with more MHRA Inspection experience in the exclusive discipline of Good Distribution Practice than any other individual working in the commercial sector in the UK.

27 years' experience in the pharmaceutical sector with 16 in Good Distribution Practice. Highly experienced auditor in both the pharmaceutical and construction sectors. Proven excellent communication skills, both verbal and written with over 35 years' experience of leading and managing high performing teams. Highly experienced project manager.

- Leading highly complex GDP inspections across the UK
- Role and responsibilities of the Responsible Person
- Extensive crisis management experience
- UK and Global supply chain management and transportation requirements for GDP
- Quality Management Systems
- Application of Quality Risk Management and particularly the understanding and application of relative risk within the supply chain.
- GDP compliant building structures and environmental control systems
- Identifying GDP compliant licencing structures for complex business models
- MHRA GDP inspection preparation, remediation, and response
- Extensive management and leadership experience
- Training and mentoring in EU GDP Regulatory requirements
- The provision of medicines within the UK shipping industry and charitable sectors.
- Advising on GDP requirements to industry stakeholder organisations and in the development of guidance to industry

#### Professional Qualifications and Accolades

- Successful completion of MCA GDP Inspector training course and certification.
- ISO 9000:2000 qualified auditor
- Member of the International Society of Pharmaceutical Engineers

- Successful completion of large number of companies led courses including Project Management, Quality Management, Risk Management, Health & Safety and Auditing.

### **Current Employment**

- Independent Consultant working on behalf of ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry

### **Career History**

#### **Operations Manager and Senior GDP Inspector MHRA (2011-2020)**

- 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.

#### **GDP Inspector MHRA (2004-2011)**

- 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.

#### **Prosecutions Manager – MCA (2001-2004)**

- Provided legal support in the court environment to barristers prosecuting Medicines Act offences on behalf of the MCA (now MHRA).
- Managed 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

#### **Project Lead – Medicines of Chinese Origin – MCA 1998 -2001**

- 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.

#### **Pharmaceutical Investigator – MCA – 1994-1998**

- 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

#### **Senior Project Manager - NHS - 1990-1994**

- 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.

#### **Facilities and Building Services Manager (Various Government) - 1985 -1990**

- 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.