CURRICULUM VITAE

Lewis Edward Corbett

BSc. Hon. MRSC.
EPIC Auditors Business Manager
and Pharmaceutical Industry Consultant

Recognised Areas of Expertise

- 5 years with the UK MHRA
- Expert at performing GMP and GDP inspections of active substances and a wide variety of dosage forms across a range of organisations in the UK and overseas.
- Trained by MHRA to conduct GMP inspections of:
    - API manufacturers, importers and distributors
    - Importation of medicinal products
    - Non-Sterile manufacturing sites
    - Contract laboratories
    - Excipient manufacturers
    - Storage and distribution sites
- MHRA and EU Inspection preparation and remediation consultancy.
- Pharmaceutical Quality Management Systems
- Training in EU GMP Regulatory requirements
- Eligible EU Qualified Person

Involvement with Professional Associations/Societies

Member of the Royal Society of Chemistry

Current Employment

- Business Manager and Senior Consultant for ExPharmaceutical Inspectors Consortium Limited; providers of consultation and audit services to the Pharmaceutical Industry

Career History

June 2019 – December 2022
Operations Manager / Head of GMP Team 1 and Senior GMP Inspector
Medicines and Healthcare Products Regulatory Agency, London, UK

- Manage a team of 8 GMP Inspectors, agree performance objectives, conduct regular 1:1s, provide support and advice.
- Provide technical input as part of policy development, write new GMP guidance, update MHRA webpages, and deliver training to stakeholders via webinars, symposia, and guest speaking engagements.
- Organise and deliver internal training on technical topics to enhance the knowledge of Inspectors.
- Review existing processes to improve efficiency, compliance, or safety, based on feedback from team members and the wider agency.
- Responsible manager for training, standard operating procedures, and Health & Safety across the GMP Compliance teams.
- Continue to perform GMP inspections to protect patient safety. Promoted to Senior Inspector in May 2022.

May 2018 – June 2019
GMP Inspector
Medicines and Healthcare Products Regulatory Agency, London, UK

Performed Good Manufacturing Practice inspections at a wide range of sites in the UK and overseas. Protected patient safety by ensuring license holders fulfilled their legal obligations and adhered to the required standard of GMP.

- Organising inspections of manufacturers, importers and wholesale dealers.
- Inspecting a site's operations against EU GMP requirements and UK law, to and assess risk and identify deficiencies.
- Providing written inspection findings and reports, assessing responses, and agreeing improvement plans.
- Maintaining current knowledge and expertise in relevant legal, professional, and administrative matters.
- Providing advice to stakeholders.

April 2017 – May 2018
Qualified Person (QP)
Eli Lilly and Company, Liverpool, UK
Ensured that products were manufactured in accordance with the relevant Marketing Authorisation and UK law, and in accordance with GMP, before certifying their suitability for release to market.

- Performing Batch Certification and the duties of a QP in accordance with EU GMP, Vol 4, Annex 16, and the Qualified Persons in the Pharmaceutical Industry Code of Practice.
- Driving completion of deviation investigations and implementation of corrective and preventative actions.
- Developing and implementing new processes and procedures to maintain an effective QMS.
- Performing self-inspection audits, authoring or approving Annual Product Reviews, site metrics, stability trend reviews and complaint trend reviews as part of management review processes.

March 2015 – April 2017
Trainee Qualified Person
Eli Lilly and Company, Liverpool, UK
Performed Quality Assurance Representative duties whilst undergoing a structured program of training to achieve Qualified Person status under EU Directive 2001/83.

- Completing residential QP training modules with NSF, and their associated assessments.
- Providing feedback to contract manufacturers so as to obtain the highest possible document completion standards and support a right first-time culture.
- Conducting audits of manufacturing and support facilities to achieve continuous improvement.
- Investigating complaints and deviations, and implementation of corrective and preventative actions.

January 2012 – March 2015
Quality Control Laboratory Group Leader
Eli Lilly and Company, Liverpool, UK
Group Leader for QC Labs (Alternating responsibilities for Chemistry and Microbiology laboratories).

- Responsible for 18 direct reports. Agreeing performance objectives, conducting regular 1:1s, and providing support and advice.
- Routine monitoring and discussion of key performance indicators (KPI) with all staff to drive improvement.
- Allocating resources and prioritising routine and ad-hoc analytical testing to meet customer needs.
- Approving root cause investigations and implementing corrective and preventative actions to prevent recurrence.
- Interacting with regulatory agency inspectors (MHRA, FDA) and numerous corporate VIPs.

December 2009 – January 2012
Lean Six Sigma Black Belt
Eli Lilly and Company, Liverpool, UK
Part of a small team dedicated to the improvement of manufacturing and support processes.

- Using Lean Manufacture and Six Sigma tools to drive multidisciplinary project teams to eliminate waste and develop sustainable solutions.
- Presentation of project information and data to Site Lead Team and corporate visitors.
- Providing coaching, guidance, and refresher training to Six Sigma Green Belts.

February 2008 – December 2009
Master Production Scheduler
Eli Lilly and Company, Liverpool, UK
Responsible for establishing production plans for all products within the fermented products supply chain.

- Generating production plans, using SAP, for interdependent, capacity constrained, manufacturing areas.
- Liaising closely with other departments to resolve issues which could impact supply.
- Collaborating with international sites to ensure timely production and supply of critical intermediates.
- Chairperson for monthly assumptions meetings, presenting plans to Site Lead Team.

December 2005–February 2008
Quality Assurance Group Leader
Eli Lilly and Company, Liverpool, UK
Responsible for the management of a team of 5 Quality Assurance Representatives and Assistants.

- Reviewing performance, setting objectives, documenting achievements, and identifying development opportunities.
- Providing leadership, advice, and support, on quality matters to team and site.
- Communicating site news, quality metrics, EHS performance, and providing training at team meetings.

June 2002 - December 2005
Quality Assurance Representative
Eli Lilly and Company, Liverpool, UK
Provided assurance that manufacturing was carried out in accordance with GMP.

- Checking of batch manufacturing records and associated documents.
- Investigation of deviations, out of specification results, and complaints, and reviewing of change control proposals.
- Conducting self-inspections of manufacturing and support facilities.
- Participating in process validation activities and the qualification of new plant and equipment.

February 2001 – June 2002
Operational Quality Officer
GlaxoSmithKline, Montrose, Angus, UK

- Responsible for the management of a portfolio of Active Pharmaceutical Ingredients (API) to ensure manufacture in accordance with GMP and other international regulatory requirements.

September 1999 - February 2001
Development Section Leader - Compliance
CP Pharmaceuticals, Wrexham, UK

- Head of a small team responsible for the design and implementation of procedures and protocols that enhanced compliance to Good Manufacturing Practice (GMP).

February 1996 - September 1999
Quality Control Analyst
CP Pharmaceuticals, Wrexham, UK

- Responsible for the QC release testing of a variety of solid dose products.

Education

October 2014 – April 2017	Qualified Person training and eligibility assessment by Joint Professional Bodies - conferred on 25th April 2017 Cert Number PDO1000
August 1998	NEBOSH General Certificate in Occupational Safety and Health
September 1991 - June 1995	BSc. Hon. Industrial and Environmental Chemistry Class II Division I University of Essex, Colchester, UK