CURRICULUM VITAE

Tracy Moore

BSc (Hons) Chemistry
EPIC Business Director and Senior Consultant

Recognised Areas of Expertise

Over 32 years' experience within the pharmaceutical environment.
10 years with the MHRA Inspectorate. Key MHRA roles include Data Integrity GXP lead, FMD GMP lead, EU GMP Annex 16, Annex 21, Annex 1, Chapter 4 and Annex 11 drafting group member, PIC/S representation, sterile products manufacture and supply chain expert.

22 years in Industry (for commercial and R&D environments), keys roles include EU Qualified Person, Head of Quality, Compliance, and Operational management for sterile products and non-sterile products dosage forms. Responsibility for CDMO oversight and API auditor.

Current Employment

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

- Director of Independent GMP Consultancy from April 2022, providing consultancy services for multiple pharmaceutical companies.

Career History

JAN 2019 – OCTOBER 2021
EXPERT GMDP INSPECTOR, MHRA

- MHRA principal supply chain and GMP advisor for COVID matters (assisting with regulatory advice to UK Government, global partners, NHS and industry partners to NHS during the Covid 19 pandemic).

- Development of a pandemic framework for assessment of unlicensed medicines to be used on mass scale and development of Regulation 174 of the Human Medicine Regulations for vaccine deployment including the development of the manufacturer's conditions.
- Development of the 'Inspectors Academy' training module framework – working with technical leads to provide more efficient accreditation of inspectors.
- GXP Data Integrity lead for Agency (and production of GXP guidance in 2018)
- Temporary Chapter 4 and Annex 11 lead for EMA IWG drafting group (prior to EU exit).
- Member of internal MHRA drafting group for Annex 1 and ad-hoc MHRA drafting meeting representative (through PIC/S).
- Frequent speaker for MHRA on Annex 1, data integrity, GMP advancements.
- PIC/S speaker on Annex 1 to global regulators (contamination control strategy)
- Falsified Medicines expert and importation advisor on EU exit negotiations to UK Government.
- JAP Auditor (for US trade agreement; human and vet competent authorities)
- PIC/S representative for MHRA at annual events; Chair of the Inspector Travel Safety Group and Co-Chair for the Informant working group, Deputy Lead for the Strategic Development Subcommittee (SCSD).
- Compliance Management Team member – review of compliance of companies and agreement of oversight required.
- MHRA representative on EMA Inspectors Working Group (IWG) Annex 21 drafting group
- Member of the Strategic Development Group for the UK Office of Life Sciences
- WHO working group guidance working party representative.
- Development of the MHRA Technology group, encompassing Data Integrity, Artificial Intelligence and Blockchain.
- Medicines and Medical Devices Act representative for importation, falsified medicines and Inspectors' powers.
- Inspection of GMP facilities globally
- WHO pre-qualification inspector
- MHRA deputy Inspectors Working Group (IWG) observer at EMA.
- Author of Expert statements and 'witness' for MHRA prosecution services

OCT 2014 – JAN 2019
SENIOR GMDP INSPECTOR AND OPERATIONS MANAGER, MHRA

- Management of GMP and Senior GMP inspectors
- GXP Data Integrity lead for Agency (and production of GXP guidance in 2018)
- Inspection of GMP facilities globally
- JAP Auditor (for US trade agreement)
- Annex 16 representative for MHRA on IWG drafting panel.
- Delivered FMD GMP requirements for implementation date.
- Inspector of the national safety features repository and co-developed the inspection requirements for EMA
- WHO pre-qualification inspector
- Development and implementation of whistle-blower protection systems
- Development and implementation of travel safety requirements including HEAT training.

DEC 2011 – OCT 2014
GMDP INSPECTOR, MHRA

- Inspections of GMP facilities globally
- Member of internal MHRA Annex 16 working group, member of steriles technical subgroup.

FEB 2011 – DEC 2011
HEAD OF QA, MARTINDALE PHARMA

- QA operational and compliance management of sterile products facility, staff, budgeting requirements and QA operational assistance with sister specials unit (ad hoc).
- EU QP certification.

JAN 2010 – FEB 2011
UK QUALITY SYSTEMS AND COMPLIANCE MANAGER, PATHEON

- Corporate compliance and quality system management for the UK facilities for GMP (commercial and R&D), EU QP, QP(IMP), quality assurance (GMP compliance) of sterile products facility, suppositories, cephalosporin facility.
- Management of quality systems, regulatory affairs group, sterility assurance group and microbiology department.
- UK facilities' regulatory compliance oversight.
- Vendor Assurance of suppliers.

JAN 2000 – DEC 2009
QUALITY ASSURANCE MANAGER AND EU QP,
QUALITY COMPLIANCE MANAGER (STERILES),
QUALITY ASSURANCE OFFICER, CP PHARMACEUTICALS

- Full range of QA and quality operational management duties for a sterile facility.
- QP batch certification for sterile products
- QP(IMP)
- Vendor Assurance of all suppliers, APIs, glass components, rubber, and sterilisation processes.

MAR 1999 – DEC 1999
QA OFFICER, IVAX PHARMACEUTICALS

- Quality Assurance duties of onsite sterile facility using blow-fill-seal technology
- Vendor Assurance of suppliers, including APIs.

SEP 1998 – MAR 1999
GXP Auditor, British Biotech Ltd

- Study auditing for R&D (pre-clinical) studies.

AUG 1996 – AUG 1998
QUALITY ASSURANCE OFFICER AND QC ANALYST, CORTECS COMPANY GROUP

Quality Assurance duties:

- Biological R&D facility and laboratories (on-site)
- Vendor assurance of contract clinical trial packers (double-blinded packaging)
- Commercial and clinical trial duties for Oral Solid Dosage manufacturing facility

- Commercial on-site ointments, liquids, and creams department
- Oversight of pre-clinical and R&D company sponsored laboratories at the London School of Pharmacy.
- Method development and QC analysis of R&D medicinal products.

JUL 1989 – AUG 1996
QC ANALYST, ER SQUIBB & SONS - BRISTOL-MYERS SQUIBB

- Full range of analytical (including chromatographic and robotic) and wet chemistry techniques. Development and validation of analytical methods, cleaning validation methods and qualification of laboratory equipment.

Education

- **1994**
  Licentiateship (by LRSC examination) - Royal Society of Chemistry

- **1996**
  Chemistry BSc (Hons) - The University of Manchester

- **2005**
  Eligible EU Qualified Person – The Royal Society of Chemistry