CURRICULUM VITAE

Tony Orme

Pharmaceutical Industry Consultant

Tony Orme is an independent pharmaceutical consultant with over 32 years' experience at MHRA in various areas of the regulation of pharmaceutical distribution. As a former MHRA GDP Inspector with 22 years within the MHRA GDP Inspectorate team where he reached Expert Inspector level, he undertook the most high profile and complex inspections across the UK.

He was the GDP EU Exit Lead and provided the guidance for import, the RPi and supply to Northern Ireland. He led on the implementation of the Falsified Medicines Directive for distributors in the UK and the continued use of the Medicines Verification system in Northern Ireland.

He was Involved in the development of most UK GDP policies, including the GDP risk based inspection strategy and supply chain security. He was GDP lead for IAG cases for many years and is ideally placed to help distributors ensure their operations are compliant or help respond to failures and to develop and implement effective remedial actions.

Recognised Areas of Expertise

Tony is an accomplished quality professional with over 32 years' experience in the regulation of pharmaceuticals with MHRA, with 22 years within the MHRA Inspectorate leading on high profile and complex inspections. He was involved in the development of most UK GDP policies and as such is ideally placed to help distributors prevent deficiencies in their operations or to help respond to failures and to develop and implement remedial action.

- Expert GDP Inspector recognised across the sector to provide timely accurate and pragmatic guidance.
- GDP Lead for the Inspection Action Group (IAG) and Compliance Management Team (CMT) from 2015 to 2021.
- Responsible for GDP Inspection strategy, development of the risk based inspection programme.

- Supply chain security, due diligence of customers and suppliers, implementation of techniques to identify suspicious transactions. Worked closely with DHSC on Export ban policy and implementation.
- GDP Lead for Covid 19 vaccine deployment and author of the temporary GDP flexibilities during the pandemic.
- GDP Lead for FMD guidance and implementation.
- GDP EU Exit Lead, provided the guidance for import, the RPi and supply to Northern Ireland.
- Provided GDP training for international regulators, US FDA, Swiss Medic and APEC nations.
- Presenting to industry at MHRA Symposium and external events on GDP and Human Medicines regulation requirements.
- Part of EMA GDP working group for drafting GDP Guidelines and Community Procedures and a member of the PIC/S GDP working group.
- Trainer for MHRA Compliance Monitor pilot project

Involvement with Professional Associations/Societies

- Regular presenter at PQG RP Forum
- Successful completion of GDP Inspector training courses including data integrity, project management, audit, quality management, computerised systems and recruitment.
- ISO 9001:2000 lead auditor
- Security vetted

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 GDP consultancy from February 2023, providing services for multiple pharmaceutical companies

Career History

Director Pharma Distribution Consulting Ltd - February 2023 - Current Employment

- Providing expert GDP inspector advice and guidance for pharmaceutical distributors.
- Providing consultancy services, written advice and support, mock inspection, third party audit, training, gap assessment and due diligence.

Expert GDP Inspector MHRA - October 2020 -January 2023

- Led the development of the GDP Inspection strategy and inspection models. Helped develop the Compliance Monitor project and provided training for the selected consultants.
- Leadership of the GDP Compliance Teams, providing technical leadership to the GDP Compliance Team, and providing support, mentorship, training and guidance to Inspectors in the GDP and GMDP Compliance teams.

- Representing MHRA at national and international level amongst government, national regulators and industry groups.
- Developed guidance on EU Exit GDP related issues, Responsible Person for Import, Northern Ireland supply, FMD, PLGB, NIMAR and CAP bridging.
- Supporting Covid vaccine deployment working with NHS, DHSC, UKHSA, FCDO, MOD and Devolved Administrations.
- Provided expert witness statements for prosecutions of Human Medicines Regulation offences and for Fitness to Practice Hearings for Professional regulators.
- Provision of specific guidance to protect the UK medicines supply chain with a targeted webinar

Lead Senior GDP Inspector MHRA (previously Senior GDP and GDP Inspector) - 2002-2020

- Trained and accredited to inspect all UK Human and Veterinary wholesale dealers' licences, Brokers, Active Substance distributors and storage and distribution sites on MIAs.
- Leading on the most serious and complex inspections including with Inspectors from GMP, GPvP, Veterinary Medicines Directorate and General Pharmaceutical Council.
- Responsible for training and accrediting GMP and GDP Inspectors for authority to inspect wholesaler dealers.
- GDP Lead of MHRA Inspection Action Group (IAG) and Compliance Management Team (CMT).
- Responsible for GDP management of sites referred for action, recommendations for interventions to be taken and management / acceptance of remediation.
- Author of MHRA blogs on various topics, and published guidance on the eligibility and suitability of the Responsible Person and the '36 hour rule' policy.
- Frequent speaker for MHRA on GDP topics and implementation of new regulation and policies.
- Membership of PIC/S GDP working group producing guidelines on GDP for participating authorities.
- Membership of EMA GDP working group to produce EU GDP Guidelines.
- Expert on supply chain security working closely with MHRA Enforcement Group to investigate suspected falsified medicines and diversions from the supply chain.
- Development and implementation of FMD for UK and SecurMed Board Member representing MHRA for FMD in Northern Ireland.
- Delivered presentations on a variety of GDP related topics at MHRA symposia and to national and international audiences including PDA, ISPE PQG , GIRP , BAEPD , HDA .

Senior Investigations Officer - MCA/MHRA Enforcement Group (previously Investigator) - 1994 - 2001

- Lead major investigations into criminal activity in relation to Medicines Act and associated offences. Areas of speciality included investigations and successful prosecutions of Internet supply of medicines and falsified medicines manufacture.
- Trained in Investigative techniques, interview skills, driving, surveillance, fraud and financial investigation and intelligence assessment.

Manager PLPI / Product Licence Renewals / Variation / Registration - 1990 -1994

- Managed various teams responsible for the administrative aspects of product licensing

Education

Educated to General Certificate of Education A level standard.