Pharmaceutical Quality Matters

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Mike Robertson established the pharmaceutical regulatory consultancy Pharmaceutical Quality Matters in September 2000 where he is the Principal Consultant in European Union (EU) Regulatory Affairs.

Mike specialises in providing companies with advice and insight on licensing strategies and regulatory requirements. He also delivers in-company and public training on Chemistry & Pharmacy [chemistry, manufacturing and control (CMC)] topics and on other subjects connected with CTD Modules 1, 2 and 3.

He writes or reviews documents for marketing authorisation applications, Active Substance Master Files (ASMFs, formerly European Drug Master Files or EDMFs), Certificate of Suitability (CEP) dossiers / applications and he prepares and signs Pharmaceutical Expert Reports and Quality Overall Summaries.

He is also a Visiting Lecturer at Kings College, London University, a Member of the British Pharmacopoeia Commission's Excipients Working Party, a Registered Pharmacist, a Chartered Chemist, a Chartered Scientist and a Fellow of The Organisation for Professionals in Regulatory Affairs (TOPRA). He is a Quality Assessor on the WHO Prequalification Programme (Geneva – Copenhagen). He also lectures internationally and writes scientific papers on CMC subjects.

Previously, for almost 20 years, Mike worked at the Medicines Control Agency (MCA), now the Medicines and Healthcare products Regulatory Agency (MHRA) in London, where he had the unique experience of being first a Pre-Clinical Assessor and then a Pharmaceutical Assessor. In the latter role he assessed many hundreds of Marketing Authorisation new applications (for New and Existing Drug Substances and New and Existing Drug Products), and several tens of thousands of Variation applications.

When at the MCA he was also a UK-nominated Expert at the European Medicines Evaluation Agency (EMEA) in London, a UK Rapporteur for the CEP Procedure at the European Directorate for the Quality of Medicines (EDQM) in Strasbourg, a Member of the Technical Advisory Board for the CEP Procedure, a Member of the European Pharmacopoeia Commission and a Member of the United Kingdom Delegation to the European Pharmacopoeia Commission.

At the MCA Mike authored several Standard Operating Procedures for Pharmaceutical Assessors including one on the assessment of EDMFs. He also had responsibilities for and opportunities to train assessors and other staff at the MCA and the EDQM about EDMFs and CEPs. For the CEP Procedure, he originated both the rapporteurs' internal guidelines for the assessment of Products of Fermentation and the process that lead to EU-wide harmonisation of regulatory guidance on the residues of metal catalysts in drug substances.

Even earlier in his career and before becoming a regulatory assessor, Mike worked from 1969 to 1981 in the pharmaceutical industry and was a Departmental Head for ten of those years. He gained industrial experience in a variety of scientific areas in Quality Control and Research & Development operations and during his industrial employment became eligible to register as a Qualified Person.