



Dr. David Inglis

B.Sc., Ph.D, CChem, MRSC.

Dr Inglis has more than 27 years of experience of quality management within the pharmaceutical industry. He has managed quality control laboratories for release and stability testing of incoming raw materials, intermediates and APIs and has extensive experience of Operational Quality Assurance including; documentation, control of change, auditing and routine regulatory compliance to cGMP. He has taken responsibility for release to market of intermediates and APIs, including bulk sterile antibiotics (EU Qualified Person role) and is a specialist in process GMP troubleshooting and CAPAs. He is an expert in product cell principles: applying ICH Q7a to develop secure GMP compliance at competitive cost.

David is an experienced auditor of API supplier/contractor sites in the United Kingdom, Italy, Austria, Netherlands, Germany and Korea and has led successful pre-FDA inspection preparation audits in the UK and Singapore. He has prepared sites for several MHRA/FDA inspections, including FDA "Systems" based inspections and has extensive experience of being the lead spokesman during major audits.

David has been a key contributor to the design of new facilities and to acceptance standards for plant decontamination. He has also given expert testimony in US patent litigation. He is a specialist in cGMP training and QA system improvement, with packages covering self inspection, plant decontamination and preparation for regulatory inspections.

David specialises in the manufacture of APIs and their intermediates and can offer advice on improvement of QA/GMP systems, auditing, GMP training, inspection preparation and plant cleaning/decontamination, especially for bulk pharmaceuticals. His skills are also particularly relevant to secondary manufacturers of drug products who require supplier audits and/or improvement to secure their supply chain or to comply with the recent EU directives concerning manufacture of API compliant with the principles of GMP.