ROGER GRAY, BSc, CEng, MIMechE

VP, QUALITY AND REGULATORY

Based in the United Kingdom (UK), Roger Gray has worked for over 35 years in the medical device industry, specializing in European and United States regulatory and quality management requirements, in particular for electro-medical, minimally invasive and associated devices.In the early nineties, as Chairman of the Association of British Healthcare Industries (ABHI) Technical Committee and a member of the COCIR Technical Committee, Mr. Gray was closely involved with the development of the Medical Devices Directive during its formative stages, helping to present the views of UK industry to both the UK Competent Authority and European Commission. More recently, from 1998 to 2005, he was a member of the EUCOMED regulatory affairs focus group.

Mr. Gray holds a degree in Mechanical Engineering and worked in military research, automotive R&D, and technical consulting with Cambridge Consultants Ltd, a member of the Arthur D Little Group, before entering the medical device industry.

Mr. Gray held management positions at KeyMed Ltd, which has been part of Olympus Corporation, the global market leader for endoscopic equipment, since the early nineties.

At KeyMed, he was responsible for Regulatory Affairs and Quality Assurance during his 29 years with the company, but also managed a variety of other departments, including manufacturing, repair, R&D, technical marketing, technical publications, and intellectual property.

Mr. Gray has participated in several European and international standards working groups including IEC SC 62D/MT 16, ISO TC 172/SC 5/WG 6 and CEN BT/TF 123. In addition, he was a member of the Editorial Advisory Board of the European Medical Device Technology magazine since its inception until its closure in 2016, regularly contributing to its conference program. Mr. Gray has also been a frequent speaker on device regulatory subjects at seminars and conferences in Europe and the US.

Mr. Gray can assist you with:

- Compliance with European medical device regulatory and quality system requirements, while taking into consideration US requirements for companies marketing in both Europe and the US
- Development of European Technical Files to help gain product entry into the European market

- Generation of risk management files in accordance with ISO 14971
- Identification of relevant voluntary standards
- Development of 510(k)s for FDA Class II devices to gain entry to the US market
- Labelling reviews for European and US markets
- European and US post-market surveillance requirements compliance
- Obtaining and maintaining quality system certification to ISO 13485/MDD Annex II, and US 21 CFR 820/803/806
- Complying with European requirements for non-European manufacturers, through the Donawa Consulting Authorized Representative service