CARLO D'ALESSANDRO, BSc

DIRECTOR, QUALITY AND REGULATORY

Based in the Rome office, Carlo d'Alessandro holds a degree in pharmaceutical chemistry and has over 15 years' experience in the IVD and medical device industries. Before joining DLC in 2011, he had 10 years' experience working as Quality Assurance and Regulatory Affairs Manager in a multinational IVD company, directly managing implementation of its quality system in accordance with ISO 13485:2003. In this role Mr. d'Alessandro was also responsible for CE marking more than 200 IVD devices, including products from Annex II List A of Directive 98/79/EC (HIV, HTLV, HBsAg, HCV, HBV, HDV test kits) and also Annex II List B. His responsibilities also included the oversight of international performance evaluations in compliance with European Common Technical Specifications.

Mr. d'Alessandro has a wide experience in the development of CE Technical Files and Design Dossiers, Class II and III 510(k)s for US marketing clearance, together with the preparation of submissions for other regulatory jurisdictions, including Canada, Brazil, Mexico, Australia, Taiwan, India and China. During his experience working with IVD companies, he was also involved in the management of radioactive materials, in full compliance with European regulations for production, personnel training and protection, waste disposal, and also as official liaison with the National Competent Authorities for Radioactive Substances.

Beginning his career in a pharmaceutical company in Milan as an R&D technician with responsibility for QC analytical method validation, Mr. d'Alessandro subsequently began working in the IVD sector, managing the Raw Material Production Department in a company near Rome. In this role his main activities involved the purification and conjugation of monoclonal and polyclonal antibodies with HRPO or I125, as well as the incoming QC of biological and chemical raw materials

More recently, Mr. d'Alessandro has also assisted various medical device companies in both the IVD and general medical device field with quality system implementation and in the preparation and submission of 510(k)s for Class II spirometry and oximetry devices, and for the CE marking of other devices under the MDD.

Mr. d'Alessandro can assist you with:

- Compliance with European medical device regulatory and quality system requirements
- Development of IVD and general medical device European Technical Files and Design Dossiers

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- Compliance with CTS Annex II List A IVDs
- Obtaining and maintaining quality system certification to ISO 9001 and ISO 13485
- Preparation for Notified Body quality audits
- Process validation of manufacturing and control processes
- European and US post-market surveillance compliance
- Generation of risk management files in accordance with ISO 14971
- Identification of relevant voluntary standards for CE marking purposes
- Development of 510(k)s for US FDA
- Definition of OEM responsibilities for CE marking
- Labelling reviews for European and US markets