Sylvie Le Glédic, Ph.D.
Director, Medical Devices & IVD

Sylvie Le Glédic is in charge of the design and implementation of global regulatory strategies for the development and registration of in vitro diagnostics medical devices (IVDs). Sylvie helps IVD manufacturers in the creation of CE mark technical files and US regulatory dossiers for FDA approval, advising on the required Quality Management System. She assists pharmaceutical companies developing Companion Diagnostics (CDx) in the drug/CDx co-development and facilitates liaison between both pharmaceutical and diagnostic developers. She is actively involved in the evolution of the EU IVD regulation, and closely follows the new rules for regulatory approval of CDx both in EU and US. Sylvie is based in Voisin Consulting Life Sciences' (VCLS) Paris office.

Sylvie brings over two decades of experience in the regulatory field of IVD medical devices, achieving the implementation of the IVD Directive at Bayer Diagnostics in the EU, as well as the registration of the CE marked Company's IVDs with the applicable European Competent Authorities. Sylvie has significant experience in the preparation and submission of regulatory filings according to the EU Conformity Assessment procedures, to achieve CE marking for placing IVD products on the market in Europe. She managed numerous contacts with regulatory bodies (Notified Bodies and EU Competent Authorities), and supported the Post-market IVD vigilance activities and reporting in Europe.

Sylvie is a graduate of the University of Paris VI, with a degree in biochemistry. Her work experience grew from marketing responsibilities and registration of diagnostics products with the French Competent Authority to extended National and European regulatory responsibilities at Bayer Diagnostics, then Siemens HealthCare Diagnostics, for all Central Laboratory and Diabetes Care devices. The Central Laboratory devices included biochemistry, haematology, immunology, blood gas and molecular biology products, under Annex II List A and List B of the current IVD Directive. She closely collaborated with the US manufacturer for the reporting of adverse events to the EU Regulatory Agencies, including the MDRs reported to the US FDA. She achieved the CE marking of the reagents and software for the risk assessment of Trisomy 21, obtained with the French Notified Body, LNE.

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