BioM ADVICE

Make standards and regulations your strength to conquer new markets

Sophie BIGNON
45A rue de Margnolles
69300 Caluire et Cuire
France
Cell. +33 (0)6 85 57 00 30
s.bignon@biom-advice.com

www.biom-advice.com

YOUR CONSULTANT

Expertise: Evaluation of allowable limits for extractables and leachables of medical devices (ISO 10993-17) – Biological evaluation of medical devices (ISO 10993-1)

PROFESSIONAL EXPERIENCE	
2017- BIOM ADVICE	**2017- BioM ADVICE – Independent consultant** - Toxicological assessment of medical devices extractables - ISO 10993-17 - Biological evaluation - ISO 10993-1
2002-2017 FLAMEL TECHNOLOGIES (AVADEL)	**2013-2017 Research Scientist in Innovation department** - Development/improvement of parenteral and oral drug delivery technologies and dosage forms **2004-2013 Research Scientist in Preclinical and Clinical department** - Technical Management of bioanalysis performed on formulated proteins and polymers (SDS-PAGE, Western blot, ELISA, enzymatic degradation, HPLC, LC-MS…) - Setting, monitoring and reporting of preclinical studies (PK/PD, biocompatibility, immunotoxicity…) outsourced to CRO **2002-2004 Research Scientist in Formulation** - Formulation of parenteral drug delivery technologies (proteins) - Development of bioanalytical methods for proteins and polymers
2000-2001 DIAGNOSTICA STAGO	**2000-2001 Research Scientist in Formulation** - Improvement of reagent formulation for a hemostasis test
EDUCATION	
Continuous training	**2024** **MD101 –** Regulatory requirements of MDSAP jurisdictions (US, Canada, Australia, Brazil) **2023** **CPE** - Determination of molecular structure by mass spectrometry **2018** **CPE** - Toxicology applied to health hazards **2018** **LNE** - Biocompatibility of medical devices **2018** **LNE** - European regulation about Medical Device (Directive 9342 CEE) **2015** **CPE -** Introduction to formulation and properties of dispersed media **2014** **IFIS -** Pharmaceutics excipients and use in formulation **2011** **CEFIRA** - Quantitative mass spectrometry for therapeutic proteins and biomarkers **2008** **CEFIRA -** Good Laboratory Practices (GLP) **2007** **CEFIRA -** Therapeutic proteins development: security and pharmacokinetics aspects **2006** **ENV -** Pharmacokinetics for non-specialists **2002** **AFICIP** - High Performance Liquid Chromatography of Proteins
Education	**1994-2000 INSA Lyon** engineer school, specialization in biochemistry
LANGUAGES	
Languages	French: mother tongue — English: fluent