

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

CONSULTANT, Engineer

Expertise: Toxicological evaluations (ISO 10993-17),
Biological evaluation of medical devices (ISO 10993-1)



PROFESSIONAL EXPERIENCE

2017- BIOM ADVICE	2017- BioM ADVICE – Independent consultant <ul style="list-style-type: none"> ✚ 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 <ul style="list-style-type: none"> ✚ Development/improvement of parenteral and oral drug delivery technologies and dosage forms 2004-2013 Research Scientist in Preclinical and Clinical department <ul style="list-style-type: none"> ✚ 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 <ul style="list-style-type: none"> ✚ 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 <ul style="list-style-type: none"> ✚ Improvement of reagent formulation for a hemostasis test

EDUCATION

Continuous training	2025 Univ. Paris - Reproductive Toxicology 2025 BioM ADVICE – Biological evaluation per ISO 10993-1: 2025 2024 Univ. Paris - Toxicology Basics: Study of methodological mechanisms and approaches 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
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