Marie-Odile FAURE, PhD

A pragmatic expertise for achieving the preclinical and clinical development of your health products

(Drugs, medical devices and cosmetics)

FOCUS

As owner of **Scientific Consulting For You** consulting society, I can help you for the preclinical and clinical development of your health products, from the strategy of development to the writing of your marketing authorization dossiers with more than 15 years' experience in writing.

SKILLS

Strategy
Analytical
Communicative
Regulatory writing
Scientific writing
Plain language
International experience
Project management

FIELDS

Toxicology (ingredient evaluation, extractables, skin ageing via pollution), dentistry (anaesthetics, sealers), ophthalmology (injected and topical drugs for Dry Eye Disease, Glaucoma), orthopaedics (bone substitutes, spinal dynamic stabilization), hospital medical devices (syringes, needles, surgery kits for hemodialysis), venous thromboembolism in pregnant women, venous ulcers, lung fibrosis, pneumology/oto-rhino laryngology (sleep apnea), oxygenotherapy, psychatrics (drugs for suicidal ideas, anxiolytics drugs), cancerology (nanoparticles, hepatocellular carcinomas), diabetes (insulin pump), obesity, interventional cardiology (percutaneous coronary intervention).

EXPERIENCE

Scientific Consulting For You (France), owner
01/2015-up to now (8 years): **Preclinical and clinical development expert and scientific/medical writing**

- Preclinical and clinical developments strategy
- Due diligence expertise
- Regulatory and scientific writing for over 100 products (drugs and medical devices from Class I to Class III, ancillary substance or implantable, cosmetics)
- High success rate of authorized regulatory dossiers due to issues anticipation
- Several Health Authorities (ANSM, MHRA, FDA, EMA) and notified bodies (Gmed, BSI, SGS, Tüv, Kiwa)
- Peer-reviewed articles as author and medical writer
- Clients from start-up to big pharma and CROs
- Technical audits with corrective actions plan (GLP and GCP)
- Trainer for preclinical and clinical development and writing strategy in order to get marketing authorization.

SEPTODONT (France)
05/2012- 12/2014 (2,5 years): **Head of Medical Affairs**

- Preclinical, clinical and vigilance activities including expertise in drugs and medical devices
- Regulatory Affairs support with answers to Health Authorities for more than 180 products (drugs, medical devices and cosmetics)
- Audits and inspections
- Management of four experimented persons.

11/2008-04/2012 (3,5 years): **Head of Preclinical and Clinical development**

- Development plans for nine medical devices defined in collaboration with experts
- Writing of preclinical and clinical reports for CE mark and 510K for 11 medical devices, 2.2, 2.4, 2.5, 2.6 and 2.7 modules for 6 drugs
- Monitoring of subcontracted preclinical studies full package (50 studies) and of three French multicentric randomized clinical studies for both drugs and medical devices
- Preclinical and clinical expertise for worldwide product registration renewal (35 products).

Novagali Pharma (SANTEN) (France)
03/2007-10/2008 (1,5 years): **Preclinical associate manager**

- Development plans defined with experts (ANSM, EMEA, FDA).
- Monitoring of seven drug candidates and medical devices preclinical developments.
- Subcontracting of 50 studies with eight CROs.
- Selection and monitoring of university collaborations.
- Direction of internal studies.
- Two IND and IMPDs writing in contact with international experts.
- Patent survey.

REGULATORY REFERENTIALS

Good Laboratory Practice, Good Clinical Practice, Good Vigilance Practice, Good Publication Practice, MEDDEV, New European Regulation for Medical Devices, ICH, ISO 10993, ISO 14155

ASSOCIATION

- President and founder of French League of Writers (FLOW)
- Member of European Medical Writers Association
- Member of Société Française de Toxicologie (French Society of Toxicology) with recommendations from Prof. MARZIN and Prof. WARNET (toxicological experts)

CONTACT DETAILS

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FORMATION

Up to now, I follow two training courses per year in toxicology, medical writing and clinical fields.

2005

- **Joint PhD in Biology (Physiology of Reproduction)**, INRA/CNRS/Haras Nationaux (Nouzilly, 37, **France**)- Medical Research Council (Edimbourg, **UK**)

2002

- **Master of Physiology of Reproduction,** University of Jussieu (Paris 6- Pierre et Marie Curie)
- **Magistère of Genetics (Cellular and Molecular Physiology)**, University of Jussieu (Paris 7- Denis Diderot)

PUBLISHED ARTICLES

Performed by Scientific Consulting For You

2022

- Fitoussi R*, **Faure MO***, Beauchef G, Achard S. Human skin responses to environmental pollutants: a review of current scientific models. Environmental Pollution. 306: 01/08/2022. *Medical writer and co-author.*
  *Authors equally contributed to the work.

2019

- Verdin A, Cazier F, Fitoussi R, Blanchet N, Vie K, Courcot D, Momas I, Seta N, Achard S. 2019. An *in vitro* model to evaluate the impact of environmental fine particles (PM0.3-2.5) on skin damage. Toxicology letters 305:94-102. *Medical writer.*

2018

- Gris JC, Aoun J, Rzaguliyeva L, Begum R, Salah H, Tugushi T, Ghani-Chabouk M, Zibdeh M, Jassar WA, Abboud J, Meziane N, Ajayi GO, Hossain N, Pyregov A, Abduljabbar H, Snyman LC, Rachdi R, Tahlak MA, Najmutdinova D; SAVE Study Group. 2018. Risk Assessment and Management of Venous Thromboembolism in Women during Pregnancy and Puerperium (SAVE): An International, Cross-sectional Study. TH Open. 2018 Apr 4;2(2):e116-e130. *Subcontractant for the CRO Altizem for the study report.*

2017

- Garrigue JS, Amrane M, **Faure MO**, Holopainen JM, Tong L. 2017. Relevance of Lipid-Based Products in the Management of Dry Eye Disease. Journal of ocular pharmacology and therapeutics: the official journal of the Association for Ocular Pharmacology and Therapeutics 33(9):647-661. *Medical writer and co-author.*
- Labbe A, Baudouin C, Ismail D, Amrane M, Garrigue JS, Leonardi A, Figueiredo FC, Van Setten G, Labetoulle M. 2017. Pan-European survey of the topical ocular use of cyclosporine A. Journal français d'ophtalmologie 40(3):187-195. *Medical writer.*

2016

- Lecas S, Boursier E, Fitoussi R, Vie K, Momas I, Seta N, Achard S. 2016. In vitro model adapted to the study of skin ageing induced by air pollution. Toxicology letters 259:60-68. *Medical writer.*
- **Faure MO**. 2016. Medical affairs writing: A key role to relay medical information. Medical Writing 25(2):6-8.

During my career before Scientific Consulting For You

2015

- Malet A*, **Faure MO***, Deletage N, Pereira B, Haas J, Lambert G. 2015. The comparative cytotoxic effects of different local anesthetics on a human neuroblastoma cell line. Anesthesia and analgesia 120(3):589-596.
  *Authors equally contributed to the work.

2014

- Caron G, Azerad J, **Faure MO**, Machtou P, Boucher Y. 2014. Use of a new retrograde filling material (Biodentine) for endodontic surgery: two case reports. International journal of oral science 6(4):250-253.

2013

- Koubi G, Colon P, Franquin JC, Hartmann A, Richard G, **Faure MO**, Lambert G. 2013. Clinical evaluation of the performance and safety of a new dentine substitute, Biodentine, in the restoration of posterior teeth - a prospective study. Clinical oral investigations 17(1):243-249.

2012

- Daull P, Buggage R, Lambert G, **Faure MO**, Serle J, Wang RF, Garrigue JS. 2012. A comparative study of a preservative-free latanoprost cationic emulsion (Catioprost) and a BAK-preserved latanoprost solution in animal models. Journal of ocular pharmacology and therapeutics : the official journal of the Association for Ocular Pharmacology and Therapeutics 28(5):515-523.

2010

- Sallon C, **Faure MO**, Fontaine J, Taragnat C. 2010. Dynamic regulation of pituitary mRNAs for bone morphogenetic protein (BMP) 4, BMP receptors, and activin/inhibin subunits in the ewe during the estrous cycle and in cultured pituitary cells. The Journal of endocrinology 207(1):55-65.

2009

- Liang H, Baudouin C, **Faure MO**, Lambert G, Brignole-Baudouin F. 2009. Comparison of the ocular tolerability of a latanoprost cationic emulsion versus conventional formulations of prostaglandins: an in vivo toxicity assay. Molecular vision 15:1690-1699.

2008

- Liang H, Brignole-Baudouin F, Rabinovich-Guilatt L, Mao Z, Riancho L, **Faure MO**, Warnet JM, Lambert G, Baudouin C. 2008. Reduction of quaternary ammonium-induced ocular surface toxicity by emulsions: an in vivo study in rabbits. Molecular vision 14:204-216.
- Nicol L, **Faure MO**, McNeilly JR, Fontaine J, Taragnat C, McNeilly AS. 2008. Bone morphogenetic protein-4 interacts with activin and GnRH to modulate gonadotrophin secretion in LbetaT2 gonadotrophs. The Journal of endocrinology 196(3):497-507.

2005

- **Faure MO**, Nicol L, Fabre S, Fontaine J, Mohoric N, McNeilly A, Taragnat C. 2005. BMP-4 inhibits follicle-stimulating hormone secretion in ewe pituitary. The Journal of endocrinology 186(1):109-121.

POSTERS

Performed by Scientific Consulting For You

2020

- Trotin-Picolo C., Lambert G., Déchelotte P., Fetissov S.O. Hafnia alvei 4597 strain reduces food intake, body weight gain and improves body composition, glucose and lipid metabolism in a mouse model of hyperphagic obesity. Probiota 10-12 February 2020. *As scientific writer.*

2018

- Ouayoun M.C., Jaeger F., Faure M.O., Lassalle T., Tounsi M., Meunier J.P. Etude observationnelle rétrospective sur la tolérance et l'efficacité de l'orthèse d'avancée mandibulaire Somnodent® dans le traitement du SAHOS. Colloque Données de santé en vie réelle AFCROs. Paris, 7 June 2018. Abs 180145. *Subcontractant to the Axonal-Biostatem CRO.*

AS TRAINER

Performed by Scientific Consulting For You

2023

- Se former à la biocompatibilité (on-site training for a client)

2022

- Le dispositif médical : quelles données pour obtenir et maintenir le marquage CE ? (on-site training for a client).

2019

- Le dispositif médical : l'évaluation préclinique (on-site training for a client)

2018

- Le dispositif médical : quelles données pour obtenir le marquage CE? (on-site training for a client)

2016

- Le dispositif médical : quelles données ? (on-site training for two clients, adapted to marketing teams, to toxicological directors and to clinical team)