Sophie Vanwetswinkel, Chemist, PhD

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PRESENT POSITION

May 2019 to now

Regulatory Affairs Associate, RLM Consulting

Experience in providing regulatory assistance to different pharmaceutical companies, in particular:

- Writing of Investigational medicinal Product Dossier (IMPD) and Investigator's Brochure (compilation of the clinical and nonclinical data on investigational product)
- Writing of modules 2.6 Nonclinical summaries and 2.7 Clinical summaries
- Literature compilation and assistance in writing of Briefing Document to request scientific advice to national European competent authorities or to EMA
- Preparation and submission of application for PRIME scheme to EMA
- Scientific writing for regulatory purposes

PROFESSIONAL EXPERIENCE

Oct 2017-Mar 2019

Regulatory Affairs and Pharmacovigilance Manager Benelux - GDP Responsible Person, Daiichi Sankyo Belgium

Oct 2015-Sep 2017

Medical Consultant

Medical information, scientific writing, medical review, preparation of training material for various clients (among others Novartis

	Belgium c/o Valesta, Daiichi Sankyo Belgium c/o XPE Pharma & Sciences)
Sep 2013-Sep 2015	**Publication Manager,** **GSK Vaccines** (c/o XPE Pharma & Sciences)
Feb 2011-Jun 2013	**Researcher, Structural Biology Brussels, VIB-VUB**
Oct 2007-Dec 2010	**Scientist, Complix**
Oct 1997-Sep 2007	**Various post-doctoral scientist positions in Belgium and the Netherlands**

EDUCATION

1991-1997	**PhD in Chemistry** (Organic chemistry, molecular biology, *in vitro* evolution techniques (phage display) Université Catholique de Louvain (UCL), Belgium
1987-1991	**MSc in Chemistry** (Organic chemistry) Université Catholique de Louvain (UCL), Belgium