Chantal Deschamps, Biology, PhD

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PRESENT POSITION

Oct 2021 to now

Regulatory Affairs Manager, RLM Consulting
Louvain-La-Neuve, Belgium

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

- Writing of Investigational Medicinal Product Dossier (IMPD) and Investigator's Brochure (IB) (compilation of clinical and nonclinical data on investigational product)
- Preparation, writing and submission of Orphan Drug Designation to EMA and FDA
- Writing of Briefing Document (including quality, nonclinical and clinical background information) to request scientific advice
- Assessment for regulatory purposes
- training for Inter-university Certificate in Regulatory Affairs

PROFESSIONAL EXPERIENCE

Aug 2021-Sept 2021

Regulatory Lead, ExeVir Bio
Ghent, Belgium

- Management of regulatory activities of the development of a nanobody candidate targeting SARS-CoV-2 in a COVID-19 clinical development

Jan 2019- Aug 2021

Senior Regulatory affairs manager, PROMETHERA BIOSCIENCES-THERAPEUTICS
Mont-St-Guibert, Belgium

- Management of regulatory activities of the development of an Allogeneic ATMP candidate
  - Phase IIb EU initial submission (VHP process, 23 countries),

- Authoring and preparing IMPD and IB
- Coordination and assistance in answering questions raised by Heath Authorities (Phases IIa and IIb)
- collaboration with CRO for submission in specific countries.
- Direct interactions with Health Authorities: FAHMP, ANSM, PEI and European Regulatory Authorities via CRO, EMA SME office

- Ensure that product development meets the regulatory requirements by providing operational and technical guidelines to departments
- Daily interactions with cross-functional teams: R&D, Operations, QA, nonclinical, Logistic, QC, clinical
- Involved in discussions and preparation for the submission of clinical trial in the US: draft IND and FDA requirements; in quality and preclinical consultations with the Japanese Authorities (PMDA) in collaboration with external consultant
- Assist with regulatory day to day intelligence by monitoring the global regulatory environment
- Literature compilation and assistance in writing of Briefing Document to request scientific advice to EMA, preparation of slide deck

Sep 2017-Dec 2018 **Regulatory affairs consultant (ALTRAN) / CMC officer for GSK-Vaccines**
Wavre, Belgium

- Partnered with Global RA department's stakeholders to support timely delivery of CMC documents within CMC outsourcing project

Feb 2017-Sep 2017 **Regulatory Affairs Associate, RLM Consulting**
Louvain-La-Neuve, Belgium

- Provided regulatory assistance to SME developing new drug candidates (i.e. Probiotic, fecal microbiota transplant, herbals) for various indications (i.e. Crohn's Disease, GvHD) from early stages until clinical development, to ensure understanding and alignment of objectives with applicable law and regulations

Feb 2015-Mar 2016 **Scientist, Analytical R&D - GSK-Vaccines**
Rixensart, Belgium

- Development and qualification of cellular methods for release activities of adenovirus-based vaccine

2005-2012 **Various post-doctoral scientist positions:**

- *2014-2012: Senior Researcher* ***Institut Cochin*** *INSERM-ANRS (Paris-France)*
  Expertise: Salmonella, HIV primary macrophage infection, Primary Human Monocytes-Derived Macrophages,

inflammatory response analysis, imagery techniques, immuno- and cell- based assays, ELISA

- *2009-2012: Post-doctoral fellow in infectious diseases - **Institut Pasteur** (Paris-France)*
  Expertise: Development of *in vivo* mouse system to study Listeria intestinal translocation and dissemination in organs.

- *2006-2008: Post-doctoral fellow cell biology: **Institut Cochin** (Paris-France)*
  Expertise: in vitro cellular techniques to study phagocytosis) in vitro cell based-assays, ELISA, Fluorescent microscopy, Flow cytometry

- *2005: Post-doctoral fellow Cell biology - **University of Montreal-CAPRION** (Montreal-Canada)*
  Expertise: Set up of Macrophage infection by Brucella in BSL3 environment to isolate Brucella containing phagosomes

EDUCATION

2000-2005: **PhD in Molecular Biology & Microbiology**
University of Namur, Belgium

TRAINING and CERTIFICATION

Sept 2019: **Regulatory, Developmental and Manufacturing Challenges for ATMPs**
PTI courses, London-UK

Sep 2016-Feb 2017: **Inter-university Certificate in Regulatory Affairs**
University of Liège, Belgium