Marie Genin, Biologist, PhD

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PRESENT POSITION

2015 – Now **Regulatory Affairs Associate, RLM Consulting**

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

- Gap analysis of quality and non-clinical data based on appropriate regulatory requirements
- Development of regulatory project plans (e.g. Development program in terms of quality and preclinical requirements)
- Writing of Investigational medicinal Product Dossier (IMPD) and Investigator's Brochure (compilation of the clinical and nonclinical data on investigational product)
- Writing of Briefing Document (including quality, nonclinical and clinical background information) to request scientific advice to national European competent authorities, EMA or FDA (pre-IND)
- Preparation and submission of Clinical Trial Applications to national European competent authorities and ethic committees
- Preparation and submission of applications for Orphan Drug Designation to EMA and FDA
- Preparation and submission of application for SME status to EMA
- Preparation and submission of application for Advanced Therapy Medicinal Product to EMA
- Scientific Writing for reimbursement dossiers.

EDUCATION

2010-2014	**PhD in Biochemistry and molecular and cellular biology** University of Namur, Belgium
2005-2010	**Master in Biochemistry and molecular and cellular biology** University of Namur, Belgium