



Charline Lays, Bio-engineer, MBA

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PRESENT POSITION

2009 – now

Regulatory Affairs Manager, 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 Briefing Document (including quality, nonclinical and clinical background information) to request scientific advice to national European competent authorities or to EMA
- Preparation and submission of Clinical Trial Applications to national European competent authorities.
- Preparation and submission of applications for Orphan Drug Designation to EMA
- Writing of modules 2.6 Nonclinical summaries and 2.7 Clinical summaries
- Preparation and submission of application for Advanced Therapy Medicinal Product to EMA
- 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)
- Setting up of a Product Specification File, a system of archival containing all the information relating to how Investigational



Medicinal Product is manufactured, tested, packages and labelled

- Scientific Writing for reimbursement dossiers.

Experience in setting up Quality Systems (e.g. writing and implementation of SOP's, management of quality system, initial training of the staff)

- Setting up of Good Research Practice in R&D department of four small biotech companies

Experience in training for small and medium sized companies:

- Clinical Trials applications in European member states
- Good Research Practice
- Development of medicinal products

EDUCATION

2008 - 2009

MBA

Louvain School of Management, Louvain-La-Neuve, Belgium

2003 - 2008

Bio-Engineer (Chemistry and Bio-Industry) Université catholique de Louvain, Louvain-La-Neuve, Belgium