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BELGIUM

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PRESENT POSITION

Feb 2022 – Now **Regulatory Affairs Associate, RLM consulting**

- 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 applications for Orphan Drug Designation to EMA and FDA
- 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
- Writing of Investigational medicinal Product Dossier (IMPD) and Investigator's Brochure (compilation of the clinical and nonclinical data on investigational product)
- Preparation and submission of Clinical Trial Applications to national European competent authorities.
- 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

EDUCATION

2014-2017 PhD in Veterinary Sciences, Institut Agronomique et Vétérinaire HassanII, Morocco

2007-2013 Doctor of Veterinary Medicine, Institut Agronomique et Vétérinaire HassanII, Morocco