Z.K.B.I

Expert, Consultant, formateur, Pharm.D., Ph.D.

Core qualification:

- Extensive pharma industry experience of more than 17 years in regulatory affairs, regulatory intelligence and CMC (chemicals and biologicals).
- Superior expertise in global drugs regulations and preparation of registration dossiers in around 40 countries (Europe, Middle East, GCC, north Africa, sub-Saharan Africa, South Africa, Russia…).
- Expertise and high knowledge in biosimilars (Ph.D and researches in biosimilars)
- High knowledge in intellectual property (patent)

Education:

March – June 2017: Leadership and Management in Health

University of Washington (USA) Online courses

Dec 2010- Feb 2017: Ph.D. in pharmacology (biological products)

University of Pharmacy of Monastir (Tunisia) and Pasteur institute Tunis

Contribution to the evaluation of a biosimilar « enoxaparine ».

Researches on biologicals and establishment of the first model and platform of preclinical toxicity studies in Tunisia and built a bridge between the academy and the pharmaceutical industry.

2003-2006 : Master's degree in drug development

University of Pharmacy of Monastir (Tunisia)

- Pharmaceutical equivalence of generic products "study on antidepressants products"

1997- 2002: Doctorate in Pharmacy

University of Pharmacy of Monastir (Tunisia)

Professional experience:

Since April 2017: Freelance consultant

- Regulatory intelligence in around 20 countries (e.g: elaboration and maintenance of data base for a multinational including CMC & regulatory for African and other countries , different regulatory intelligence projects in Africa & middle east for pharma industries)
- Regulatory affairs strategy and market support (e.g: support of pharma industries through studies reports to classify their product in target countries and suggest best regulatory and marketing strategy)
- Evaluation/gap analysis of CTD and technical files
- eCTD provider and expert (Partner of Extedo Germany)
- Providing registration service in 17 countries (Africa) and marketing through local partners
- Labelling (for conventional Rx, OTC, IMP..)
- Market analysis & Market access
- Business development projects

2004-2017: Global Regulatory Affairs Manager

Les Laboratoires Médis (Tunisia)

- Global Regulatory affairs strategy and procedure
- CTD compilation
- CMC procedure and activity
- Regulatory affairs management and training of a regulatory affairs staff working in site and globally in around 40 countries (Europe, Middle East, GCC, north Africa, sub-Saharan Africa…)
- Interaction and relationship with health authorities
- Regulatory intelligence procedure and activity
- Principal support for QA system. Set up Site Master file and Good manufacturing certification procedures and inspections (European GMP, SFDA, GCC…)
- Audit and due diligence of pharmaceutical companies in Senegal, Serbia, Algeria, Czech Republic
- Support for commercial/export teams.

- Member of the strategic committee deciding on strategic orientation and investments of the company during five years (from 2010 to 2015)
- Pilot of the process "Sales and Marketing": setting and monitoring marketing performance indicators (from 2014 to 2016)
- Intellectual property management.

2003-2004 : Research & Development associate

Les Laboratoires Médis (Tunisia)

- Formulation and development of analytical physical chemistry methods for oral and injectable products
- Comparative dissolution and BCS classification

Membership: **Drug Information Association (DIA)/ Member of TABC (Tunisia–Africa Business Council)/ Member of Editorial Board of Macromolecules: An Indian Journal**

Publications:

- Comparative subcutaneous repeated toxicity study of enoxaparin products in rats. Regulatory Toxicology and Pharmacology 84 (2017) 9-7.
- Evaluation and Structural Characterization, A Comparison Study for Enoxaparin. American Journal of PharmTech Research. 2015; 5(3)
- Under review: Preclinical study testing in rodent: development and optimization of protocols during enoxaparin biosimilarity study.

Patent:

- Le sucralose solution sterile sans conservateurs (Sterile sucralose solution without preservative), PCT/TN2007/000002, EP 2111124 , WO 2008100235:

  Redaction of patent and claims, follow up of approval in Europe Japan and many countries.

Training: **37 trainings (trainings with DIA in Europe, USA and others)**

Conferences: **8 (speaker in 2 conferences)**

Language skills: **Arabic/French/English**