Dr. Tyler I. SAINKOUDJE

Senior Regulatory Affairs Consultant

PROFILE

Industrial pharmacist with 20+ years of experience in pharmaceutical industry as a specialist / Manager first and then as a Consultant (10 years) in several global Top – 10 pharmaceutical / medical companies, mainly in the field of the regulatory affairs.

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Bastion Tower - Level 20
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PROFESSIONAL SKILLS

- REGULATORY STRATEGY
- REGULATORY FILINGS
- CMC AUTHORING/REVIEW
- SITE TRANSFERS
- PROJECTS MANAGEMENT
- QUALITY/CAPA MANAGEMENT

REGULATORY AFFAIRS EXPERIENCE

- **BRAND-NEW RA** / APR 2015 – PRESENT
  Regulatory Affairs Consultant: Regulatory Strategy, Regulatory Intelligence & Regulatory CMC. Project Management.
- **MSD EUROPE** / DEC 2011 – MAR 2015
  Regulatory Affairs Senior Consultant: Regulatory filings (legal entity & CMC changes) in Europe: regulatory submissions ; review & contribution to CMC documents authoring ; regulatory compliance. Handling & leading of the implementation and the maintenance of an internal Master database for CMC Variations.
- **PFIZER FRANCE** / MAR 2011 – SEP 2011
  Regulatory Affairs Consultant: Management of a portfolio of over 70 new generic drug products: NDA & post-approval submissions in France under NP/MRP/DCP/CP routes ; providing guidance to the company's stakeholders ; preparation of strategic pre-filing work & regulatory submissions planning.
- **SANOFI FRANCE** / AVR 2008 – DEC 2008
  Regulatory Affairs Consultant: Review of the CMC dossiers ; contribution to CMC documents authoring & regulatory compliance ; providing guidance to the company's stakeholders on CMC regulations ; representation of the regulatory affairs department on key projects ; reparation of strategic regulatory planning.
- **SANDOZ CANADA** / OCT 2005 – JUL 2006
  CMC – Global Regulatory Manager: Regulatory development & writing of the entire new modules 2 & 3 dossiers ; providing guidance to the company's stakeholders on Global CMC related regulations ; representation of the Global Regulatory Affairs department on key projects ; preparation of strategic regulatory planning & project management.
- **AVENTIS PHARMA** / JAN 2001 – DEC 2003
  Regulatory Affairs Specialist: Development & life cycle management of multiple medicinal products in multidisciplinary teams successively in the international headquarters (Paris), in the Moroccan affiliate (Casablanca) and in one of the most strategic manufacturing site (Compiègne) of Ex-Aventis Pharma.
- **OTHER – PLEASE REFER TO MY LINKEDIN**

PERSONAL SKILLS

- ANALYTIC
- TEAM WORK
- CHARISMATIC
- CREATIVE

EDUCATION

- **DOCTOR IN PHARMACY** / JAN 2009 – JUN 2010
  European University of Brittany (France): Disserted on: The analysis of the American New Drug Application type 505(b)(2) for innovative generic drugs registration and comparison with the similar applications in Europe and France
- **MASTER'S DEGREE** / SEP 1998 – SEP 1999
  European University of Brittany (France): Master of Industrial Pharmacy on drug conception, manufacturing and analysis
- **PHARMD** / SEP 1992 – JUL 1998
  European University of Brittany (France): PharmD program – Pharmacist
- **TECHNICAL DEGREE** / SEP 1991 – JUL 1992
  Auvergne University Technical Institute (France): Applied Biology – Biological & Biochemical Analysis

PROFICIENCY

- CMC REGULATIONS
- TRACKWISE
- DOCUMENTUM
- SAP / ERP