Regulatory Affairs / Drug-Device-Regulatory / Expert

IN LIFE Management AG, headquartered in Basel / Switzerland, specializes in the timely assumption of personnel and management tasks at management level. Exclusively for Life Sciences, Pharmaceuticals and Health Care. The projects cover all functional areas of management in the pharmaceutical, biotech, medtech, hospital and other healthcare industries.
We have a new, exciting 6 month-project on Drug-Device Regulatory and are looking for a

Expert Regulatory Affairs - (m/w)

Area of responsibilities:

- Provide regulatory leadership for project teams, functional areas, executive management, and during meetings with agencies
- Support product development through Regulatory Affairs and Project Management
- Plan, prepare and coordinate documentation for designated IMPDs, MAAs, INDs, NDAs and related filings to regulatory agencies EMA, PMDA and FDA; incl. amendments, supplements and annual reports for regulatory submissions
- Review and evaluate reports, briefing, packages for agencies' meetings, and comprehensive submissions for regulatory authorities
- Support and reviews preparation, assembly and regulatory submissions to Notified Body for achieving CE mark registrations of medical devices
- Support review of Technical Files prior to submission to the Notified Body or Competent Authorities
- Support and reviews change submissions to Notified Body
- Ensure successful pre-approval inspections resulting in marketing clearance

Your profile:

- A university degree in life sciences or medical device engineering (e.g. chemistry, biology, pharmacy or medical) and a healthcare industry background is required
- HealthCare (pharmaceutical and/or ophthalmic) industry experience, preferably within a global company
- Extensive regulatory affair (>2 years) background, preferably in ophthalmology and or dermatology with specific focus on EMA or FDA (active and direct negotiation experience, with these authorities)
- Hands on experience in preclinical and clinical development (strategies, planning and execution)
- Minim 5+ years successful management experience with strong negotiation and decision making skills
- Through knowledge of GMPs, GLPs, GCPs, ICH guidelines, and preferably US regulatory guidelines, as well as of European medical device regulations (MDD/MDR)
- Sufficient presence at headquarters is mandatory to ensure development of direct reports and peers
- Strategic mindset; importance of thinking and acting globally; proven track record of effective planning and organizational skills
- Excellent written, verbal and communication skills, very good English skills
- <30% travel expected (local and global basis)

Offer:

- Attractive interim manager compensation
- Temporary up to 6 months

We are looking forward to your contact. Mr. Rudolf Schulze Vohren is available for further questions and a first confidential exchange of ideas. Discretion and compliance with blocking instructions can be required.

Please send your application documents by stating the code 2017-11-927 by e-mail to rsv@inlife-ag.com.
Spezialist für internationales Interim Management im Bereich Health Care und Life Sciences!