Example of Senior Manager, Regulatory Affairs Job Description

Our company is hiring for a senior manager, regulatory affairs. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

Responsibilities for senior manager, regulatory affairs

- Establish and support a work environment of continuous improvement that supports MAQUET's Quality Policy, Quality System and the appropriate regulations for the areas this position supports
- Develop and strengthen relationships with Chinese Regulatory agencies – CFDA, CDE, CFDI, NIFDC, Ch.P
- Responsible for performance (quality, profitability, utilisation) of direct reports, ensuring consistent regulatory support, in accordance with Global Regulatory Affairs business plans
- Provide regulatory guidance regarding advertising and promotional materials, new campaigns and launch strategies
- Contributes to the compilation of high quality documentation for submissions in the region ensuring content and format requirements are met
- Monitor current and proposed regulatory requirements to provide applicable regulatory advice to project teams to ensure HA compliance while meeting business objectives
- Mentor Regional Managers and /or Regulatory Specialists
- Work with CN Law department to develop CN strategy for negotiated cost sharing negotiations involving grade separations, road and utility crossings and fencing
- Preparation and timely completion of FDA submissions for in vitro diagnostic devices (assays, instruments, software) to meet project and business needs

- Define, develop and implement Area & Affiliate regulatory strategies & deliverables for compounds at all stages of development

Qualifications for senior manager, regulatory affairs

- Broad background of experience working in pharmaceutical business and prior experience in several areas within regulatory affairs, Global, European, International, Marketing Company or experience at a health authority
- A minimum of 6 years of directly related regulatory international bio/pharmaceutical experience
- Demonstrated leadership, problem-solving ability, flexibility and teamwork
- Experience managing relationships with CROs and/or contractors
- Proven ability to provide strategic regulatory guidance to drug development, registration and post-market support team
- Good working understanding of projects in assigned area of responsibility allowing for creative and innovative solutions to address potential hurdles in development