Example of Manager Regulatory Affairs Job Description

Our company is growing rapidly and is hiring for a manager regulatory affairs. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

Responsibilities for manager regulatory affairs

- Responsible for overseeing the conduct of quality assurance audits of RI trials and ensuring compliance with study protocols, program SOPs, policies, GCP and FDA regulations
- Based on business priorities & capabilities, the Regulatory Specialist will provide support for licensing, approbations, registrations (new & renewals), CTDs, PIFs, Technical Files, regulatory administration, labeling (under supervision), and other assigned projects
- Audits current data systems to assure integrity of the system (timeliness of data entry, accuracy, reliability, and validity of the clinical research data, adherence to regulatory requirements)
- Prepares and submits regulatory documentation including IND/IDE applications, annual reports, Serious Adverse Event reports, to the appropriate regulatory agencies including the U.S. Food and Drug Administration (FDA)
- Leading Regulatory Affairs Council meeting to ensure the council members are apprised of new and upcoming regulatory requirements, and be a liaison for collecting information from BIUs to support Quarterly management reviews or any other metrics requested by Management
- Develop and deliver training within RA and PV &
- Undertake a variety of administrative duties to support the Centre
- Instruct and guide other employees across the University within RA and PV &
- Ensure that work is undertaken and documented in a regulatory compliant

- Maintain liaison with raw material vendors, container/closure manufacturers, and distributors

Qualifications for manager regulatory affairs

- Develop and implement training and enhancement of policies and standards within the N&H regulatory framework
- Monitor international best practice, including global benchmarking of the regulatory environment and regulatory affairs functions
- Create effective communication channels for the regulatory strategy and framework across the N&H businesses
- Monitor and advocate Codex position in Codex Asia, Codex country committee consistent with business needs based on science and global position
- Work collaboratively with regulatory and business leads of specific portfolios to map regulatory pathways and communicate clearly on timeline to advocate right through approvals and support needed to business partners
- Honesty in defining gaps and failures, and find solutions to improve and/or find solutions to achieve business goals