Example of Quality & Compliance Manager Job Description

Our company is growing rapidly and is hiring for a quality & compliance manager. We appreciate you taking the time to review the list of qualifications and to apply for the position. If you don't fill all of the qualifications, you may still be considered depending on your level of experience.

Responsibilities for quality & compliance manager

- Ensure the site's quality system development, effective maintenance and continued compliance with business unit requirements, medical device regulations and standards (i.e., U.S. – FDA, ISO 13485, ISO 9001)
- Lead department activities within the Quality Systems function (i.e., Document and Data Control, Retain and Records Retention, Training, Corrective and Preventive Action, Change Control, Deviation, Supplier Audits, Supplier Corrective Action Requests, Electronic System Development/Validation, Management Review, Risk Management, Auditing, Agency Inspections and Quality Improvement Initiatives)
- Support the effectiveness of the Quality Systems and Compliance programs by working collaboratively with other stakeholders to ensure effective and compliant processes
- Work closely with Quality Management to increase communication and leverage Quality Management Systems, assure Stewardship policies and Regulatory requirements are implemented
- Perform Compliance and QMS functions system and processes based audits at Breeding field sites, Pathology locations, and provide candid and constructive feedback to the audited sites/teams
- Work closely with the Quality Management team to increase communication, leverage quality control and management systems, assure stewardship policies and regulatory guidelines are in place

identified initiatives
- Partner with the site teams to perform GAP analyses and build relationships to provide support
- Develop, implement and continuously improve processes of the ongoing co-packer assessment and re-approval program based on risk
- Collation of information supporting continued approval of co-packer and ensuring RB continued confidence in the co-packer to perform at the required standard to supply RB (using a database or similar format)

Qualifications for quality & compliance manager

- You are willing to travel in support of business needs to different geographical locations
- You are fluent in English and have a very good command of German
- A minimum of a Bachelor's of Science degree + 6 years drug safety or relevant experience
- Strong working knowledge of ARGUS safety database, PV regulations/FDA regulations, ICH guidelines, GVP modules and EU regulations and other relevant global requirements in the post market and clinical trial environment
- Project management skills including management of both time and priority constraints
- Solid expertise in all Microsoft office applications (e.g., Word, Excel, PowerPoint)