

MedPharm Ltd Job Description

Job Title:	Senior Quality Manager
Location:	MedPharm US but with global interaction
Report to:	VP of Global Quality

Main purpose of job
<ul style="list-style-type: none"> • To ensure Quality Strategy for the business is in compliance with all relevant regulations, guidelines and quality best practices
Significant internal and external relationships
<ul style="list-style-type: none"> • Senior Management • Study Directors • MedPharm US Laboratory staff • Quality Assurance team • Sponsor Auditors and Regulators • External suppliers
Responsibilities
<ol style="list-style-type: none"> 1. Provides input to the strategic, tactical planning of Quality aspects relating to business growth including those related to potential acquisitions. 2. Ensures the development, implementation and maintenance of appropriate Quality Systems meet the strategic vision 3. Oversees the Quality Function at MedPharm US and assists in multiple sites to ensure that adequate systems and personnel are positioned to support the business in achieving its objectives. 4. Manages a small quality team to provide leadership, mentoring, and career development 5. Oversees and manages the overall Quality Functions at MedPharm US through the performance planning, development and evaluation process. 6. Directs a Quality Risk Management program for MedPharm US, ensuring that significant risks are immediately addressed and that mitigation and contingency are established. 7. Ensures the overall strategy for continuous improvement and facilitates the sharing of best practices throughout the business. 8. Interacts and collaborates with the junior and senior levels of the organization to develop and deliver on Quality Assurance. 9. Oversees the development programs to focus employees on quality improvement. 10. Maintains regulatory currency and provides expertise and guidance in interpreting policies, regulations and guidelines to assure compliance across the business. 11. Operate as primary support to the VP of Global Quality as the internal champion for quality measurement and improvement within the company including; setting goals for the Quality Function in setting quality goals for the organization. 12. Ensures managers and lower organization quality functions are aware of significant risks and options for

<p>mitigating risks.</p> <p>13. Works with the VP of Global Quality in the performance of all internal and external audit programs. This includes establishing the compliance requirements, collecting objective evidence, and writing audit reports to ensure the quality management system is operating effectively.</p> <p>14. Ensures effective, ongoing communication and coordination with UK Quality and compiles US quality metrics relating to the performance and effectiveness of the Quality systems on a monthly basis.</p> <p>15. Evaluates the effectiveness of corrective actions to ensure preventative measures are in place to avoid repeat occurrences.</p> <p>16. Provides guidance, support and mentoring to staff on matters of quality.</p> <p>17. Responsible for all quality led projects</p> <p>18. Communicates information to staff, as appropriate.</p> <p>19. Other duties as assigned.</p>
--

<p>Education / Experience</p>	<ul style="list-style-type: none"> • Minimum of Bachelor's degree in a related scientific field. • 10+ years of relevant pharmaceutical industry experience in a cGMP environment. • 10+ years in a Quality role • Direct experience of working within US and EU regulations and guidelines pertaining to pharmaceutical Research and Development, GLP and GMP • 5+ years of supervisory experience. • Previous experience hosting regulatory and sponsor inspections • Previous experience performing external audits and inspections
<p>Skills/requirements</p>	<ul style="list-style-type: none"> • Highly knowledgeable in pharmaceutical regulatory requirements, including within the development arena • Superior written/oral communication skills • Driven to build on current knowledge and experience • Must be comfortable in a rapidly changing environment • Self-motivated; ability to work independently and work as constructive team member • Ability/flexibility for regular travel