



Job Description | Contract Quality Assurance Consultant

ABOUT CLOUDRISE

Cloudrise is a security services provider focused on protecting organizations' data - wherever it resides. Whether on-prem, in the cloud, or someplace in between, Cloudrise protects organizations' data throughout its entire lifecycle. We build, deploy, optimize, and manage data security programs and market-leading platforms. With centers of excellence in Colorado and London, our experience spans multiple industries, geographies, and organizational sizes. Cloudrise is an innovative and proven alternative to customers' talent acquisition and retention problems.

Cloudrise is looking for team members with a deep understanding of data protection and privacy, but more importantly, a strong business acumen that will resonate in the boardrooms of our customers. Each team member is selected not only for their expertise, but also for their energy, drive, and can-do attitude.

Our vision is to create a leadership culture focused on the development and happiness of our people. We equip our staff with the resources they need to make a positive impact and believe this is essential to become an undisputed leader in the industry.

If you are driven to deliver exceptional results to your customers, looking for a "home" where you can make an impact every day, revel in being part of the solution, and enjoy working with a team of driven and passionate professionals, we would warmly welcome you to the team.

POSITION SUMMARY

This is a Contract 1099 Position in the Cloudrise Governance, Compliance and Risk (GRC) practice. You're experienced in investigational writing and Root Cause Analysis within the Life Science, Pharmaceutical, or Medical Device space. You understand how your skills support regulated business processes and the science your skills support. You write well and often. Your background is in Quality Assurance, Regulatory, Computer System Validation (CSV), or GAMP5 critical.

We're looking for a minimum of 1 year experience working in pharmaceutical, biotech or medical device quality assurance, or regulated business processes in a life sciences environment such as packaging, manufacturing, medical devices, pharmaceuticals, or biotechnology. This is a remote, contracted position for 6 months with the opportunity to expand as approved by our customer. The position is on contract, paid hourly at between \$80-\$100/per hour depending on your experience. This position does not include Cloudrise company benefits.

Skills we're seeking

- Experience with Life Sciences Quality Assurance Investigations (Non-Conformance and/or Complaint Handling)
 - Familiarity with quality management systems (QMS), to understand complaint investigation processes and documentation requirements.
 - Knowledge of investigative methods, including root cause analysis, failure mode and effects analysis (FMEA), and risk assessment.
 - Effective communication skills to interact with various internal stakeholders.
 - The ability to make informed decisions, often under pressure, to resolve complaints promptly and appropriately.
- Experience with FDA or EU life sciences regulations including 21 CFR Part 820 and Part 11 is essential.
- Strong project management, self-awareness, and time management skills are essential.
- Knowledge of any of the following is useful: 4M&E, Six Sigma, or 5 Why Root Cause Analysis Techniques.

QUALIFICATIONS

- Minimum of 1 year of experience in pharmaceutical, biotech or medical device quality assurance, or regulated business processes
- Ideal candidates will have experience in Life Sciences Quality Assurance Packaging, Serialization, Complaint



Management, or Incident Management

- Excellent documentation, communication and interpersonal skills
- Ability to work remote and independently, while managing time effectively

This list of duties and responsibilities is not intended to be all-inclusive and may be expanded to include other duties or responsibilities that management may deem necessary from time to time. To apply, please send your resume and a cover letter to careers@cloudrise.com.