

## Quality Systems Associate

### Job Description

We are currently looking for an experienced quality professional to ensure activities within the QA system, in order to ensure ongoing compliance to cGMP expectations and Company QMS

### Main responsibilities would be (non-exhaustive list)

- Ensure the QA oversight of analytical equipment qualification
- Ensure the QA oversight of a QC lab move into a new location, including the modification / set up of appropriate process
- Act as the QA host of the regulatory inspection of the new laboratory; prepare and conduct the inspection; define relevant CAPA plan if applicable
- Participate in investigations and CAPAs; perform the QA review and approval of selected deviations and change requests
- Support quality operations to ensure quality related actions (CAPAs, change management, commitments) are handled (executed and closed) in a timely manner
- Conduct periodic trending analysis e.g. of quality systems performance and water systems performance
- Review and approve SOPs and similar documents
- Maintain and update instructions related to viable monitoring
- Manage change notifications received from suppliers
- Bring support to develop and/or report quality performance metrics
- Ensure site documentation (e.g. Site Master File, Veterinary Master File, Blueprints and Legends) is kept updated

### Requirements

- University degree in a Science or Engineering discipline (e.g. Pharmacy or Biological engineering)
- 7+ years of experiences in the pharmaceutical industry, in a QA or production environment
- Experienced in QA oversight of Analytical Equipment qualification
- Excellent understanding of EU GMP and FDA cGMP
- Proficient in pharmaceutical quality management systems (e.g. deviations, CAPA and change control)
- Knowledge of Data Integrity requirements, both for hard copies and computerized systems
- Good communication skills (oral and written)
- Able to act as a Quality reference and to influence colleagues in interdepartmental projects
- Fluent in French; full professional proficiency in English

### CONTACT

Wendy Rees

Sales Support Consultant

Real Staffing Group

9 Kreupelenstraat, Brussels, 1000, Belgium

-----  
T: +32 (0)2 610 59 59

E. w.rees@realstaffing.com