Quality Assurance Assistant

RDDT, a vivoPharm Company
Gilles Plains SA 5086
Science & Technology
Quality Assurance & Control

Quality Assurance Assistant Position Description

*vivo*Pharm, a Vyantbio Company, is a contract research organization supporting the preclinical research needs of the biotechnology/pharmaceutical sectors. It offers an extensive portfolio of contract services for preclinical drug development and clinical support including efficacy testing, safety and toxicology of new therapeutic drugs and bioanalytical services.

An opportunity exists for a skilled and experienced Quality Assurance Assistant to join our Quality Unit focusing mainly on the daily operations of our *in vivo* toxicology team. The successful applicant will be an independent, efficient, and self-motivated individual capable of working to time-sensitive deadlines while maintaining industry standards in accordance with international regulatory guidelines and *vivo*Pharm's GLP quality system.

The successful applicant for this position will be responsible for assuring GLP compliance of records generated either within a study or in support of our commercial studies. Duties will include conduct of study-based and other internal audits to ensure the quality and integrity of records are in compliance with regulatory and company quality system standards. Applicants should possess a Bachelor of Science (or similar), have demonstrable experience in internal audit or quality assurance related experience, and a comprehensive understanding and working knowledge of GLP. The ideal candidate will possess excellent interpersonal skills and professional qualities consistent with working in an industrial setting.

Individuals with a detail-oriented approach, enthusiasm, initiative, and the desire to be an active team participant will be looked highly upon. This position is a permanent part-time position; 2-days a week, but requiring some flexibility. There may be an option to

extend hours in the future. Remuneration is dependent on qualifications and experience.

The position will be based at *vivo*Pharm's operation in Gilles Plain, Adelaide

***vivo*Pharm offers an extensive portfolio of contract services for preclinical and clinical research and development, including toxicology, safety testing of new therapeutic drugs and bio-analytical services.**

Company

- Excellent reputation and product range within preclinical contract service sector.
- Australian company with domestic and international operations.

Position

QA Assistant, reports to QA and Regulatory Affairs Manager (quality) and Department of in vivo Toxicology (operational)

Responsibilities will include:

- Assuring GLP compliance of records generated either within a study or in support of our studies
- Conduct internal audit and study based audit etc to ensure the quality and integrity of commercial studies are in compliance with regulatory and company quality system standards
- Support laboratory activities that require quality assurance involvement
- Provide assistant and guidance to in vivo toxicology team for improvement opportunities and correction action
- Keep updated with amendments to OECD Principles of Good Laboratory Practice and Compliance Monitoring
- Timely and effective communication with internal staff on project status in an environmental with rapidly changing priorities
- Provide technical leadership to fellow colleagues, including a wiliness to train staff in GLP on formal and informal bases
- other duties and responsibilities may be required as needed.

Key Selection Criteria

- Degree in the appropriate discipline or appropriate industry experience with previous experience GLP
- Attention to detail
- Demonstrate efficient problem solving and understanding of scientific data collection
- Excellent interpersonal skills and professional qualities consistent with working in an industrial setting

- Proven ability to deliver tasks on time and with high degree of accuracy
- Proven ability to set priorities, analyse problems, formulate clear and effective solutions and coordinate a number of task simultaneously
- Demonstrated enthusiasm, initiative, trust and reliability
- Ability to work unsupervised and work well cross functionally with various groups of the company
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Desirable Selection Criteria

- Experience and understanding of GLP and ICH guidelines
- Experience in preclinical toxicology and pharmacology *in vivo* studies
- Experience in *in vitro* assays (e.g. immunoassay, cell-based assays, bacteria assays)
- Experience in the pharmaceutical industry/CRO working in regulated laboratory

Benefits

- Attractive basic salary
- Potential for individual growth and development as company expands.

General enquiries can be directed to Ms. Lynne Clapham (Lynne.clapham@vivopharm.com.au). Applications should address the key selection criteria. Apply online or send cv with cover letter to hr@vivopharm.com.