

Open position Quality Manager

DGr Pharma, member of the Symeres group, is a young and dynamic consultancy company with a very strong client base. DGr Pharma is specialized in guiding drug development programs from end lead selection to Phase II clinical development. To expand and strengthen our support in drug development, we are searching for a senior Quality Assurance Manager, with a focus on GxP in general and GLP/GcLP in detail.

Top candidates are proficient multitaskers, client-oriented and have the ability to prioritize tasks and work independently.

Quality Manager Responsibilities:

- Maintenance and improvement of the quality management system.
- Scheduling and performance of study, process, system and facility-based audits according to the QA audit program and the applicable Guidelines e.g. OECD GLP guidelines or other appropriate guidelines.
- Reporting of audits to the responsible persons e.g. Study Director/Principal Investigator, leading QA and management and follow up on audit responses.
- Preparing and signing QA statements in GLP studies.
- Maintenance of the Master Schedule.
- Evaluation of CAPA plans and follow up of CAPAs.
- Review (draft) of SOPs and other controlled documents for compliance with the appropriate Guidelines.
- Involvement in training and guidance related to QA.
- Acting as advisor/member in internal projects.
- Contribution to acquisition of new projects and public relations.
- Acting as a QA consultant for external companies.
- Hosting of external client audits and regulatory inspections.
- Facilitating quality management review.

Quality Manager Requirements:

- BSc and at least 5 years of experience in working in GxP compliant organisation in a quality-related role, a good understanding of OECD GLP is essential.
- As most of our GXP-compliant activities are in the field of pharmaco- and toxicokinetics, a good understanding of this area is preferred.
- Outstanding communication skills, both verbal and written.
- Proficient with Microsoft Office Word, Excel, and Project.
- Ability to work independently and prioritize duties.
- Available to travel, about 2-4 times international per year.

DGr Pharma is based in Breda, the Netherlands, and working on-site for at least 2 days a week is required.

Please forward your application and CV to Marleen Janus, marleen.janus@dgrpharma.com Acquisition as a result of this vacancy is not appreciated.