QFINITY∞

Job Offer GxP Quality Manager (gn)

QFINITY∞ is a globally operating consulting company based in Saarland, Germany. It was founded in 2004 by Oliver Herrmann with the vision of combining process management with validation requirements for computerized systems and making them available via an integrated service portfolio. Essentially, our main concern is to reduce risks for our clients. We value solution-oriented, pragmatic solutions, openness, transparency and reliability and the success of this approach is demonstrated by the loyalty of our clients.

Experience from a multitude of projects of all sizes and scopes has generated a solid body of knowledge that can be leveraged to offer our clients suitable solutions for their needs.

Our client base now consists of over 140 companies, including companies in the life science industries, such as pharmaceuticals, medical technology and biotechnology, as well as their suppliers and service providers.

Through active membership in national and international associations and organizations, as well as a wide range of contacts in industry, academia and government, we are very familiar with both current standards and upcoming developments, and we provide substantial input to many of them.

QFINITY offers you an interesting employment position with promising opportunities for professional and personal growth. QFINITY values the individuality of each employee and tries to develop everyone individually. Therefore, we are interested in getting to know your personal and professional goals and supporting you in achieving them. To this end, we offer a creative and open environment with competent colleagues and access to a large worldwide network of experts. This is accompanied by individual mentoring and extensive training opportunities tailored to your needs.

We are looking for motivated and committed individuals who would like to contribute to the planning, implementation, integration and further development of our holistic quality concepts on a long-term basis. You should be confident, highly motivated and mobile.

In return for your commitment, social skills and abilities, we offer you an attractive and inspiring working environment, as well as extensive and diverse opportunities for personal and professional development.

As a future GxP Quality Manager, you may already have experience in general QM processes, validation of computerized systems, infrastructure qualification and controlled development of software. You may already be familiar with data integrity requirements in the GxP environment and how to ensure compliance. You are familiar with relevant GxP regulations, guidance documents and good practice guides from your past professional history (e.g. ICH, GAMP®, EU GMP, FDA 21 CFR Part 11, 211, 820, PIC/S). Within this framework, your activities will be primarily focused on consulting and conducting audit and training activities for our clients, keeping the goal of reducing risks for our clients in mind.

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In this position, your responsibilities include:

- Advising and training our clients and conducting audits.
- Supporting our clients in questions concerning QM systems.
- Working with our clients to develop customized strategic concepts for the validation of computerized systems, making use of recognized approaches and standards (e.g. GAMP®, CSA, ITIL, ISO).
- Assuming responsibility for supporting and leading validation projects at customer sites and ensuring full compliance with regulatory, internal and client requirements.
- Creating and maintaining validation and qualification documentation.
- Planning and executing risk management activities (e.g. risk assessments, risk communication, action planning).

Our expectations:

- You have a degree in the natural sciences, engineering, information technology or related fields of study.
- Ideally, you already have at least five years of professional experience in a regulated environment as a quality manager, validation manager, auditor or similar activities.
- Your good verbal, written and interpersonal communication skills are coupled with active listening skills.
- You are accustomed to persuasive communication across different hierarchical levels.
- You are familiar with the GxP requirements of regulated industries for computerized systems validation, software development, qualification, data security and data integrity.
- You are familiar with relevant laws, guidelines, regulations and standards such as ISO, GAMP, ICH.
- You are characterized by a well-organized, proactive, results- and client-oriented work style.
- Life-long learning is natural and desirable for you.
- Your knowledge of English and German is very good.
- You are willing to travel and have no problems working remotely.
- Ideally, you have industry-recognized certificates such as CISA, CDPSE, CISM, CRISC or similar.

If you do not currently meet one or more of the listed expectations but are nevertheless interested in engaging intensively with the topics in the future, please do not hesitate to send us your application.

We offer:

- Attractive salary package
- Flexible work location within Germany (home office)
- Extensive training, as well as individual support and mentoring
- Flat organizational structures with fast decision-making processes
- Individual support for your professional and personal development
- A competent team of colleagues with a high level of professional experience and extensive access to worldwide networks.

If you are interested, please contact us or send us your job application, preferably by e-mail.

job-application@q-finity.de // **www.q-finity.de**