

Senior Consultant - Computer Systems Validation (m/f/d)

MAIN5 GmbH & Co. KGaA is an independent and successful management consulting company headquartered in Frankfurt am Main, Germany. We solve key challenges of our customers sustainably and reliably, each of which is of high relevance in the growing international competition.

Our focus is on the leading companies in the life sciences sector. This is the industry in which we are at home and in which we have sustainable success through the definition, implementation and introduction of forward looking methods, strategies and solutions.

To strengthen our IT Systems & Process division, we are looking for a

(Senior) Consultant – Computer Systems Validation (m/f/d)

Your tasks:

- Ideally, you have professional experience in the field of process and system validation in clinical R&D, regulatory affairs and/or quality in the pharmaceutical industry
- They already have convincing project successes in the validation of regulatory processes and corresponding system solutions.
- You will master both the conception and implementation of validation measures with a focus on Research & Development (R&D) and related regulatory-relevant business solutions.
- They moderate, document and present results in direct dialogue with our customers.
- You will take responsibility for your tasks and manage them independently to the agreed results.

Your profile:

- You have successfully completed a degree in the technical or scientific field, e.B biology, chemistry, pharmacy, bioinformatics, computer science or similar with a bachelor's, master's, or PhD.
- You have gained experience in computer system validation (CSV) in several projects.
- You have experience in the development of validation plans and their implementation and know how to bring about and implement viable solutions in an environment of competing interests.
- Ideally, you have a good knowledge of the processes and systems within the life sciences industry with a focus on R&D, regulatory affairs and/or QA
- You have sound practical experience in the application of relevant regulations and know how to derive practicable measures according to GAMP5 from this.

Our offer:

- We offer you individual development, methodical and professional coaching by our experienced colleagues in a dynamically growing company.
- We offer exciting projects and enriching challenges in an interesting market segment with top-class customers.
- You will work in an international environment and belong to a highly motivated and excellent team.
- We offer flexible working hours, home office, state-of-the-art technology for networked collaboration in a virtual organization, performance-based compensation, fairness, openness, freedom for individuality, regular team events, training, and a lot of fun at work.

Your application:

Please send your complete application with cover letter, résumé, and – if appropriate – relevant references and certificates to Tore

Bergsteiner, E-mail: recruiting@main5.de.

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