

FyoniBio GmbH is a biologics service provider with more than 15 years of scientific experience and a solid track record across over 100 biologics projects for biotech and pharma partners worldwide. Our work supports programs that have progressed to clinical development in both FDA and EMA regions. We offer a broad service portfolio along the development chain — from cell line and process development to analytical characterization and clinical bioanalysis. Based at the Biotech Campus Berlin-Buch, FyoniBio is ISO 9001:2015-certified, with parts of our operations conducted under GCLP conditions.

To strengthen our team, we **are** looking for a **full-time** (40 hours/week)

Scientific Researcher (m/f/d) Clinical Bioanalysis

Your responsibilities

In this role, you will be part of our Clinical Bioanalysis team and contribute directly to customer and clinical projects. Your tasks will include:

- Development, optimization, and validation of cell-based as well as ELISA-/ECLIA-based bioanalytical methods for determining active ingredient concentrations, biomarkers, immune responses, and potency assays.
- Planning, execution, and oversight of method validations, qualifications, and transfers under GCLP/GMP conditions.
- Planning and oversight of innovative, diverse client projects, as well as independent coordination of associated bioanalytical investigations.
- Management and analysis of clinical samples under GCLP conditions.
- Planning, execution, and evaluation of equipment qualifications (IQ/OQ/PQ), along with participation in the creation and review of associated documentation.
- Participation in the qualification and validation of computerized systems and software (CSV) in a laboratory environment.
- Evaluation and assessment of analytical data, including statistical analysis, plausibility checks, and targeted troubleshooting.
- Creation, review, and maintenance of test plans, protocols, reports, and other quality-relevant documents.
- Active participation in GxP-compliant quality management, including handling deviations, OOS/OOT cases, and change controls, as well as supporting root cause analyses and CAPA measures.
- Ensuring compliance with relevant GxP requirements, regulatory guidelines, SOPs, and work instructions.
- Technical guidance and support for technical assistants in carrying out bioanalytical testing.
- Close collaboration with internal departments, external laboratories, and clients, as well as providing support in the scientific and technical alignment of projects.

Your profile

This position is particularly interesting for you if you enjoy combining scientific bioanalytics with regulated GxP processes and bring experience in assay development, equipment qualification, or software validation.

You thrive on managing diverse client projects both independently and collaboratively, and are eager to contribute your expertise to advancing innovative methods and lab processes. Ideally, you bring:

- Completed degree in natural sciences, e.g., Biology, Biochemistry, Biotechnology, Chemistry, Pharmacy, or a comparable qualification; a PhD or equivalent professional experience is desirable.
- Professional experience in a bioanalytical or analytical laboratory, ideally within a pharmaceutical, biotechnological, or diagnostic environment.
- Practical experience with bioanalytical methods and their validation, particularly ELISA/ECLIA; knowledge of cell culture, flow cytometry, or comparable techniques is an advantage.
- Ideally initial experience with GxP-regulated work environments (e.g., GCLP/GLP/GMP) as well as an interest in quality-related topics.
- Experience in the development, optimization, validation, or verification of analytical methods is desirable.
- Enthusiasm for structured planning, diligent evaluation, and scientific interpretation of analytical data; knowledge of statistical data evaluation is an advantage.
- Interest in or experience with equipment qualification (IQ/OQ/PQ) and the qualification/validation of computerized systems (CSV) is a plus.
- Good proficiency in using MS Office, especially Excel, Word, and PowerPoint; experience with laboratory or data management systems is an advantage.
- Strong organizational skills, autonomy, and a sense of responsibility, along with a diligent and quality-oriented way of working.
- Enthusiasm for diverse scientific tasks, collaboration on various projects, and the continuous development of methods and lab processes.
- Strong teamwork and communication skills, as well as the ability to work flexibly and independently.
- Very good written and spoken German and English skills.

What you can look forward to with us

At FyoniBio, you will join a collegial team with short decision paths and a respectful, appreciative working culture. You can expect varied and hands-on tasks with room for independent work. We also offer:

- Flexible working hours, including the option to work from home part of the time
- 30 days of holiday
- Cost sharing for the BVG ticket or the Deutschlandcard
- Attractive company pension schemes and capital-forming benefits
- Structures that support a good work-life balance
- Thorough onboarding and training by experienced and supportive teammates
- Modern equipment and state-of-the-art instruments
- Regular team and company meetings
- Structured training and further education opportunities for all employees
- Company events such as summer and Christmas parties
- Free water, tea and coffee; discounted food and drinks in the campus canteen
- An attractive working environment on the green [Campus Berlin-Buch](#) with good transport connections

Interested?

We would be happy to get to know you.

Please send your application documents by email, including your possible starting date and salary expectations, to:

Mrs Stefanie Klunker
personal@fyonibio.com

For questions, you can reach us at **+49-30-9489-2500**.

By sending us your application documents, you agree that we may store your documents for up to six months. After this period, your data will be permanently deleted.

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