# Belgium Jobs Expertini®

**Senior Scientist Bioanalytics**

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Company: Argenx

Location: Ghent

Category: other-general

argenx is actively seeking a highly motivated Senior Scientist in Bioanalytics to join our expanding Bioanalytical team. The ideal candidate will possess extensive expertise in biomarker assay development and validation for large molecules.
Operating under an outsourced model, argenx collaborates with bioanalytical vendors. The Senior Scientist will serve as the representative of the Bioanalytical team within one or multiple project teams, fostering close collaboration with internal and external stakeholders. Responsibilities include implementing bioanalytical strategies and contributing to the development of biomarker strategies aimed at enhancing the likelihood of successful drug development and approval. The Senior Scientist will play a pivotal role in evaluating, selecting, developing, and analytically validating clinical biomarker assays, primarily on ligand binding assay platforms.
In addition to exceptional communication skills, experience in regulatory requirements associated with biomarker research is advantageous. The ideal candidate should possess a minimum of 5 years of industry experience in the field of bioanalytical sciences.

**Responsibilities**

• Develop and implement the bioanalytical strategy in collaboration with cross-functional team members, serving as a pivotal member of project/indication teams.
• Leverage expertise in biomarker assays to actively shape biomarker strategies, translating the biomarker context of use (COU) into analytical requirements for the development of fit-for-

purpose biomarker assays.
• Define and execute the biomarker assay validation strategy, ensuring alignment with regulatory requirements and industry standards.
• Collaborate with sourcing and program managers to select external vendors capable of supporting clinical biomarker activities, and participate in vendor governance meetings as needed.
• Oversee biomarker assay development and provide scientific oversight during transfer and validation processes at external vendors.
• Ensure timely implementation of biomarker assays to support clinical biomarker activities.
• Serve as a subject matter expert for biomarker assay validation, promoting harmonization of validation strategies across projects.
• Act as the bioanalytical study monitor, overseeing bioanalytical study phases of clinical trials, reviewing sample analysis plans and reports, and providing input into clinical trial documents (e.g., Protocol, Data Transfer Agreement, lab manual).
• Collaborate with Medical Writers to draft bioanalytical modules for regulatory documents.
• Contribute to interactions with regulatory agencies.
• Stay abreast of relevant literature and advancements in scientific and bioanalytical development, applying insights to argenx clinical development programs.
• Present results and findings at internal multidisciplinary project, clinical, and biomarker (sub)team meetings.

**Profile**

• PhD degree or equivalent experience.
• Minimum of 5 years of industry experience in bioanalytical sciences.
• Extensive industry experience in developing biomarker assay strategies and translating the biomarker context of use (COU) into assay validation strategies.
• Proficiency in ligand binding assay methods and platforms.
• Experience in analyzing human samples for clinical trial support, with a thorough understanding of GCP/GCLP guidelines and global regulations.
• Experience in developing and validating PK and ADA assays for large molecules, including knowledge of relevant regulatory guidelines, is advantageous.
• Experience in managing outsourced activities.

• Excellent communication and interpersonal skills, enjoys collaborating in multidisciplinary teams and with external partners.

• Strong regulatory writing and report writing skills, with a focus on quality.

• Proven problem-solving abilities.

• Ability to work independently.

• Proactive and adaptable, capable of thriving in the dynamic environment of a rapidly growing biotech company.

**Offer**

A full time position in a successful, dynamic, rapidly growing biotech company.

A competitive salary package accompanied by comprehensive benefits.

Exposure to all aspects of pre-clinical and clinical development in the company, but also with external vendors, contract partners and the scientific world.

Open to remote work with regular days spent working in the Zwijnaarde (Ghent) office.

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