

Senior Scientist Bioanalytical

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Company: Argenx

Location: Ghent

Category: computer-and-mathematical

For the expansion of our Bioanalytical team, argenx seeks a highly motivated Senior Scientist in Bioanalytics with specialized expertise in immunogenicity assay development/validation for large molecules and/or clinical immunogenicity risk assessment and data interpretation.

Operating under an outsourced model, argenx collaborates with bioanalytical vendors. The chosen candidate will represent the Bioanalytical team in one or multiple project teams and engage closely with both internal and external stakeholders.

The Senior Scientist will spearhead the implementation of bioanalytical and immunogenicity strategies for our clinical development programs, providing scientific oversight of bioanalytical vendors. Additionally, they will contribute to drafting bioanalytical and immunogenicity sections in regulatory documents. Consequently, proficiency in both scientific and regulatory requirements related to immunogenicity assay development and validation is essential. Strong communication skills are a must, along with expertise in PK and PD assay development and validation.

Candidates should possess a minimum of 5 years of industry experience in the field of Bioanalytical sciences.

Responsibilities

- Develop and implement the bioanalytical strategy in close collaboration with cross-functional team members, serving as a key member of project/indication teams.

- Act as an expert in immunogenicity assays, ensuring validation strategies align with regulatory guidelines and industry best practices.
- Collaborate with sourcing and program managers to oversee the timely commissioning of validation packages and bioanalysis of clinical trials by external bioanalytical vendors. Participate in vendor governance meetings as needed.
- Take responsibility for immunogenicity assay development and provide scientific oversight during transfer and validation processes with external bioanalytical vendors.
- Serve as the bioanalytical study monitor, overseeing bioanalytical study phases of clinical trials, reviewing sample analysis plans and reports, and offering input into clinical trial documents (e.g., Protocol, Data Transfer Agreement, lab manual).
- Work closely with Medical Writers to draft bioanalytical modules and immunogenicity sections in regulatory documents (e.g., Clinical Study Report/Integrated Summary of Immunogenicity/Module 2 documents).
- Contribute to interactions with regulatory agencies.
- Stay informed of relevant literature, keeping abreast of scientific and bioanalytical developments and their potential application to argenx clinical development programs.
- Present results and findings at internal multidisciplinary project and clinical teams meetings.

Profile

- Ph.D. degree or equivalent experience.
- Minimum of 5 years of industry experience in bioanalytical sciences.
- Strong expertise in immunogenicity assay development/validation and/or immunogenicity risk assessment, along with proficiency in clinical immunogenicity data interpretation, including regulatory requirements.
- Thorough understanding of the development and validation of bioanalytical assays for PK/PD of large molecules, including relevant regulatory guidelines.
- Extensive (hands-on) experience with ligand binding assay methods and platforms.
- Experience in managing outsourced activities.
- Excellent communication and interpersonal skills, with a passion for collaborating in multidisciplinary teams and with external partners.
- Proficient in regulatory writing and report writing.
- Strong problem-solving skills.

- Strong emphasis on quality.
- Ability to work independently.
- Proactive and flexible, capable of thriving in the dynamic environment of a fast-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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