Job title: IVD Assay Developer – Mid level position

About ShanX Medtech BV

ShanX Medtech BV (SXM, NL) is a dynamic young company dedicated to revolutionizing healthcare through innovative diagnostic tools. Our journey began with a deeply personal experience—the founder's mother's near-fatal struggle with a poorly treated bacterial infection. This ignited our mission to transform infection management, propelling us to develop pioneering solutions that prevent unnecessary suffering.

At SXM, impact is paramount. We're proud to introduce KAIROS™ IVD, our groundbreaking rapid antibiotic susceptibility testing device, poised to redefine how bacterial infections are treated. Our goal is clear: to equip healthcare professionals with the means to make informed treatment decisions swiftly and accurately. Through our innovative solutions, we're combating antibiotic resistance, enhancing patient outcomes, and saving lives.

Join us in shaping the future of healthcare, where every moment is vital in the fight against bacterial infections. We're seeking a motivated IVD Assay Developer to join our team and contribute to the development of this crucial diagnostic device. This is an exceptional opportunity to join us in our early stages and play a pivotal role in our future success.

About the role

As an IVD Assay Developer at SXM you will be responsible for the development and optimization of our diagnostic assays for future commercialization. The role of the IVD Assay Developer is crucial in driving assay development efforts, optimizing assay performance, and laying the groundwork for future commercialization and regulatory approval of diagnostic products.

Responsibilities

Your responsibilities include, but are not limited to:

Assay Development: Crafting and refining our current and future diagnostic assays.

Optimization: Enhancing assay performance parameters such as sensitivity, specificity, capability and reproducibility through iterative experimentation. This includes identifying and refining assay protocols and formulations to achieve optimal results.

Validation: Conducting validation studies to assess the analytical and clinical performance of diagnostic assays. This involves testing assay performance with clinical samples and analyzing data to demonstrate accuracy and precision.

Documentation: Thoroughly documenting all aspects of assay development, including experimental protocols, results, and findings. This meticulous record-keeping will be used for regulatory submissions and intellectual property protection.

Regulatory Compliance: Ensuring adherence to regulatory requirements governing diagnostic assay development. This includes compliance with FDA regulations and ISO standards.

Quality Assurance: Implementing quality control measures to uphold the reliability and consistency of our diagnostic assays. Adherence to standard operating procedures and quality management systems ensures high-quality standards are maintained.

Required Qualifications

- Master's degree in biology, Microbiology, Biomedical Engineering, or a related field with a preference in Biochemistry.
- Minimally 3 years' experience in a relevant position in an IVD company, having developed IVD assays that received IVDR approval.
- Past assay development according to regulatory requirements and standards relevant to the FDA regulations, ISO standards, and Good Laboratory Practices (GLP). Ability to work according to quality management systems.

- Fluency in English.
- Strong analytical and problem-solving skills with attention to detail.

Preferred Qualifications

- Flexibility and adaptability to work in a dynamic and fast-paced environment with evolving priorities and timelines.
- A passion for innovation and a creative, out-of-the-box mindset are highly valued.
- Passionate about working in a young IVD company.
- Commitment to continuous learning and professional development to enhance skills and knowledge in assay development, rapid Antibiotic Susceptibility Testing (AST) diagnostics, and related areas.

Perks and benefits

- Competitive compensation and benefits package
- Access to professional development opportunities for career growth and advancement, including training resources.
- Flexible schedule and work arrangements
- Dynamic and collaborative work environment

Important Dates: The application period for this position will remain open until July 1st. Interviews will be conducted during the first two weeks of July. The anticipated start date is July 15th, 2024, with flexibility for a later start date by mutual agreement.

Position Details: This is a full-time contract for 40 hours per week, extending over three years, with the possibility of extension.

Location: The position will be in Nijmegen, with regular commuting to Eindhoven and frequent international travel to the US.

Disclaimer: At SXM, we're dedicated to equality and diversity, welcoming individuals from all backgrounds.

Position reference name: SXMRef006-2024_IVD Assay Developer

Interested?

Ready to Make Your Mark?

If you're ready to drive meaningful impact and be part of a team that's changing the game, we want to hear from you! Apply now by sending your resume and a cover letter detailing why you're the perfect fit for the role to info@shanxmedtech.nl.