Design Control Specialist

Are you ready to make a meaningful impact in the world of healthcare? BioPorto is seeking a talented and driven Design Control Specialist to join our dynamic Research & Development team!

About Us

At BioPorto, we're on a mission to save lives and enhance patient care with our cutting-edge in vitro diagnostic solutions. As experts in antibodies and assay development, we transform innovative research tools into clinically actionable biomarkers that make a real difference in patient outcomes. Headquartered in Hellerup, Denmark, and listed on the NASDAQ Copenhagen stock exchange, we're proud to have recently achieved US FDA clearance for our ProNephro AKI (NGAL) test, a critical tool for early detection and management of Acute Kidney Injury.

Our Team

Join a passionate team of around 45 dedicated professionals globally who embody a roll-up-your-sleeves attitude and an innovative mindset. We are energetic, collaborative, and laser-focused on our goal: to successfully launch our FDA-cleared NGAL test in the US market and improve the quality of life for patients worldwide. At BioPorto, we believe in fostering a supportive and engaging work environment where every team member can thrive and contribute to groundbreaking advancements in healthcare.

Your Role

We are looking for an enthusiastic colleague to join our Research & Development team developing novel biomarker assays (turbidimetric immunoassays for clinical chemistry platforms).

Your primary responsibilities will be to:

- Lead design control activities, author and review design control documents
- Lead in the creation of design documentation to clearly trace user needs through design input, design output, design verification and design validation
- Create and manage risk management documents and activities in alignment with our Quality Assurance department.
- Lead preparation and performance of design review milestones within the design and development process.
- Manage design changes to existing devices.
- Assume ownership of the Design History File (DHF)
- Design, review and approve verification/validation test protocols and reports, ensuring that the testing meets regulatory requirements and quality objectives.
- Lead design transfer activities
- Liaison between marketing, QA, and production teams to appropriately create design and development documents that create the product DHF

Your Qualifications

- M.Sc. in biotechnology, biochemistry, or equivalent
- Prior Design Control experience in the medical device industry
- An understanding of turbidimetric technologies and clinical biochemistry analyzers
- An understanding of relevant guidelines (e.g., CLSI)
- Experience with regulatory submissions (FDA, IVDR) is a plus
- Familiarity with electronic quality management system (eQMS)
- Fluent in English (written and oral)

As an individual, you are flexible and able to meet timelines while managing multiple activities. You can work independently, ensuring high-quality standards and attention to detail. You enjoy a dynamic working environment where effective teamwork is critical to succeed.

Your workplace can either be in the office in Hellerup, Denmark, or you may be located in the US, working remotely from home. No relocation benefits are provided.

Our Offer

We offer you an exciting and dynamic position, with great opportunities for personal and professional development. You will work in a small and informal team, collaborating with other departments (Production, QA/RA, etc.), where your expertise and opinion will be valued.

Additional Information

If you have any questions, please contact the SVP of R&D, Ursula Klause (ukl@bioporto.com; +1 317 306 9450)

Please send your application and CV **in English** using the link: http://www.bioporto.com/careers

Your application will be treated with confidentiality.

Interviews will be conducted in parallel to the application period. We reserve the right to proceed with the employment process if the right candidate is identified during this period.

BioPorto provides equal employment opportunities to all employees and applicants for employment and prohibits discrimination and harassment of any type without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws.

This policy applies to all terms and conditions of employment, including recruiting, hiring, placement, promotion, termination, layoff, recall, transfer, leaves of absence, compensation and training.