(Sr.) Scientist Design Control

BioPorto is looking for a highly skilled (Sr.) Scientist Design Control to join our Research & Development team.

About us

BioPorto is an in vitro diagnostics company that provides tests and antibodies to clinicians and researchers around the world. We use our antibody and assay expertise to transform novel research tools into clinically actionable biomarkers that can make a difference in patients' lives. BioPorto is headquartered in Hellerup, Denmark, and is listed on the NASDAQ Copenhagen stock exchange. We are currently pursuing a De Novo pathway and has received Breakthrough Device Designation from the US FDA.

Our people

BioPorto has approximately 35 dedicated employees globally, most of whom work in Hellerup, Denmark. We have a roll-up-your-sleeves attitude, where we help each other achieve our common goal of launching an FDA-cleared NGAL test in the US market. Our organization is energetic, passionate, and committed to providing a supportive work environment.

Your role

We are looking for an enthusiastic colleague to join our Research & Development team developing novel biomarker assays (ELISA, turbidimetric immunoassays and lateral flow assays).

Your primary responsibilities will be to:

- Lead design control activities, author and review design control documents (e.g., requirement specifications) and risk management documents in alignment with our Quality Control department.
- Lead preparation and performance of design review milestones within the DCC process.
- 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.

Your qualifications

- M.Sc. in biotechnology, biochemistry, or equivalent.
- At least 3 years of experience in Design Control in the medical device industry.
- An understanding of ELISA, clinical biochemistry analysers, and/or lateral flow assays.
- An understanding of guidelines (e.g., CLSI).
- Experience with regulatory submissions (FDA, IVDR) is a plus.
- Proficient computer skills and familiarity with statistical programs (Analyse-it, SAS JMP, etc.).
- 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 Hellerup, DK, office, or 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 VP 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 performed in parallel to the application period. We reserve the rights 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.