

Student Worker, Regulatory Affairs

We are looking for a skilled Student Worker to join our Regulatory Affairs team in Denmark.

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 a dedicated employee who will help ensure the quality of our products. You will be part of a team consisting of four committed professionals who, in collaboration with sales, marketing, R&D and production, will handle quality assurance and registration tasks related to production and sales of antibody products and in vitro diagnostic (IVD) equipment. If you like to have an impact on quality, have a clear ability to maintain an overview but at the same time a sense of detail and a wish to make a difference in a small company, it maybe you that we are looking for.

The position is for occupation as soon as possible.

Key Responsibilities

- Continuous optimization and standardization of the department's and the company's processes and existing procedures.
- Participation in the company's transition to new European rules for IVDR.
- Preparation of technical dossiers.
- International registrations, new and renewal.
- Maintenance of the regulatory documents.
- Regulatory Intelligence.

Your Qualifications

- Academic background (engineer, cand. Pharm., Cand. Scient. or similar) and preferably knowledge of immunochemistry. At least passed 3rd semester of Bachelor.
- Experience in an RA function or interest in RA is preferable.
- Ability to write, read, and speak in English at a professional level.
- Can work independently while maintaining a high quality and attention to detail.
- Ability to work in a dynamic environment where effective teamwork is critical to succeed.
- Can stay focused and meet timelines while managing multiple activities.

As a person, you are structured, thorough, and responsible as well as good at meeting deadlines. The position also requires that you are capable of having influence and are not afraid of being "hands-on". Finally, you are used to communicating constructively and entering into collaborations with a focus on finding the right solutions. You can simplify complex situations and are good at stakeholder management.

Our Offer

As our new Student Worker, you will be a part of a small and informal team, working closely across functions (Production, R&D, etc.), where your expertise and opinion will be valued. As part of BioPorto, you will work from the scenic Tuborg Havn, with easy access through public transport and biking distance from Copenhagen, and will enjoy lunch when on-site at our amazing in-house rooftop terrace canteen.

Additional Information

If you have any questions, please contact Monika Bak, Director of Regulatory Affairs

Please send your application and CV **in English** via our careers site using the link below.

<https://bioporto.com/careers/>

Your application will be treated with confidentiality.

Interviews will be performed 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.