Site Director of Quality Assurance and Regulatory Affairs

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.

Our People

BioPorto has approximately 35 employees globally, most of whom work at our headquarters. Our organization is characterized by an energetic, committed and supportive work environment. If you wish to be part of this organization, we are eager to hear from you.

The Position

We are seeking a Site Director of Quality Assurance and Regulatory Affairs. As Site Director of QA/RA, you will manage and lead the Quality Assurance and Regulatory Affairs team at BioPorto Diagnostics A/S.

Together with your team of quality and regulatory professionals, you will ensure compliance to quality system procedures related to CAPA, non-conformities, complaint handling, auditing, adverse event reporting and field actions through development, maintenance and adherence to documented processes. You will also lead regulatory filings and maintain registrations in various countries.

You will be responsible for the company's global Quality Management System and maintaining its effectiveness. An important part of your role is to promote the awareness of quality, regulatory, customer and other requirements throughout the organization.

As head of QA/RA, you will represent the regulatory perspective for new designs and design changes and assess compliance. As part of BioPorto's management team, you will inform executive management of changes to regulations and standards that impact BioPorto Diagnostics A/S products.

Other responsibilities:

- Identify and report any quality or compliance concerns and take immediate corrective action as required.
- Maintain up-to-date knowledge and understanding of current regulatory requirements within your area of responsibility.
- Monitor and communicate standard version updates and new or updated medical device regulations to the organization.

Your Qualifications

- Several years of medical device quality and regulatory experience.
- Demonstrated knowledge of regulatory issues, and experience interfacing with local and international regulatory bodies.
- Ability to influence and make recommendations at multiple levels of the company.
- Excellent verbal and written communication and presentation skills with the ability to speak and write clearly in English and Danish.
- Demonstrated knowledge about complaints and vigilance reporting in different territories.

To be successful in this position, you must have leadership experience and the ability to handle and prioritize conflicting demands from multiple business entities in an extremely fast paced environment.

You work well both independently and as part of a team. As a manager, you consistently build trust and provide feedback and coaching to your team members.

If you have any questions about this position, please feel free to contact VP of QA/RA Kristina Christensen at +45 20 31 15 20.