HYDRUSTENT
NON-DEGRADABLE IS SO 20TH CENTURY®

Regulatory Affairs Manager (m/f)

Full-time position

HydrUStent is a start-up company focused on developing new medical devices. Bringing to the market innovative medical devices that improve patients' lives is our mission. Our growing portfolio is comprised by several technologies mainly used in the treatment of urologic disorders. We also offer services in medical device engineering that go from early concept to preclinical pilot batches.

Job title: Regulatory Affairs Manager
Hours: 1.0 FTE
Status: Full time
Location: AvePark – Parque de Ciência e Tecnologia, Zona Industrial da Gandra, Guimarães, Portugal.

Your Responsibilities

- Complete the drafting of regulatory strategies and regulatory submissions (medical devices);
- Maintenance of regulatory and project files, archives and databases;
- Proof-reading, editing and submission of regulatory documents and submission packages;
- Conduct design assurance activities: safety risk management, usability, design verification and design validation;
- Prepare administrative documents required for product certification (Europe, Asia, America);
- Complete work activities, as defined by the project lead, on schedule and in accordance with the allotted hours;
- Keep projects updated in accordance to QMS Project Management Procedure;
- Work with manager and project lead to ensure all projects are on schedule and hitting cost targets, profit margin, and follow Quality Management System.

Skills and Experience

- Degree in biological engineering, biomedical engineering, pharmaceutical sciences, biochemistry or related area
- Proficiency in English (working language);
- Experience with medical device regulatory affairs (familiarity with Medical Device Regulation, ISO 13485:2016, ISO10993) will be valued;
- Readiness to work with legal and regulatory documents;
- Ability to work to tight deadlines;
- Willingness to travel (nationally and internationally).

What we offer

- Opportunity to work in a dynamic, friendly and growing environment;
- Competitive salary (according to experience);
- Opportunity to access training and improve the professional skills in the Medical Devices field;
- An extensive network in the healthcare area with excellent partners that collaborate on innovative projects.

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Application process

Applications consists of sending a full curriculum vitae and a cover letter describing briefly how you meet the above criteria, outlining your interest and vision for the role.

- Applications shall be filed via e-mail **info@hydrustent.com** by 30 September 2019. When sending your application please include the email headline "Regulatory Affairs Manager– **Your name**".
- Please indicate your earliest possible entry date as well as salary expectations.

For more information, please visit: www.HydrUStent.com

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