

Vacancy Regulatory Affairs Associate

Our company

Polyganics is an innovative medical technology company. We develop, manufacture and commercialize worldwide, innovative bioresorbable devices to facilitate tissue repair and regeneration after surgery. We adapt our versatile polymers for different clinical applications, improving surgical outcome and patient recovery.

The job

As Regulatory affairs associate you will prepare submissions (CE, IDE, PMA) of high-risk medical devices.

You manage preparation of new regulatory documents and dossiers to enable new products to be launched and maintained in the market, with the correct alignment and compliance to regulations. You provide support with change notifications and initiate and maintain technical files and registrations. You perform vigilance / medical device reporting.

Your profile

We are looking for an associate who maintains current knowledge of medical device regulations, guidance and standards applicable to product submissions.

You understand and have working knowledge of FDA medical device regulations, European Medical Device Directives/Regulation, and/or other global regulations.

You demonstrated working knowledge of scientific principles.

You have a Bachelor or Master degree in Regulatory Affairs or related discipline and up to three years work experience in a similar function.

This position demands a high level of interpersonal skills, personal integrity and excellent written communication skills in English.

Our offer

We offer a responsible, independent and challenging position in a growing organization with the opportunity to develop yourself.

Polyganics has a professional but informal working environment and a pleasant work atmosphere. We offer a competitive salary, good secondary benefits and support your efforts to improve yourself.

Would you like more information?

Please contact Ms. Betty IJmker, director QA/RA at +31 (0)50 588 65 88 or Ms. Henne Barkema (HR) at +31 (0)6 520 61 635.

You can send your resume with a short motivation to hrm@polyganics.com BEFORE September 28, 2021.

Recruiters and headhunters need not apply.