

Senior IVD Program Manager – Project Manager

- A solid technical background: BSc or MSc degree in for example Physics, Technical Medicine, Mechanical Engineering, Electrical Engineering or Biomedical Engineering.
- Product development experience in medical product development and knowledge of ISO 13485, IVDR and MDR, experienced in the use of regulatory requirements and standards is a pré.
- 32-40 uur/week

Enzyre, a spin-out of the Radboudumc is developing a diagnostic point-of-care platform able to measure multiple biomarkers in just a few drops of blood by either the patient at home or nearby the patient by healthcare workers. Our goal is to prevent patients from bleeding to death by bringing the laboratory to the patient. .

We are looking for a Senior Program Manager – Project Manager willing to work in an inspiring team in a flat organization with social impact. Are you also interested in point-of-care developments and are you curious about what it's like to work in a MedTech start-up? Then read on!

Enzyre is building a point-of-care platform called the EnzySystem. The EnzySystem consists of three elements: EnzyPad, EnzyCard and EnzyApp. The EnzyCard is a small credit card-sized disease-specific disposable card containing all the reagents and controls to perform up to sixteen analysis reactions simultaneously. The EnzyPad is a handheld card-reader, whereas the complete EnzySystem shows its results through its software the EnzyApp.

The EnzySystem will be focused on blood coagulation, the current core expertise of the company. The technology can, however, be applied more broadly in collaboration with partners with expertise in different fields. The system is driven by user friendly EnzyApp software, based on underlying firmware for system control and signal detection and processing. Data is collected and transferred to a host, which is either a mobile phone or a laptop. This is all being monitored and serviced from web-based applications.

Responsibilities

The Senior Program Manager – Project Manager is responsible for defining and monitoring the overall Enzyre development program and managing the major product development project(s).

You will help to define, structure, and manage the activities needed to reach market introductions of the Enzyre products now and in the future in the broadest sense. Communication to the team and stakeholders will be an important part of your tasks.

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Required Education / Experience:

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- Product development experience in medical product development and knowledge of ISO 13485, IVDR and MDR
 Experience in state of art project management methodologies

Competencies:

- Ability to bring structure and keep focus in complex situations.
- Problem solving skills with the ability to define problems, collect data, establish facts, draw valid conclusions and to identify opportunities for process improvements.
- Self-motivated and takes initiative.
- Ability to take leadership.
- Strong organizational & time management skills, multitasking capabilities required.
- Ability to work under pressure and steer on deadlines.
- Ability to work as part of a team and individually. Offer ideas and identify issues.
- Ability to communicate clearly and effectively in English (oral and written), with knowledge of the Dutch language being a plus.

We offer as conditions of employment:

- A challenging position in a fast-growing mid-sized informal start-up company.
- Salary level:
 - o Competitive salary (range €55.000-€80.000 gross annual salary)
 - We offer additional benefits based on your performance, experience, and qualifications.

Travel allowance or public transport reimbursement.

Holidays: 25 holidays and holiday pay.

Place of employment: Inspiring working place on the Novio Tech Campus in Nijmegen, The Netherlands. Part-time working from home possible.

Are you the person we are looking for to join our fast-growing research and development team?

Please apply before September 15st, 2023

Send us a motivation letter and your personal resume to <u>r.vestering@enzyre.com</u>. For more information: Rachel Vestering <u>r.vestering@enzyre.com</u> / +31 246690036) **Website**: www.enzyre.com

Recruitment agencies are asked not to respond to this job posting

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