# REGULATORY AFFAIRS MANAGER (HQ POSITION)

*Posted on 23 februari, 2021*

**Company Name** Perimed AB

**Location** Stockholm

**Job Description**

In line with Perimed's expansion plans, regarding both new products and new markets, the company is establishing a new position as **Regulatory Affairs Manager.** This is an exciting opportunity to take on global responsibility for strategic and operative tasks in a growing company, with headquarter in Sweden. It is an independent operating role where you will have support from especially the Head of Quality Assurance & Regulatory Affairs.

**Overall tasks:**

- Enable Perimed expansion through management of registration activities in new markets and registration of new products on current markets.
- Secure continued sales on current Perimed markets by maintaining regulatory compliance related to product changes and updated regulations.
- Manage communication with regulatory authorities and distributors on regulatory matters.
- Represent regulatory affairs in new product development and maintenance projects.
- Create and maintain product related regulatory documentation.
- Monitor regulatory requirements on Perimed markets.
- Initiate and make changes in the Perimed management system to maintain compliance with relevant regulatory requirements.
- Contribute to and handle process improvement.
- Handle communication within the organization e.g. with Sales and with customers, when there are questions regarding regulatory matters.
- Perform Post-Market Surveillance of Perimed products and initiate improvement actions.

**Overall responsibilites:**

- Manage new product registrations and maintain current product registrations.
- Communicate with regulatory authorities.
- Initiate and make changes in the Perimed management system due to changed regulatory requirements.

- SOP's within product registrations and reporting to authorities.

**Background of successful candidate:**

Required:

- At least five years experience within the Medical Device industry.
- At least two years experience within Medical Device Regulatory Affairs.
- Background from development and production based environment.
- Knowledge on medical device regulations.
- Ability to interpret the regulations in different countries.
- High degree of integrity and responsibility and ability to work independently of others.
- Able to speak and write fluently in English and Swedish.
- Ability to communicate effectively with global regulatory authorities and distributors.
- Organized, structured, and accurate way of working. Strong analytical skills.
- Education: University degree in engineering or science.

Preferred:

- Good knowledge on medical device regulations in Europe, USA and China, e.g. ISO 13485, FDAs GMP, MDD and MDR, NMPA regulations in China.
- Knowledge on technical product standards.
- Good knowledge on environmental regulations, e.g. RoHS and REACH.

To apply, please send your CV to Daniel Kremer (daniel.kremer@moveup.se) as soon as possible!

**Om företag**

Perimed is a global company founded in 1981 and headquartered just outside Stockholm, with subsidiaries in USA, China, France, Italy and Germany,

Perimed develops, manufactures and markets state-of-the-art diagnostic equipment to assess microcirculation and peripheral perfusion as well as peripheral arterial disease.

The vision is to provide instruments for accurate diagnosis and monitoring of all patients with ischemia in order to save limbs, lives, costs and reduce human suffering.

Perimed's instruments are used to diagnose the blood circulation in legs and feet. We improve

quality of life for people suffering from vascular diseases, mainly patients with diabetes. The equipment is used to determine the correct treatment. If the blood circulation is inadequate, the treatment will be to restore circulation and to avoid amputation.

Perimed offers a unique combination of vascular tests in one instrument and it is particularly useful for diabetic foot complications and non-healing wounds. In fact, the PeriFlux 6000 is the only instrument on the market that performs all vital tests recommended by the Society for Vascular Surgery (SVS) in one instrument.

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