Senior Regulatory Affairs Manager

The Senior Regulatory Affairs Manager at Philips is part of the Regulatory Affairs Team of the Innovation Site Eindhoven (ISE). In this position the Senior Regulatory Affairs Manager will be responsible for leading High Profile Medical Device development projects for the Beauty business who is part of Personal Care. The Senior Regulatory Affairs Manager is a strategic partner for the business groups. The activities will focus on the hair removal devices called Lumea.
The Senior Regulatory Affairs Manager with strong commercial business sense, who has consumer safety and product compliance top of mind. Able to work in a high pressured, result driven, and project environment. Strong communicator, and collaborator and team player.

Samenvatting

- Vacature nummer: PUB208993
- Markt: Life Sciences & Health Care
- Branche: Medische apparatuur
- Expertisegebied: Wetgeving
- Uren per week: 40
- Opleidingsniveau: WO Bachelor

- Sluitingsdatum: zaterdag 8 juni 2019

De functie

The Senior Regulatory Affairs Manager at Philips will take “Regulatory Ownership” of the Medical Devices, being the primary point of contact for the development teams. In this role the manager is expected to be involved early in Advanced Development Projects and Value Proposition Creation as well as in Clinical Claim Development. A part of the role is to create assessments of Medical Device Classifications for applicable Markets globally and regulatory Strategy Plan for new Lumea Hair Reduction device projects as well as review Product Compliance Plans as created by Safety & Compliance Managers. Create Product Labeling Plan along with Clinical Study Plan and Reports. Eventually, regulatory Medical Device Submission Packages for markets like EU, U.S., Brazil, China will be created.

Over jou

- 10-15 year experience in medical device regulations, in a commercial environment
- Global medical device regulation knowledge for EU (MDD and EU-MDR), United States (FDA), Brazil (Anvisa)
- Proven successful track record in regulatory submissions for medical devices
- Knowledge of Clinical Study setup, execution and reporting
- Familiar with MDSAP and ISO 13485
- Knowledgeable on Product Risk Assessment strategies
- Strong Senior personality being able to take position and guide a project team

Wat wij bieden

Brunel supports your international career: since you are living in another country and probably don’t immediately know how to find your way in the Netherlands, Brunel can help you with this. As an international company, we know better than anyone what it is like to move to a foreign country to work. This is why we can arrange the most important things - including those that don’t involve your job - for you and your family so that you can fully focus on your career in the Netherlands. We will support you by housing, administrative matters and health insurance, but also by education and other facilities to make the international career as pleasant as possible.

Vragen? Neem contact op

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