For our, in the middle of Berlin located, office,

we are looking for a

QUALITY & PROCESS MANAGER (M/W)

Smart Helios GmbH develops proprietary digital solutions for patients by connecting all relevant providers along the entire care continuum with an initial focus on colorectal cancer care.

We are an independent spin-off from Helios Kliniken, Europe's largest private hospital group. We belong to the Fresenius group and are hence part of a large multinational healthcare enterprise network. We are hence in a unique position to leverage the access to patients and professional expertise through our well-established partners.

www.smarthelios.de

Currently we are implementing our Quality Management System (QMS), that will help us to deliver maximum safety to our users and enables the adoption of agile software development practices. Therefore, we are looking for a professional with experience in the field of Process and/or Quality Management as soon as possible.

Your Role:
As *"Specialist for Quality Management and Regulatory Affairs"*, you will be responsible for all aspects of our quality management system according to ISO 13485, with extensive support from the experts of the Johner Institute and our own diversely qualified team including the:

- Designing and implementing the inaugural quality management system including internal and external stakeholder management, orchestration and moderation of SOP development workshops across the functional teams,
- monitoring of changes in regulatory requirements,
- implementation of respective processes and documentation,
- supporting our agile product development teams to ensure conformity with regulatory requirements and compiling Technical Files for market approval in Europe, and potentially also to the US and other international markets in the future.

You will be expected select and use a Business Process Modeling tool based on company's requirements. You will directly report to the management board of the company.

Your Qualifications / Profile:
You should have an academic degree (e.g. in Business Administration, Engineering, Law, Clinical Trials, Medical Software development, Medical Affairs, or related fields), bring profound knowledge in process management, business process modelling, medical device quality management and regulatory affairs, as well as a professional track record in the medical device industry, excellent analytical and communication skills (English and German are a must). You enjoy working in an interdisciplinary team and take pride in both coaching your colleagues to help them perform at their best as well as learning from their skills.

Particularly preferred skills/experience include the following:

- QM systems according to ISO 13485 and/or ISO 9001; 21 CFR Part 820 is a plus.
- European (Directive 93/42/EEC) medical device regulatory approval processes; U.S. (510k/DeNovo) is a plus.
- Risk management according to ISO 14971.
- Managing and conducting audits by the European notified body and FDA inspections.
- Usability studies according to IEC 62366-1.
- Knowledge of agile processes in the context of the medical device regulations is a plus (e.g., AAMI/TIR 45 and IEC 62304)

INTERESTED? CONTACT US!

For further information, please send your application to Dr. Sven Jungmann (sven.jungmann@smarthelios.de). We look forward to receiving your application!