# Clinical Affairs Manager (m/w/d), CorFlow Therapeutics AG, Switzerland

**About CorFlow Therapeutics AG**

CorFlow Therapeutics was founded in 2016 by renowned interventional cardiologists and medical device entrepreneurs with a life-long dedication to medical device innovation in interventional cardiology. The company is incorporated in Baar, Switzerland, and is developing proprietary technologies for diagnosis and treatment of microvascular obstruction (MVO). The technologies will enable interventional cardiologists to diagnose and treat severe heart attack patients with MVO thereby potentially reducing the short- and long-term complication rates in these patients. The CorFlow CoFI System is a medical device with a mode of action achieved through a combination of device function and intracoronary drug infusion into the coronary microcirculation. The company has developed the 1st generation CorFlow Controlled Flow Infusion (CoFI) console and catheter and is running the First-in-Human multi-center European clinical trial, called the MOCA I trial, to investigate safety and feasibility of the device and procedure. A 2nd generation device is currently under development together with external partner companies.

CorFlow has a strong management, R&D and clinical team located in Baar and Bern, Switzerland. The company has established a world-wide recognized Scientific Advisory Board and enjoys support from Key Opinion Leaders in interventional cardiology in Europe, the United States and Japan.

CorFlow is seeking an experienced and thoughtful Clinical Affairs Manager, who has a documented track-record of experience in Medical Affairs and Clinical Operations with medical devices.

**Job Description:**

As a Clinical Affairs Manager your key responsibilities will be:

- Develop clinical strategy needed to obtain reimbursement and regulatory approvals in Europe, the United States and Japan
- Continue operation of the CorFlow First-in-Human MOCA I clinical trial on 1st Gen device in collaboration with CorFlow assigned personnel or CRO:
    - Management and control of enrolment process and study compliance, key point of contact for enrolling sites
    - Full local sites management from feasibility to close out, including monitoring activities, training of site staff and maintenance of study related documentation
    - Sites contracts and budget negotiations
    - Study related submissions to RA and EC in Switzerland
    - Assure the handling and reporting of safety information in clinical studies according to regulatory requirements
    - Assure readiness for internal and external audits
    - Coordinate CEC/DSMB activities and meetings
    - Authoring study protocol and informed consent forms and other study related documentation
    - Management of assigned CRO personnel and core laboratories
    - Author interim and final reports and annual safety reports for submission to EC and RA, according to current regulation and guidelines

- Initiate and manage in collaboration with assigned CRO a EU/US pivotal trial on 2nd Gen device, including but not limited to:
    - Development of study design and study documentation
    - Identification and qualification of possible sites
    - Management of assigned CRO/vendors/core labs/CEC-DSMB for study initiation and execution
- Contribute to the development of clinical SOPs
- Plan, control, and report budget for assigned clinical activities
- Assist in abstract and publications submissions and prepare presentation sets
- Support KOL activities for publications and training

**Qualifications:**

- Minimum of 5 years' experience in Medical Affairs and Clinical Operations in medical devices, including monitoring activities
- Experience in clinical strategy development to achieve market approval and reimbursement for medical devices in EU and US
- Implementation of First-in-Human clinical trials including SAE reporting, data management, CEC/DSMB/Steering Committee interactions and corelab interactions
- Knowledge of Good Clinical Practice (GCP) and ISO 14155, experience with Class II & III medical devices preferred
- Proven ability to interact with competent authorities, ethics committees and investigators
- Ability to manage CRO's where needed
- Understanding of device – drug combination products and experience in the field of interventional cardiology is a big plus
- Organized individual who is self-motivated, detail oriented and able to work with little supervision
- Strong critical thinking and problem-solving ability
- Team player who likes to get things done
- Fluent English language skills orally and in writing, German language skills preferred
- Ability to work well independently as part of a small team with different functions and backgrounds

We offer a full-time contract with a competitive salary in a pioneering start-up environment with work location in our headquarters in Baar, our laboratory and offices in Bern (Switzerland) or from a remote location. If you possess the required experience and qualifications and want the challenge of growing with our company, please submit your application including latest CV and all other relevant documents.

Please note: For this position we do not consider applications from recruitment agencies.

**Contact: Sabrina Frey, sfrey@corflow.ch**