PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs for out-patient and hospital-based sedation, anesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic drug candidate for which PAION has completed the clinical development for use in procedural sedation in the U.S. Outside the U.S., PAION is currently focused on the development of remimazolam for general anesthesia. A full clinical development program for general anesthesia has been completed in Japan. In the EU, PAION initiated a Phase III trial in July 2018. Development of remimazolam for intensive care unit (ICU) sedation is also part of the longer-term life-cycle plan for remimazolam.

For our team in **Cambridge** we are currently searching for a

Development Manager CMC (m/f)

Your tasks & responsibilities:

- Support the completion of the pharmaceutical development of PAION's main compound remimazolam including the completion of process validation programs.
- Ensure supply of drug substance and drug product to meet requirements of clinical development plans, regulatory submissions and commercial requirements for PAION's programmes.
- Support the technical CMC needs of licensees around the world, including support to Technology Transfer needs.
- Secure the availability and quality of medication for pre-clinical as well as clinical trials. May also be involved to support labelling and packaging activities
- Author and / or review internal (SOPs) and external documents for both the drug substance and drug products, i.e. specifications, batch records, validation reports, shelf life justifications, CMC parts of regulatory submissions including NDAs for various territories, etc..
- Involved in selection of and responsible for co-ordination and control of external vendors managed by PAION and co-ordination of interactions with these vendors.
- Responsible for supporting product / material supply and analytical testing for pre-clinical studies outsourced in collaboration with PAION's pre-clinical staff.
- Select and liaise with manufacturing, pharmaceutical, regulatory and other consultants as required.
- Together with PAION QA, involved in documentation to ensure manufacturing/testing activities are conducted to GMP and in accordance with current guidelines and PAION procedures

Your profile:

- A minimum of 3-5 years practical industrial experience working in pharmaceutical / biotechnology industries or service providers (CROs / CMOs) to those industries and in three or more of the following areas associated with the development of pharmaceutical products: chemistry support, formulation development, manufacture of clinical trial supplies, analytical development, quality control, stability testing, technical project management with a particular emphasis in supporting clinical trial manufacture.
- A good knowledge of regulatory requirements, including ICH requirements and national EU / US regional requirements is required, especially in relation to pharmaceutical development activities.
- Good practical knowledge of Good Manufacturing Practice/Good Laboratory Practice and of working within a Quality Management System.
- Experience with the development and / or validation of manufacturing processes and analytical methods. Understanding of the requirements for commercial manufacturing would be beneficial.
- Experience of technical management and direction of external vendors would be extremely beneficial as the company works with a network of vendors.
- Experience gained in working for R&D based pharmaceutical, biotech or contract development / manufacturing organisation (CDO/CMO).

Do you want to work in an international and dynamic environment and would like to play an active role? We look forward to receiving your application preferably by email, to HR@paion.com

PAION AG
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For further information please visit our website:
www.paion.com