PAION is a publicly listed specialty pharmaceutical company focused on developing and commercializing 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. Remimazolam is partnered in multiple territories outside of Europe. Remimazolam was approved in the U.S. for procedural sedation in July 2020 and was approved in Japan for general anesthesia in January 2020. In China, licensee Yichang Humanwell received market approval in procedural sedation in July 2020 and in South Korea, licensee Hana Pharm filed for market approval for remimazolam in general anesthesia in December 2019.

In Europe, PAION is seeking approval of remimazolam for general anesthesia and for procedural sedation. PAION submitted a Marketing Authorization Application (MAA) for procedural sedation in November 2019. Results of a Phase III trial in general anesthesia are expected in the second half of 2020.

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

QC Manager (m/f/d)

Your tasks & responsibilities:

- Together with PAION QA, review QC documentation and QC-related parts of manufacturing and ensure manufacturing / testing activities are conducted in-time and in accordance with current GMP guidelines, PAION specifications and PAION procedures.
- Drawing up of Specifications in coordination with relevant PAION departments and CMOs
- Perform Life Cycle Management of analytical methods by establishing and executing an analytical method validation master plan and follow up of required periodical and ad-hoc measures in cooperation with other departments and PAIONs CMOs.
- Review and update / improve analytical methods as appropriate, including changes / updates of pharmacopoeia's methods (Ph.Eur., USP and other).
- Ensure overall compliance of PAION with ICH requirements, especially ICH Q1, ICH Q2 and ICH Q6
- Manage samples and reference materials together with Supply Chain and external partners
- Manage QC related change controls and deviations internally as well as externally with PAIONs vendors.
- Provide support to PAION's licensees in QC related topics where applicable, including the organisation and support of method transfer programs.
- Draw up, review and maintain internal and external QC-related documents i.e. validation reports, shelf life justifications as well as SOPs.
- Provide technical support with the drawing up and maintenance of PAION's registration documentation.
- General management and control of external vendors of PAION and co-ordination of interactions with these vendors in all QC related topics.
- Provision of subject matter expertise to support audit of manufacturing / testing facilities in accordance with GMP, current guidelines and PAION procedures.

Your profile:

- Master degree / Diploma or ideally a post graduate in Pharmacy, Pharmaceutical Sciences, Chemistry or Life Sciences, preferably with a focus on analytical methods / analytical chemistry
- At least 5 years practical industrial experience working in pharmaceutical or biotechnology industries and in three or more of the following areas associated with industrialization and manufacturing of pharmaceutical products: analytical method's development and validation, method lifecycle management, quality control, stability testing with a focus on analytical chemistry.
- Deep-rooted knowledge of regulatory requirements, including ICH requirements and national EU / US regional requirements like national pharmacopoeias (analytical method development and validation (ICH Q2), QC analysis, method lifecycle management).
- Proven knowledge of Good Manufacturing Practises and of working within a Quality Management System. Experience in managing change controls, deviations and OOS.

- Proven Experience with commercial manufacturing and on-time release of API and drug products as technical expert in cooperation with a QA team.
- Proven knowledge of method validation
- Knowledge of risk management
- Fluent in English and German

Desired skills:

- Knowledge of additional national regulatory requirements outside EU / US (e.g. Japan, Korea, Brazil) as well as their national pharmacopoeias
- Experience of technical managements and direction of external vendors would be extremely beneficial as the company works with a network of vendors.
- Additional experience in microbiological and sterility testing

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

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