AiCuris
Anti-infective Cures

Medical Director/Studienleiter (m/f/d) für multizentrische klinische Studie in full time

The Powerhouse for Anti-infectives – Committed to making the difference

AiCuris is a pharmaceutical company specializing in the discovery, research and development of novel, resistance-breaking antiviral, and antibacterial agents for the treatment of serious and potentially life-threatening infectious diseases. Founded in 2006 as a spin-out from Bayer Infection Research, AiCuris today manages an innovative pipeline of anti-infective agents with a team of internationally recognized scientists in Research and Development. We are one of the few European biotech companies which has brought a drug with „blockbuster" potential to the market (Prevymis® 2017/18).

Ready to fight against infectious diseases? Join our team!

Responsibilities

- Clinical and medical input at any stage during development, good understanding of the pharmaceutical value chain and experience in clinical development
- Development of the clinical part of the project development plan incl. clinical trial protocols or CRFs (paper or electronic)
- Creation of the trial reports, critical review and quality checks of the clinical data
- Development of the clinical part of the investigator brochure, specifically the risk benefit section, information to the investigators and reference safety information
- Interaction with investigators, coordinating investigator and the key experts
- Development of the clinical part of regulatory documents, e.g., briefing books, summary documents, answer questions to authorities

Skills and qualification

- MD degree and holds a license to practice medicine
- Five to ten years proven experience in running clinical trials specifically Phase II and Phase III trials in the pharmaceutical industry or with international CROs
- Experience in running anti-infective clinical trials would be preferred
- Previous experience in working as a treating physician in a hospital setting
- Ability and experience in working as a team, e.g., in-house, with CROs, experts and opinion leaders
- Results-oriented, capable of setting priorities and managing high workload at times
- Small biotech mentality and flexibility to accept and perform the tasks of his/her direct reporting workers and colleagues across projects in case of need
- Fluent in business English

Pharmacovigilance Manager/ Pharmakovigilanz Manager (m/f/d) in full time

Responsibilities

- Responsible for drug safety aspects within development and future marketed new drugs
- Overseeing the risk-benefit profile of drugs under development
- Being the PV-contact for regulatory agencies
- Taking over EU-QPPV responsibility as well as the Graduated Plan Officer (Stufenplanbeauftragter (m/w/d)) function as needed in the future
- Implementing and maintaining the PV-system and establishing its system master file
- Continuous observation of the regulatory landscape and scientific literature regarding pharmacovigilance
- Reviewing and amending safety information within development documents
- Responsible for writing and reviewing adverse event narratives and periodic reports

Skills and qualification

- Academic degree in life science, preferably in human medicine
- At least 5 years proven work experience in managing pharmacovigilance in the pharmaceutical industry including regulatory drugs in development
- Profound medical and pharmaceutical knowledge
- Good organizational, communication and intercultural skills
- Highly motivated to contribute and work in a growing and changing organization
- Good knowledge of standard and specific software (e.g., Microsoft Office and electronical pharmacovigilance software)
- Good English (oral and written) and possibly German (advantageous but not a primary requirement) language skills

What we can offer

- Cooperation in multinational and interdisciplinary teams
- An exciting field of activity in a promising research and development company
- Flexible working hours and self-determined time management
- Flexible combination of on-site and mobile work
- Regular and targeted further training and individual development opportunities
- Attractive remuneration and company pension scheme
- A wide range of offers in terms of health and reconciling work and family life

How to apply

Interested in joining our team? Please send your application to jobs@aicuris.com

If you have any questions, please do not hesitate to contact our Head of Development / CMO Prof. Dr. Hubert Trübel at hubert.truebel@aicuris.com or dial +49 (0)202 317 63-0.

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