

HMNC Brain Health

HMNC Brain Health (HMNC) is a clinical-stage neuroscience company pioneering new therapies for mental health disorders. Its pipeline includes Nelivabon (BH-200), a vasopressin V1b receptor antagonist being developed as a biomarker-guided precision therapy for biologically defined depressive disorders. Used with a genetic test to identify patients most likely to benefit, Nelivabon offers a precision neuroscience approach to treatment. HMNC is also developing Ketabon (KET01), an oral prolonged-release ketamine formulation for treatment-resistant depression, designed as a differentiated and scalable option for outpatient and at-home use. By advancing targeted and accessible treatment options, HMNC aims to address significant unmet needs of millions of patients who are not helped sufficiently by existing mental health therapies. The Company is headquartered in Munich, Germany.

And you can go the way with us. Join our team and define tomorrow's treatment success as

Senior Clinical Pharmacologist (m/w/d)

Location:

Munich – Remote

Job Summary

We are seeking a senior Clinical Pharmacology expert who can combine deep pharmaceutical industry experience with a strong understanding of regulatory authority expectations. The successful candidate should not only understand clinical pharmacology, DMPK, PopPK, PBPK, PK/PD, ADME, and safety data, but also be able to interpret these data critically and translate them into clear development decisions.

This person will act as a senior scientific and regulatory advisor to HMNC, helping the team decide what data are sufficient, what additional studies are truly needed, how to justify dose and study design decisions, and how to communicate these decisions credibly to authorities such as BfArM, EMA, FDA, and other national competent authorities.

The role requires someone who has worked in or closely with the pharmaceutical industry and understands how development decisions are made under real-world constraints of time, budget, regulatory risk, and clinical feasibility. At the same time, the person must understand the mindset and expectations of regulatory authorities and be able to prepare persuasive, scientifically sound documentation, briefing materials, position papers, and responses to authority questions.

Responsibilities:

- Lead HMNC's clinical pharmacology and DMPK strategy across pipeline programs, ensuring alignment with clinical development, regulatory expectations, and future labeling considerations.
- Develop integrated clinical pharmacology, DMPK, ADME, PK/PD, and model-informed development plans to support dose selection, study design, safety assessment, and regulatory submissions.
- Interpret clinical and nonclinical pharmacology, PK, safety, exposure–response, and modeling data and translate them into pragmatic, regulatorily defensible development decisions.
- Provide senior oversight of PopPK, PBPK, PK/PD, exposure–response, and other quantitative pharmacology activities, including critical review of vendor outputs, assumptions, and conclusions.
- Advise on the need, design, interpretation, and regulatory relevance of clinical pharmacology studies, including formulation, food effect, drug interaction, QT/QTc, organ impairment, and special population assessments where applicable.
- Prepare, review, and challenge key development and regulatory documents, including protocols, study reports, investigator brochures, briefing packages, IND/CTA/IMPd documents, CTD sections, authority responses, and scientific position papers.
- Support preparation for and participation in interactions with BfArM, EMA, FDA, and other relevant authorities, including development of clear scientific arguments and response strategies.
- Advise on nonclinical DMPK, ADME, pharmacology, toxicology, and translational data packages to ensure they support clinical and regulatory objectives.
- Manage and guide external CROs, pharmacometricians, PBPK vendors, DMPK laboratories, consultants, and other development partners.
- Support strategic development planning, due diligence, partnering, and business development activities by identifying clinical pharmacology, DMPK, safety, and regulatory risks and proposing practical solutions.
- Collaborate closely with clinical development, regulatory affairs, CMC, nonclinical, safety, biomarker, and business development colleagues.

Requirements / Professional Expertise:

- MD, PharmD, PhD, or equivalent advanced degree in Clinical Pharmacology, Pharmacology, Pharmaceutical Sciences, Medicine, DMPK, Pharmacometrics, Toxicology, or a related discipline.
- Approximately at least 15 years of relevant experience in clinical pharmacology, DMPK, ADME, PK/PD, translational pharmacology, or regulatory-facing drug development; exceptional candidates with slightly less experience may be considered if they bring strong strategic and authority-facing expertise.
- Demonstrated experience in pharmaceutical or biotech drug development, ideally covering several stages from early development through IND/CTA and later-stage regulatory planning.

- Strong understanding of how clinical pharmacology, DMPK, nonclinical, safety, CMC, regulatory, and clinical development decisions interact in real-world drug development.
- Proven ability to interpret clinical and nonclinical pharmacology, PK, safety, exposure–response, and modeling data and translate them into clear, pragmatic, and regulatorily defensible development recommendations.
- Experience with DMPK, ADME, PK/PD, PopPK, PBPK, exposure–response, dose selection, drug interaction strategy, formulation-related clinical pharmacology, safety considerations, and special population assessments.
- Ability to critically review and challenge modeling outputs, study reports, vendor analyses, assumptions, and conclusions, even when analyses are performed by external experts.
- Demonstrated experience preparing, reviewing, and defending regulatory and development documentation, including protocols, study reports, investigator brochures, briefing packages, IND/CTA/IMP documents, CTD sections, responses to authority questions, and scientific position papers.
- Experience preparing for and participating in interactions with regulatory authorities such as BfArM, EMA, FDA, or comparable agencies.
- Experience in CNS, neuropsychiatry, or psychiatry-related drug development would be an advantage; experience in Major Depressive Disorder (MDD) and/or Treatment-Resistant Depression (TRD) would be particularly valuable.
- Ability to think from both perspectives: the pharmaceutical sponsor’s need for efficient and feasible development and the authority’s need for robust scientific justification and patient safety.
- Strong scientific writing, communication, and stakeholder-management skills, with the ability to explain complex clinical pharmacology and DMPK topics clearly to cross-functional teams and senior decision-makers.
- Pragmatic, hands-on, and solution-oriented working style suitable for a small biotech environment, with the confidence to challenge assumptions and recommend practical solutions.
- Experience managing or guiding external CROs, pharmacometricians, PBPK vendors, DMPK laboratories, consultants, or other development partners.

Why HMNC?

- An inspiring work environment in a young, motivated and international team with flat hierarchies.
- A permanent position with a competitive salary in an early stage, growing and dynamic company based in Munich.
- Multiple learning and development opportunities.
- A growing benefit portfolio including a yearly career development budget.
- Flexible and family-friendly working hours with the possibility of individual solutions including remote work.

- Good connection to public transportation as well as a parking garage in the office building.
- We value diversity – regardless of gender, nationality, ethnic and social origin, religion/belief, physical abilities, age as well as sexual orientation and identity.

Have we awakened your interest? Send your complete application via e-mail to:
jobs@hmnc-brainhealth.com

We look forward to meeting you!

CONTACT:

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