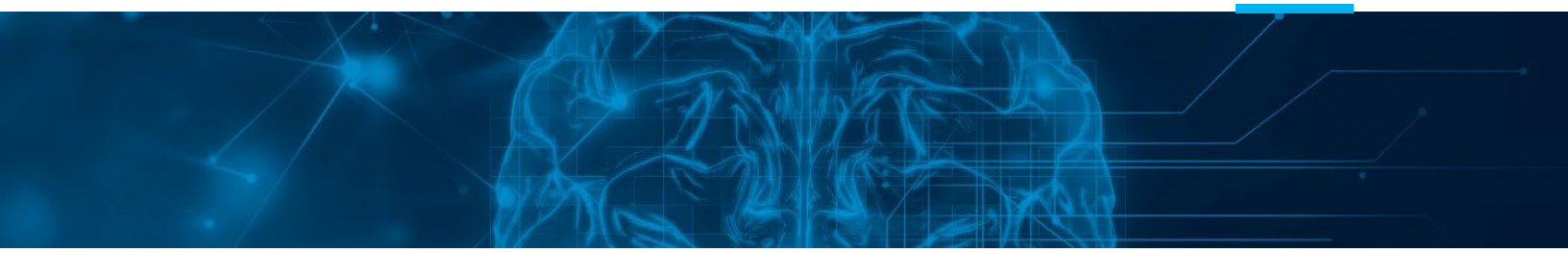


HMNC Brain Health
HMNC Brain Health (HMNC Holding GmbH) is a precision psychiatry biopharmaceutical company developing personalized treatments for depression based on predictive genetic selection tools. The company's pipeline includes three Phase 2 programs in Major Depressive Disorder (MDD): Nelivabon, with a vasopressin V1b receptor antagonist guided by a proprietary genetic selection tool; Cortibon, with a CRHR1 antagonist with a matching genetic selection tool; and KET01, a prolonged-release oral ketamine formulation designed for safe, at-home treatment.

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

CMC Project Leader – Small Molecule Development **(m/w/d)**

Location:

Munich – Remote

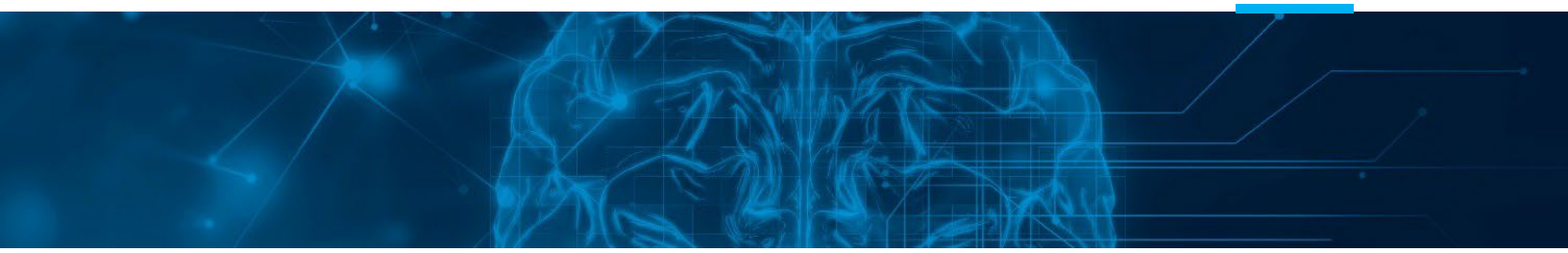
Job Summary:

We are seeking a CMC Project Leader with a strong background in small molecule chemistry and development, who combines technical knowledge with regulatory insight and a hands-on, communicative approach. This position is key in driving CMC strategy and execution across development phases — from preclinical to clinical — ensuring alignment with quality standards and global regulatory expectations.

You will coordinate cross-functional CMC efforts including chemistry, formulation, analytical, and manufacturing development, and act as a central interface with regulatory affairs and external partners (CDMOs) with a deep understanding of GxP regulations. Experience in preparing for and supporting CMC regulatory submissions and audits is essential.

Responsibilities:

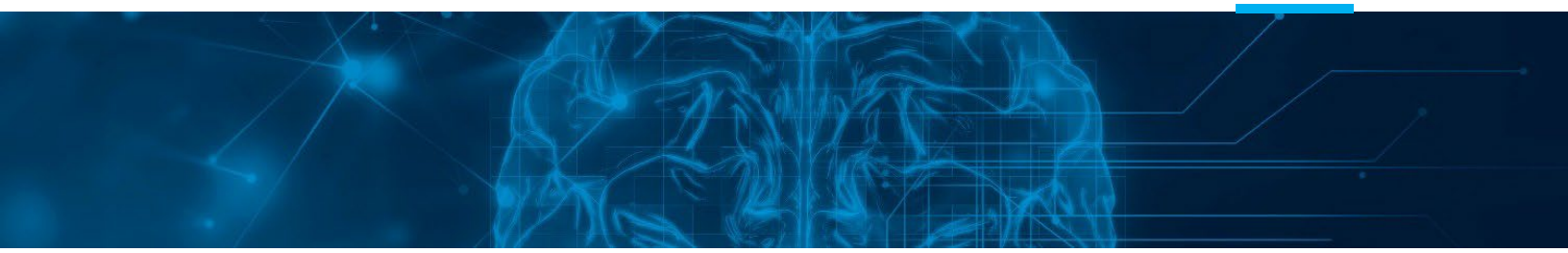
- Lead CMC activities across drug substance (DS) and drug product (DP) development and IMP production for small molecules.
- Coordinate e.g. DS related activities and DP formulation development including analytical method development, process development, and tech transfer to manufacturing partners.



- Represent CMC in cross-functional project teams and ensure seamless collaboration across internal and external stakeholders.
- Drive the preparation and review of CMC sections of regulatory dossiers (e.g., IMPDs, INDs, amendments).
- Independently draft and write CMC sections of regulatory dossiers (e.g., IMPDs, INDs), ensuring quality and compliance.
- Ensure compliance with ICH guidelines, GxP, and other relevant regulatory requirements.
- Support and/or lead CMC audits (regulatory inspections and partner audits), including audit readiness activities and deviation / CAPA management.
- Maintain oversight of CMC activities such as timelines, budgets, risks, and deliverables.
- Facilitate communication and decision-making across CMC sub-functions and leadership teams.
- Support operational oversight of IMP activities during clinical trials in collaboration with Clinical Operations, including label management, temperature excursions, randomization processes, and document review.

Requirements / Professional Expertise:

- MSc or PhD in Pharmaceutical Sciences, Chemistry, or related discipline.
- 5–8 years of industry experience in pharmaceutical R&D, with direct involvement in CMC project leadership.
- Deep understanding of small molecule development, including API synthesis, formulation, and manufacturing.
- Hands-on knowledge of CMC regulatory submissions, ICH guidelines, GxP, quality documentation, and audits/inspections.
- Strong organizational and project management skills.
- Excellent interpersonal and communication skills with a proactive and collaborative attitude.
- Experience at the CMC–Clinical Operations interface, ideally with hands-on involvement in operational oversight of Investigational Medicinal Product (IMP) supply at CDMOs and/or CROs.
- Preferred Qualifications
  - Experience working with CDMOs in development and GMP manufacturing.
  - Involvement in Phase I–III development programs.
  - Ability to work effectively in matrix environments and drive results in lean structures (e.g., biotech/start-up settings).



- Excellent written and verbal communication skills.
- Strong organizational and project management skills.
- Ability to work independently and as part of a team.
- Flexibility to travel domestically and internationally, as required.

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:

HMNC Holding GmbH
Katharina Schwabe
HR-Manager
Wilhelm-Wagenfeld-Str. 20
80807 München
www.hmnc-brainhealth.com