Versantis AG
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CAREER OPPORTUNITY

Head of CMC (w/m) 100%

Are you seeking for broad and meaningful responsibilities in a patient-focused company? Do you want to leave a mark and work in a dynamic and flexible environment? Join Versantis on its ambitious mission to revolutionize the care of patients with liver diseases. You will report directly to the CEO/COO and be empowered to lead the CMC development of Versantis' flagship clinical program – VS-01.

The company and lead asset

Versantis is a clinical-stage biotech company focused on the development of orphan drugs in liver diseases and pediatric inborn errors of metabolism. Founded by leading scientists from ETH Zurich and industry experts, Versantis is pursuing innovative therapies for the acute care of serious liver conditions based on its proprietary liposomes-based detoxification platform technology. Versantis has successfully raised private and public capital and was rewarded with the most prestigious scientific and entrepreneurial prizes (MassChallenge winner, Best Swiss Biotech Startup (Top100 Award), VentureKick, and Pfizer Research Award).

Versantis' lead candidate, VS-01, uses a disruptive approach to effectively treat adults with decompensated cirrhosis (Versantis' most advanced program) as well as children with rare hyperammonemic crisis caused by genetic disorders. VS-01 is currently being evaluated in first-in-human clinical trials, with outcomes expected mid-2020. It was granted two orphan drug designations in acute liver failure by the EMA and in ACLF by the FDA, which will streamline its clinical development pathway. In parallel, Versantis' R&D programs continue to grow via close collaborations with Top Research Institutions.

The position

The goal of this position is to scale-up the GMP production, validate the manufacturing processes as well as optimize and manage the supply chains of Versantis' products in view of multi-sites clinical trials and commercialization. The successful candidate will be a highly motivated, entrepreneurial, CMC expert with large hands-on experience across all phases of drug development. This is a unique opportunity to significantly contribute to the success of a disruptive therapy tackling high unmet medical needs while being part a promising early-stage biotechnology company.

Essential duties and responsibilities

- Work closely with the senior executive team in a collaborative and welcoming environment.
- Identify, select, and manage CROs/CDMOs.
- Deliver and continuously work on optimizing robust, scalable, and cost-effective manufacturing routes, from raw materials to packaging.

- Prepare or edit quality agreements with third-party manufacturers.
- Drive third-party manufacturers through technology transfer, process and method development, and analytical qualification/validation of all manufacturing operations.
- Prepare, review or edit all required documents prior to GMP productions (*e.g.*, cGMP batch records, product specifications, in-process controls etc.…).
- Manage all QC/QA relevant issues and support third-parties' investigations (out of specifications, stability issues…).
- Anticipate the needs and ensure timely supply of drug product to support on-going non-clinical and clinical programs.
- Manage supply chain and logistics in support of clinical studies. Ensure proper release of clinical batches on a global level.
- Outline or edit CMC sections in all regulatory submissions and interact with FDA, EMA and other agencies as required (*e.g.*, document preparation, Q&A…).
- Work with QA on external audits as well as internally to develop SOPs and guidelines related to the production, planning, disposition, and management of drug product.

Experience, know-how, and required characteristics

- PhD or MS in Life Sciences/Biotechnology/Chemistry/Pharmaceutical Sciences with at least 8 years of experience in a pharmaceutical or biotechnology CMC/cGMP environment.
- Substantial experience in managing international CROs/CDMOs as well as CMC activities.
- Substantial CMC experience with projects in clinical development *e.g.*, Phase 1 through Phase 3 and ability to integrate non-clinical and clinical inputs.
- Relevant experience with sterile parenteral formulations (*e.g.*, *i.v.* and *i.p.*) and other pharmaceutical dosage forms.
- Experience in liposomal formulation would be a plus.
- Hands-on experience in writing CMC sections of various regulatory submissions across drug development phases and thorough knowledge of relevant FDA and EMA regulations.
- Solution-driven person with strong initiative and positive drive. Must be an organized, rigorous self-starter who is able to anticipate the company's needs.
- Comfortable in a fast-paced small company environment with minimal direction and able to define its own workflow and execute it independently, while handling multiple priorities.

Why should you apply?

- You will actively contribute to the development of new potential life-saving medicines.
- Your work will give you a sense of ownership as you directly contribute to Versantis' success and will be entitled to receive company's options. Each of your decision will have an impact on the future of the product, the company, and patients' lives.
- Young, dynamic, and flexible working environment – perfect for innovation to thrive!

If your profile matches the requirements of this exciting position, we are looking forward to hearing from you. Please send us your detailed application (CV, cover letter, and references if available in English and in PDF) to: career@versantis.ch. Only direct applications will be considered, no solicitations from recruiting agencies are desired.