Director of CMC Development

ZERION is a pharmaceutical company enabling the development of novel drug products by improving the solubility and bioavailability of small molecule drugs. We aim to bring our first drug formulation to the market within 4-5 years and obtain regulatory acceptance of our whey protein as a novel pharmaceutical excipient. This is an ambitious plan, but we want to challenge the established pharma industry and show that this is possible. We are now moving into upscaling of our unique Dispersome® formulation technology aiming at producing GMP material at a CDMO for our first clinical trial. Therefore, we need an experienced professional who can take the lead on our CMC strategy and activities to accomplish these goals.

The position

Overall, you will be responsible for the CMC development tasks in ZERION and building ZERION’s further competencies in the area of CMC. This includes – without limitation – responsibility for:

- Developing a CMC strategy from research to commercialization for our novel Dispersome® amorphous formulations containing marketed APIs.
- Leading the transfer, upscaling, and establishment of full manufacturing processes for final products - in close collaboration with our research department and CDMOs.
- Design of project plans and protocols with internal and external stakeholders, including CDMOs.
- Execution and compilation of the required documentation according to GMP and ICH guidelines for operations in the CMC area. Including analytical method development and quality control. Definition of critical process parameters and process validation.
- Technical reports and updates to the ZERION management.
- Hiring and managing the necessary competencies for the department as the company grows.

Your profile

We are seeking a self-motivated and independent person, with a degree in pharmacy, chemical engineering, or similar, having 8-10 years’ experience from working within CMC in the pharmaceutical industry.

We would prefer that you have experience with all or most of the following areas:

- Manufacturing of oral solid dosage forms, by unit operations such as milling, spray-drying, hot-melt extrusion, and final dosage preparation by granulation, tableting, coating, etc.
- Working in and setting up a regulated cGMP manufacturing environment, including analytical method development and quality control.
- Transfer of lab process to pilot scale and full-scale manufacturing (oral solid dosage forms).
Familiar with EMA, FDA and ICH regulations for small molecule drug formulations, in particular for generic/generic+ products.

Writing of submission documents for CTA/IND/NDA/MAAs.

We expect that you aim at meeting high-quality standards in your work, dedicated to meet deadlines critical to the team and the company. Based on your experience and creativity, you should be able to determine and execute the right CMC path for ZERION to reach the market.

The opportunity

You will be our CMC anchor and work closely with the dedicated and innovative colleagues at ZERION. We offer a challenging job in an exciting environment where you will be responsible for bringing our novel amorphous formulation technology from our research lab to industrial manufacturing and the market. Over time, you will be instrumental in building the CMC department. You will become a member of ZERION’s management team and involved in all significant decisions in the company. We do offer a decent compensation package including stock options and a pension program.

ZERION has offices/lab facilities at KU Campus and in Birkerød.

- Please submit your application and CV to ZERION ApS, Blokken 11, 3460 Birkerød by email to ow@zerion.eu, attention Ole Wiborg before June 28, 2020.
- If you want to hear more about the position, please contact Ole Wiborg, CEO at +45 40 96 80 18.