



Polyphor is a clinical stage biopharmaceutical company based in Allschwil, Switzerland, and is focused on the discovery and development of antibiotics and other specialty pharma products for severe or life-threatening diseases.

We are currently looking for a:

## **CMC-Leader / External Manufacturing Manager**

The position will report to the Head of CMC Development and will be based in our Allschwil offices. Ideal start would be Q2/2019.

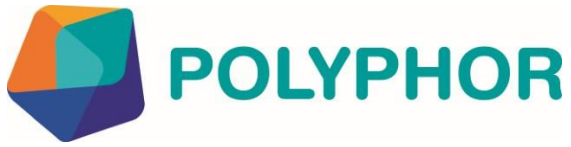
### **Responsibilities:**

- Develop robust and reproducible API chemical synthesis methods for Polyphor's clinical drug candidates together with CMOs (Contract Manufacturing Organisations) with focus on scalability and cGMP industrial manufacturing feasibility
- In discussion and collaboration with the CMOs:
  - Design suitable chemical process
  - Define process optimization of these processes to achieve reproducibility, robustness and scalability appropriate for the project's development phase. Knowledge of DoE approaches are a plus.
  - Define and approve phase adequate specifications and analytical methods.
  - Support technology transfers
  - Review and comment on batch records, in later phases also validation documents
- Write technical reports and Quality sections of IND/IMP/ND/MAA and support regulatory submission
- Plan and monitor budget for the assigned projects
- Represent CMC function as team member in Global Project Teams

### **Qualifications:**

Desired personal qualities should include: high emotional intelligence and teamwork attitude, hands-on approach to problem solving, strong self-motivation, hard-worker with ability to adapt to a fast-paced working environment.

- PhD in organic synthesis is required
- Demonstrated strong experience in tech transfer, industrial scale-up and process development & validation of synthetic molecules
- Regulatory experience with submission being familiar with EU and US regulations relating to clinical trials and cGMP
- Good understanding of QbD principles, risk management by FMEA and determination of PAR/NOR (Proven Acceptable Range / Normal Operating Range) for new manufacturing processes
- Solid knowledge of main analytical techniques
- Robust negotiation skills and ability to manage outsourced activities at CMOs, with excellent monitoring of deliverables on time, quality and cost



- Excellent knowledge of English language is required
- Knowledge of German language would be a plus
- Availability to travel at our collaboration partners (EU, US, Far East), ca 10-20% of time
- At least 5 years work experience in the relevant areas

Please send your full application documents to the following address: [hr@polyphor.com](mailto:hr@polyphor.com) with reference: 10061 CMC Leader / External Manufacturing Manager.

Direct applications are preferred. For further information about the offered position, please contact: Ard van Beek (+41 61 567 16 55).