Immutep is hiring:

Bioprocess Engineer / Manufacturing Specialist (m/f/d)

Company:

We are Immutep, an emerging international biotechnology company developing immunotherapeutic products for cancer and autoimmune diseases. With operations based in Australia, USA, Germany and France, Immutep is dedicated to bringing innovative treatment options to market for patients. The company is publicly traded on the ASX and NASDAQ.

Location:

Berlin, Germany; office based, 75-100 % negotiable

Summary:

As a result of continuous progress in our projects we want to expand our team and therefore seek a Bioprocess Engineer / Manufacturing Specialist. You will work closely with the Director of Manufacturing to support the tech transfer and scale up of Immutep's manufacturing process including Up-Stream-Process (USP), Down-Stream-Process (DSP) as well as final formulation and fill. Your responsibility includes to oversight and manage the tech transfer and scale up operations at our Contract Manufacturing Organization (CMO). This implies the supporting of national and international projects under consideration of local laws, international guidelines (ICH) and applicable SOPs.

Job description:

- Planning and implementing scale-up of manufacturing processes of biologics for USP, DSP as well as final formulation and fill
- Support and manage the planning of Process Characterization and Process Validation activities
- Assist in the qualification of suitable vendors in conjunction with Quality Assurance, if applicable
- Writing / review of GMP documentation (SOP, batch records, deviation, change control, out of specification, qualification and validation documents, risk analysis, etc.)
- Writing / review of reports, batch summary reports, process validation reports
- Participate in management reviews of process performance, product quality and the quality management system
- Contribute to CMC core documents (e.g. IMPD, IND)
- Assist with regulatory submission preparations
- Provide requested input on forecast of annual budgets
- Provide requested input to Product Development Plans and Portfolio Review
- Actively participate in internal and external project teams
- Represent the Company at external conferences and meetings

Skills/Experiences/Qualifications:

Essential:

- Post graduate degree in natural / life sciences / engineering background
- At least 5 years of experience in an industrial GMP manufacturing / clean room environment preferably with biologics
- Experience of tech transfer of processes and scale-up to commercial scale
- Understanding of QC techniques applicable for biologics
- Background in Process Characterization and Process Validation to support BLA / MAA
- Experience of writing and or review of GxP documents (including SOP's, qualification / validation plans / reports, batch records)
- In depth working knowledge of EU GMP
- English Language skills
- Good working knowledge of using Microsoft office programs
- Project management skills

Desirable

- Experience of equipment and method qualification / validation
- Experience of working in or liaison with a Contract Manufacturing Organization
- Experience in manufacturing recombinant protein / antibody / fusion protein
- Background in CHO cell manufacturing
- Experience in viral safety evaluation
- Experience in scale-down models
- Experience in preparation and execution of comparability protocols
- Knowledge of US GMP

Job expectations:

- Multifunctional interesting tasks in the emerging field of immune therapeutics
- Be part of the development of a "first in class" drug
- Highly motivated and energetic international team
- Competitive compensation

Expected start date:

- 1st March 2021

If you are interested in this challenging career opportunity, please send your CV, certificate of employments, salary expectations, application letter and your earliest possible entry date until January 31st, 2021 to the following e-mail address (confidentiality is of course guaranteed):

hr-germany@immutep.com

Privacy Statement for Applicants