Immutep is hiring:

Manufacturing Manager/Specialist Biologics (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 Manufacturing Specialist for Biologics. You will work closely with the Director of Manufacturing to support the process characterization and validation of Immutep's manufacturing process to support product commercialization of our lead candidate eftilagimod alpha. You will work conceptual and office-based. Your responsibility includes to oversight and manage the PC/PV 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 of process characterization and validation of commercial scale manufacturing process of biologics, especially antibodies and fusion proteins
- Support and manage PC/PV activities in liaison with external Contract Manufacturing Organization having profound knowledge in:
  - Drafting/reviewing master plan
  - Perform risk assessments
  - Identification of critical quality attributes (CQAs)
  - Identification of critical process parameters (CPPs)
  - Scale-down model (SDM) qualification
  - Process mapping
  - Proven Acceptable Range (PAR) studies
  - Unit operation(s) DOE studies
  - In-process sample stability
  - Impurity clearance
  - Process performance qualification (PPQ)
  - Comparability
- Writing / review of reports, batch summary reports, process validation reports
- Preparation of document package for BLA/MA
- Participate in management reviews of process performance, product quality and the quality management system
- Assist with regulatory submission preparations

- Provide requested input on forecast of annual budgets
- Provide requested input to Product Development Plans and Portfolio Review
- 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 PC/PV processes
- Experience of working in or liaison with a Contract Manufacturing Organization
- 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 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 2022

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 to the following e-mail address (confidentiality is of course guaranteed):

hr-germany@immutep.com

Privacy Statement for Applicants