Zumutor Biologics

https://www.zumutor.com/job/sample/

AD/QC – Head

Job Location
Bangalore, India

Date posted
July 3, 2019

Description
We are looking for people who share our passion for technological excellence and have process development capabilities with proven leadership qualities to oversee upstream process vertical in a competitive biotech environment.

Responsibilities

- Responsible for characterization and lot release assays of Biologics (intermediates, Drug substance and Drug product) using orthogonal methods,
  with different equipment skills (Analytical, Microbial and Biological)
- Preparation/Review/Revise of SOPs, STPs and data recording sheets
- Stability study protocols, method development protocol, qualification & validation protocols and respective reports
- To ensure that processes are followed as per ISO and GLP
- Carries out duties in compliance with local, state and CDSCO/RCGM regulations and international guidelines including USFDA and EMA
- Executes the Development, Qualification / validation of analytical methods
- Maintains detailed records in compliance with applicable GLP, safety and environmental requirements
- Provide technical reports, tech transfer documents, and prepare scientific presentations as needed. Write/revise SOPs when required
- Collaborate and coordinate with colleagues from all other groups
- Participate in technology transfer to external collaborators and partners
- Schedules, mentors, trains and supervises the quality control staff
- Problem solving and finding alternative solutions, smart ways to handle issues
  and come to logical conclusions

Preferences:

- Having complete knowledge on monoclonal antibody analysis and characterization
- Having experience in method tech transfer to CMO/CRO
- Preparing CMC dossier, IND application for NME (Biologics)
- Immuno-onco product experience is added advantage