




Company Description

Biocruces Bizkaia Health Research Institute is a Scientific Institution created by the Department of Health of the Basque Government, the Basque Health Service (Osakidetza), The University of the Basque Country, the Basque Foundation for Innovation and Research (BIOEF) and BBK Fundazioa.

Information

 Deadline: 2023-03-30
 Category: Business
 Province: Bizkaia

 Country: Basque Country
 City: Barakaldo

Company

Biocruces Bizkaia Health Research Institute

**biocruces
bizkaia**
osasun ikerketa institutua
instituto de investigación sanitaria

Main functions, requisites & benefits

Main functions

Design, development and implementation of quality management systems for Cleanroom. GMP documentation management: Writing of Standard Operating Procedures (SOPs), Quality Control instructions and validation protocols and reports. Maintenance and qualification of equipment and instruments, as well as documentation, preparation of protocols and reports. Registration and approval of materials and reagents required for the manufacture of advanced therapy medicinal products. Warehouse management, stock control and expiry dates of materials and reagents. Validation of analytical techniques according to European Pharmacopoeia: conventional PCR, real-time and quantitative PCR, quantification of endotoxins, sterility test and other analytical techniques. Preparation of samples for quality controls, registration and management of the sample library and stability studies. Performing and interpreting quality controls necessary for the release of advanced therapy drugs (Gram, mycoplasma, endotoxins, sterility, identification of mycoorganisms, agar plate seeding, microbiological monitoring of production rooms, DNA quantification by quantitative PCR, protein quantification by Elisa, cell characterisation by flow cytometry, virus titration, etc.). Compliance with environmental protection and occupational risk prevention standards in all activities of the production process. Monitoring, evaluation and analysis of action and training plans. Coordination of customer satisfaction surveys

Requisites

Requeriments: Degree in pharmacy, biology, biochemistry, biotechnology or related fields. Experience in quality control and quality assurance systems and training in Good Manufacturing Practice (GMP). Experience in cell culture. Experience in PCR/molecular biology, micro-organism culture, flow cytometry, virus production or virus control. Eligibility Criteria: Previous work experience in similar positions. 25. Formal training in advanced therapies or regenerative medicine. 25. Training/experience in quality management systems. 20. Communication and negotiation skills. 5. Proactive attitude and problem-solving orientation. 5. Proficiency in office automation. 5. Results-oriented. 5. Ability to organise, analyse and work as part of a team. 5. Disability certificate minimum 33%. 5

Benefits

Contract: Indefinite. Work day: Full time. Annual gross remuneration: 34.078,52 – 37.443,60 € gross annuals. Workplace: Biocruces Bizkaia Health Research Institute. Expected start date: Immediately