

TECHNICAL MANAGEMENT/QUALIFIED PERSON FOR CLEAN ROOM

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: 2023-05-03

Category: Business
Province: Bizkaia

Company

Biocruces Bizkaia Health Research Institute



Main functions, requisites & benefits

Main functions

Ensure that the production of each batch of medicinal product is carried out and controlled in accordance with current legislation. Record all procedures and document compliance with GMP in the manufacture of each batch of medicinal product, including quality assurance controls. Periodic review of documentation. Audits and inspections. Supervision of qualification and validation of equipment and processes. Risk management in validations. Data integrity and validation of IT systems. Validation of sterile areas. Equipment. Aseptic filling. Elemental impurities. Cleaning validations. Complaint management Quality defects and product recall. Quality in clinical trials and pharmacovigilance. Technical agreements, licensing and third-party manufacturing. Practical requirements in the export/import of medicinal products. Expert and expert reports

Requisites

Requeriments: Degree in pharmacy, biology, biochemistry, biotechnology or related fields. Training in Good Manufacturing Practice (GMP). Work experience in entities with manufacturing authorisation, qualitative analysis of medicinal products, quantitative analysis of active substances or tests and verifications that ensure the quality of medicinal products between 1 and 2 years minimum, depending on the training cycle undertaken (as specified in Community regulations for qualified persons). English (B2 minimum). Eligibilty Criteria Previous work experience as a qualified person in a drug manufacturing laboratory (30%) Training/experience in advanced therapies/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%) Ability to organise, analyse and work in a team (5%) Certificate of disability minimum 33% (5%)

Benefits

Contract: Indefinite. Work day: Full time. Annual gross remuneration: 34.078,52 - 38.856,80 € gross annuals. Workplace: Biocruces Bizkaia Health Research Institute. Expected start date: Immediately