QA TECHNICIAN

Company Description

VIRALGEN es una empresa dedicada a la fabricación de productos de terapia avanzada (ATMP), en concreto, de terapia génica a escala comercial o bien en las fases avanzadas de la etapa clínica. Un innovador desarrollo de la medicina que permite corregir los "defectos genéticos" de enfermedades genéticas y oncológicas gracias al desarrollo de la tecnología Pro10™.

Information

Deadline: 2022-12-15
Category: Business
Province: Gipuzkoa
Country: Basque Country
City: Donostia

Company

VIRALGEN VECTOR CORE

Main functions, requisites & benefits

Main functions

About the role We are seeking a QA Technician who will play a key role for our new Commercial Plant within the Quality Assurance department. The job involves stablishing and maintaining commercial QA department with the assistance of Quality Assurance Lead. Responsibilities Create, review, approve and maintain GMP documentation. Assist the technical teams on daily quality events with the support of all the Quality Assurance team. Support on project activities such as validations executions, creation of protocols, and write-ups of summary reports. Prepare and review: API, raw materials, bulk and finish product, release specifications. Review and approval of Pharma bulk and packaged batch records. Review and approve batch records for placing on the market or for regulatory purposes on different countries to be commercialized. Evaluation of daily problems encountered during the review of batch documentation and production necessities. Monitoring deviations reports raised on batches for approval. Review, maintain and approve all master batch records and their validation on SAP to manufacture according to the marketing authorization. Evaluate all requirements/requests made by the client (documentation request or information pertaining to product registration).

Requisites

Requisitos Pharmacist, Chemical Engineer, Chemist, Biologist, or similar University Degree. Quality Assurance expertise and extensive knowledge on revision of GMP documentation. Knowledge on electronic systems such as LIMS, Trackwise and SAP will be an asset. Biologics experience and sterile process is desirable. Familiar with GMP environment. Solid experience of 2-3 years within the sector with similar responsibilities. Desirable EMA or FDA. Desired Competencies: Fluent in English (writing and reading) and in Spanish, is highly desired. Ability to multi-task and meet deadlines in a fast-paced environment Demonstrated ability to work both independently and in a team environment Demonstrated ability to work well under pressure and meet tight deadlines Demonstrated passion for producing high-quality work Proactive management and positive attitude to change and challenges. Communication skills and self-management.

Benefits

Other benefits: Indefinite contract. Opportunities for professional development. Flexible schedule. Accompaniment in the learning and development process. Good working and international environment. Company activities. Social benefits.