LIMS SPECIALIST

Company Description

About us Viralgen is a CDMO born as a joint venture between Askbio and Columbus Venture Partners created in response to the unmet need for manufacturing of gene therapies. Our goal is to help broaden the access to these life-saving therapeutics and contribute to the advancement of health and human welfare around the world.

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

About you Degree in life sciences or clinical or healthcare related field (Pharmacy, Biology, Chemistry, Biotechnology or similar degrees) At least 2 years of experience working with the LIMS application or other operational technology systems e.g., MES, ERP etc.; knowledge and understanding of LIMS or other system application configuration. Knowledge of lab processes, preferably in Pharma/ Biotech including an understanding of GLP, cGMP (understanding of LIMS logics and flows, quality control and translating lab requirements into LIMS workflows) Knowledge of Microsoft Office tools and SQL. Fluent English, and Spanish Proactive management and positive attitude to change and challenges Communication skills

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.