QA CSV Specialist – GENETIC TESTING, BIOTECH

Nombre empresa: GENinCode

Funciones

As a QA CSV Specialist, your role will be:

Establishing and executing the company software validation master plan for all software in the following categories: In-vitro diagnostic medical device software (IVD-MD), internal platforms, and software for IVD-MD quality systems.
Establishing product source coding controls, managing, and tracking all changes, by liaising with internal SMEs and external subcontractors to make sure source code is stored in secure and access-controlled locations.
Ensuring that software internal or external applications and related infrastructures are validated for their intended use by a controlled and documented process within the company QMS before this is transferred to the production environment.
Ensuring that new software and changes to existing software or infrastructures are properly implemented in line with all phases of software Life Cycle Management including deployments and implementations.

Ensuring compliance with 21 CFR part 11 and equivalent EU requirements for all QMS electronic records.

Working with internal SME and external subcontractor to ensure compliance with regulatory cybersecurity and data integrity requirements.
Authoring and/or reviewing Product Manuals where applicable.
Authoring and/or reviewing software validation deliverables for IVD-MD product software and non-IVD-MD software, including but not limited to risk assessments, traceability matrix, user and system requirements, verification and validation plans, and executed test results reporting, ensuring accuracy and completeness of all documentation and raw data.
Authoring or reviewing Standard Operating Procedures within the company QMS related to In-vitro diagnostic medical device software (IVD-MD), internal platforms, and software for IVD-MD quality systems.

Working on issues of diverse scope where analysis of situation or data requires evaluation of a variety of factors, including an understanding of current business trends, providing support on customer enquiries and/or complaints management.
Abide by our company core behaviours for staff and all other policies, codes and practices

Descripción oferta

We are a leading Genetic Testing Organisation seeking an experienced QA CSV Specialist to join our team working remotely on a permanent, Full-time basis.
The post is open to applicants in the U.K. (commutable distance of London) and Spain (commutable distance of Barcelona).

THE PERSON

As a QA CSV Specialist, you MUST:
have at least 5 years of experience in a similar role, with a strong background in FDA, ISO and EU regulations for In-Vitro Diagnostics Devices and/or Medical Devices in particular FDA 21 CFR Part 820/Part 11 and ISO 13485.
have expertise in validation of enterprise-wide quality IT systems using established Computer System Validation (CSV) methodology such as GAMP 5, ISO/TR 80002-2, and FDA guidelines.

have training in Computer Systems Validation in In-Vitro Diagnostics Medical Device/Medical Device under IEC 62304 and IEC 82304.
have good knowledge of risk management tools (ISO 14971).
have good understanding of language programming, being desirable knowledge on the following languages R, python , Microsoft, NET", Java.
be fluent in English (oral and written) and desirable in Spanish.
live within a commutable distance to London or Barcelona.
regular local and some international travel required.

THE PACKAGE:

Subject to experience
Excellent company benefits

APLICAR