



Job Offer

Performing critical work that impacts our industry and our world's health while problem solving and innovating in the field – that's what Scientists at Active Biomarkers get to do every day. If that gets you excited too, then maybe working as a Computerized Systems Validation (CSV) Specialist at Active Biomarkers is a role to consider.

Within our Data Review & Lab support department, the **CSV Specialist is dedicated to supporting validation of computerized systems for the scientific departments.** In this role you get to further our mission as the core of Active Biomarkers, supporting critical aspects of our studies.

Learn more about what we do here: www.active-biomarkers.com.

Computerized Systems Validation Specialist

Full-time & permanent job (Contrat CDI à temps complet)

Location : Lyon (France)

Your Missions

Within our Data Review & Lab support department, you report to the Laboratory Director. The CSV Specialist is dedicated to supporting validation of computerized systems.

In this context, you:

- Are responsible for the development and the execution of the Computerized System Validation (CSV) deliverables for the company's systems, including control systems, complex instruments, and validated spreadsheets/reportables
- Participate in all aspects of validation projects, including documentation of project needs, analysis/research of needs and possible solutions, understanding technology and business solutions, gathering, documenting and updating business requirements; reviewing workflow process mapping; understanding business testing strategies and working with project members to execute the test plan.
- Analyze and identify areas to make efficiencies in the data management life cycle.
- Are responsible for development and execution of CSV deliverables through formal assessment, protocol development, testing, and reporting; providing a high degree of assurance that critical computerized systems meet design criteria/specifications for intended use and perform as intended.
- Support recommendations on software and system procurement to support lab goals.
- Support qualification processes and documentation. These documents include but are not limited to; User Requirement Specifications, Validation Plans, traceability matrix, design qualification, IOPQ protocols and summary reports, regression testing, data migration testing, supplier assessments, risk assessments, 21 CFR Part 11 assessments.

- Support software system maintenance and IQ/QO from supplier, qualification/validation plans, execution, and closure of all phases of validation projects.
- Manage the site computerized systems inventory and overall critical computer system lifecycle management, including Change Control and Periodic Review.
- Own / manage implementation of critical computerized systems (such as LIMS).
- Participate in investigations as needed.

REQUIRED BACKGROUND AND SKILLS

WHO YOU ARE

You will thrive at Active Biomarkers if you enjoy a relational environment, are purpose- and values-driven, embrace constant development and supportive leadership, and enjoy being part of innovative work.

BACKGROUND AND SKILLS

- Master's degree in science (BAC+3; BAC+5), Engineering, or Computer Science discipline preferred.
- Excellent English communication skills (oral and written).
- Accuracy and attention to detail.
- Reliability and consistency in work effort.
- Good understanding of Word and Excel.
- Ability to work independently and as a member of a team.
- Demonstrated relationship, team building skills and able to encounter challenges.
- Advanced understanding of the authoring of protocols, Validation Summary Reports and associated documents.
- Advanced understanding and experience with CSV regulations and guidelines such as GLP, FDA; 21 CFR Part 11 Guidance, Data Integrity and Compliance with CGMP Guidance for Industry; and cGAMP5.
- Advanced understanding of the Quality Management System, Change Control, and CAPA.

WHO WE ARE

We are a fast-growing contract research organization (CRO) based in Lyon, pioneering the latest drug development in both human and animal health fields. Demand for our expertise is growing and so is our need for great people to work in nimble, empowered teams committed to one another's growth. At Active Biomarkers, we advance both great science AND great people.

Interested in joining our Active team? Please send your application to info@active-biomarkers.com