Software Validation Analyst - Remote Job

Employer Name:

SpiderID: 12459363

Location: Tempe, Arizona

Date Posted: 4/26/2022

Wage: Negotiable

Category: Information Technology

Job Code: 2122/1351

Celerion is committed to swift, exceptional clinical research through translational medicine. Every day, we use our experience, agility, and innovative research strategies to help get drugs to market faster.  
  
   
  
 Are you looking for an opportunity to support a business creating life-saving treatments? If so, we can't wait to meet you!  
  
   
  
 We are hiring a Software Validation Analyst to join the team! In this role, you will ensure all of the computer systems Celerion uses work effectively in a highly regulated environment.  
  
   
  
 This is a full-time, 100% remote opportunity. You can work from home anywhere in the United States.  
  
   
  
 In this role, you will be responsible for direct interaction with internal customers to determine hardware, software and system requirements. You will define and analyze system needs/problems; design and test standards and solutions, create SDLC documentation and ensure validation documentation meets GxP requirements. You will organize and conduct project meetings and ensure timelines are established and met as well as liaise with software vendors for support and implementation needs.  
  
   
  
 Essential Functions:  
  
   
  
Performs and oversees software project validation in line with departmental SOPs and guidelines.  
  
Coordinates cross-functional leads responsible for UAT - providing them with test schedules, test data, direction, and detailed test scripts in accordance with the Release Schedule.  
  
Defines application requirements/problem by conferring with clients; evaluating procedures and processes.  
  
Develops solutions by preparing and evaluating alternative workflow solutions and analyzing potential software/hardware solutions.  
  
Implements solutions by establishing specifications/standards; coordinating production with programmers and/or software vendors.  
  
Oversees software installation according to software installation qualification requirements.  
  
Validates results by creating testing programs, test cases; performing and coordinating a team of users to execute test cases.  
  
Ensures system compatibility with operations by training client personnel; providing ongoing support.  
  
Ensures SDLC validation documentation content is complete, maintained and meets GxP requirements.  
  
Authoring of all validation deliverables including Plan, Requirements, Test Plan, Design, Protocols, Traceability Matrix, Baseline, Reports and Standard Operating Procedures (SOPs).  
  
Accomplishes information systems and organization mission by completing related results as needed.  
  
Coordinates IT vendors when working through software issues/defects and resolution paths.  
  
Monitors and performs monthly Microsoft patching and testing schedules for regulated applications.  
  
Performs system administrator functions for various software applications.  
  
 Qualifications:   
  
Bachelor's degree in a computer science field OR applicable experience in a medical, clinical, pharmaceutical or analytical setting  
  
Experience in a software validation or testing role  
  
Experience with MS Office software  
  
Awareness of 21 CFR part 11 requirements  
  
Awareness of US and European requirements for GMP/GLP/GCP computerized systems  
  
Excellent organizational skills  
  
Excellent communication skills  
  
Excellent problem solving/analytical skills  
  
Ability to work remotely from your home  
  
Flexibility to accommodate calls outside of normal business hours, when needed  
  
As a leader in clinical research, we consider COVID safety of paramount importance. We have supported COVID vaccination trials and related research. We have implemented strict protocols to ensure the safety of our employees and study participants. We continue to refine our approach and processes as UK local health authority guidance evolves.  
  
   
  
 Celerion Values: Integrity Trust Teamwork Respect  
  
   
  
 Are you ready to join our team?  
  
   
  
 Celerion is an Equal Opportunity Employer.

Start Date: ASAP  
  
  
Position Type: Full-Time Permanent  
  
  
Years of Experience Required:   
  
  
Education Required:   
  
  
Overnight Travel:   
  
  
Vacation Time:

Contact Name: Celerion

Company: Celerion