



COMPUTER SYSTEMS VALIDATION ENGINEER

Status: Full Time, Employee
Location: Miramar, Florida - USA
Work Status: Will *not* consider sponsorship for work authorization
Job Number: 2010-441

SUMMARY

This person will perform validation of computer systems in an FDA regulated environment. Responsible for preparation of change control and validation documents, preparation of summary reports, and preparation of test scripts.

With general guidance, employee will work with different functional areas to develop and implement efficient, defensible validation solutions for the site enterprise computer systems.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following. Other duties may be assigned.

- Confer with staff, users, and management to establish requirements for new systems or modifications.
- Perform and lead risk assessment exercises in support of validation activities.
- Participate in the development and implementation of change plans to existing validated computer systems.
- Developing and implementing validation plans of new computerized GxP systems
- Review deliverables for adequacy and completeness prior to systems implementation into production.
- Review requirements and design documentation to ensure traceability and testability
- Developing and executing IQ, OQ, PQ protocols.
- Development of test strategies for Off-The-Shelf and custom applications.
- Coordinate all validation activities by constant communication with affected departments and personnel.
- Ensure validation efforts are conducted in an appropriate and timely manner.
- Act as back up to validation peers as needed.
- Developing test scripts, user acceptance tests and Summary Reports.
- Participate in the resolution of test errors and validation issues.
- Participate in the periodic review of existing validated computer systems.
- Compilation and quality review of validation binders.
- Prepare procedures related to IT and computer system validation.
- Document activities and work according to SOPs.
- Other duties as assigned by area management.
- Maintain record of daily activities, problems and remedial action taken.
- Ensure that IT remains a desirable work environment, satisfying the career aspirations of all IT staff, consistent with the company objectives.
- Provides updates, status, and completion information to manager, problem request tracking system, and/or users, via voice mail, e-mail, or in person communication.

SUPERVISORY RESPONSIBILITIES

There are no supervisory responsibilities.

QUALIFICATIONS

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Experience in interpreting and implementing with regulatory (GMP, GxP, Validation, 21 CFR Part 11) requirements
- Excellent written and verbal communication skills
- Excellent interpersonal, organizational, and project management skills
- Ability to prioritize and manage multiple tasks
- Ability to work in a challenging and fast-paced work environment
- Excellent presentation and writing skills
- Good time management and organization skills; the ability to prioritize own work to meet tight deadlines while maintaining the highest standards of work
- Excellent project management skills

LANGUAGE SKILLS

Ability to read, analyze, and interpret general business periodicals, professional journals, technical procedures, or governmental regulations. Excellent written and verbal communication skills. Ability to write reports, business correspondence, and procedure manuals. Ability to effectively present information and respond to questions from groups of managers, clients, customers, and the general public. Excellent interpersonal, organizational, and project management skills.

MINIMUM QUALIFICATIONS

- BS in Engineering, Computer Science, Life Sciences or equivalent with 3 - 5 years experience
- Experience in a Biologics or pharmaceutical manufacturing environment is highly preferred
- Experience with validation of Manufacturing Execution Systems and Laboratory Systems) preferred
- Demonstrated experience in validation, investigations and change control
- Demonstrated experience in computer system validation

For consideration, submit resume to: careers@avevadds.com.

No phone calls please.

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