Validation Manager

Come join a growing company and learn more about Validations in the Life Sciences industry!

Based upon our customer contract requirements, SBS conducts both a background investigation as well as a drug screen following a conditional offer of employment.

Job Summary:

The Validation Manager will provide leadership and guidance to the Validation department, enabling them to perform at a high level that will support the achievement of the Company's strategic business goals. The Validation Manager will not only be responsible for ensuring timely completion of all Validation and Calibration activities, but will also hold a critical role in the growth and development of the Validation activities, as well as the growth of the Company as a member of the Management Team.

Job Responsibilities:

- Manage the validations, re-validations, and calibrations scheduling and ensure there is a forward-thinking plan for scheduling
- Ensure the activities within the department (Validation and Calibration) are performed according to approved procedures
- Lead the development, implementation and maintenance of Validation and Equipment procedures
- Develops a plan and strategy for outsourced Validation and Calibration at client sites. Communicates efficiently with client representatives regarding scheduling and results of outsourced Validation activities
- Responsible for ensuring SBS' strategies for temperature data acquisition and environmental monitoring are constantly assessed and improved upon. Must be able to plan the environmental monitoring strategies for future expansion
- Responsible for all departmental deviations and out of tolerance equipment, and will be responsible for identifying appropriate root causes and implementing effective Preventive Actions
- Will be a critical member of SBS' Audit Team as the expert on all Validation and Calibration issues and questions. Will be available during site visits or audits conducted by clients or regulatory/accrediting agencies including the

FDA. Will be responsible for providing audit responses to clients and or regulatory agencies within set deadlines

- Manage the validations, re-validations, and calibrations scheduling and ensure there is a forward-thinking plan for scheduling
- Ensure the activities within the department (Validation and Calibration) are performed according to approved procedures
- Lead the development, implementation and maintenance of Validation and Equipment procedures.
- Develops a plan and strategy for outsourced Validation and Calibration at client sites. Communicates efficiently with client representatives regarding scheduling and results of outsourced Validation activities
- Responsible for ensuring SBS' strategies for temperature data acquisition and environmental monitoring are constantly assessed and improved upon. Must be able to plan the environmental monitoring strategies for future expansion
- Responsible for all departmental deviations and out of tolerance equipment, and will be responsible for identifying appropriate root causes and implementing effective Preventive Actions

SKILLS / KNOWLEDGE / ABILITIES

- Must have the following personal attributes: personal accountability, work ethic, sound judgment, eagerness to learn and continuously improve, and a dedication to quality
- Strong leadership skills and the ability to effectively lead a team
- Ability to identify strategies to address complex issues and manage changing priorities and tasks in an active office and warehouse setting
- Strong knowledge of cGMP requirements and current industry practices
- Requires effective communication (written and verbal), organizational skills and the ability to exercise independent administrative judgment.
- Ability to understand and comprehend data generated during the course of testing, or other related activities as well as understands spreadsheet data, including charts and graphs
- Strong computer skills including Microsoft Office
- Requires in-depth understanding of SBS' monitoring systems and how they function
- Knowledge in building and facility operations is a plus

Desired Qualifications:

- Ability to operate forklift and scissor-lift.
- Experience in cGMP, GLP or other regulated environments.
- Familiar with SOPs, documentation and processes.

Working Conditions:

- Working in a repository and office environment
- Working in various temperatures from 23C to 20C
- Occasional work performed outside
- Very minimal travel is required for this position

EDUCATION & EXPERIENCE

• Bachelor's degree or equivalent education and experience

As part of our commitment to a diverse and inclusive workforce, SBS provides reasonable accommodations to qualified employees and applicants with disabilities to enable them to perform the essential functions of their jobs. The Company will not provide an accommodation that would create an undue hardship on the Company or endanger the health or safety of the employee or others.

SriSai Biopharmaceutical Solutions, LLC has been an industry leader since 2002 specializing in providing Clinical Supply Management services to the Pharmaceutical and Biotech industries. We maintain a high level of service excellence and excel in meeting the needs of our clients. Critical to SBS's mission and the foundation of every position at our company are our core values: Integrity, Excellence, Respect and Customer Focus. Our dedicated team of professionals take great pride in supporting scientific innovation.

SriSai Biopharmaceutical Solutions is an EEO/Affirmative Action Employer and does not discriminate on the basis of race, color, religion, sex, sexual orientation, gender identity, national origin, protected veteran status, disability or any other legally protected status. Based upon our customer contract requirements, SBS conducts both a background investigation as well as a drug screen following a conditional offer of employment.

Benefits:

Comprehensive benefits package including health coverage, dental, vision, life, IRA and company matching

- Paid holidays and floating holidays
- Generous PTO
- Continued training
- Emphasis on promotion from within

Work Remotely

• No

Work Location: One location

Job Type: Full-time

Salary: \$75,000.00 - \$95,000.00 per year

Benefits:

- 401(k)
- 401(k) matching
- Dental insurance
- Employee assistance program
- Flexible spending account
- Health insurance
- Health savings account
- Life insurance
- Paid time off
- Vision insurance

Schedule:

- 8 hour shift
- Day shift
- Monday to Friday

Work setting:

• In-person