Process Validation Engineer
Upstate South Carolina

Summary

This position executes process validation activities that meet worldwide regulatory agency requirements, internal company standards/best practices and current industry practices. This position interacts with the client and the cross functional client team members to develop process validation strategies and creates process validation protocol and summary documents. This position reports to the Validation Manager.

Essential Duties and Responsibilities (these are primary responsibilities of the role and the incumbent will perform other duties as assigned)

- Supports the process validation program.
- Interacts with the client and client team to define process validation scope.
- Designs and executes the appropriate development studies to define process parameters.
- Creates a risk assessment of the process to be validated.
- Creates process validation protocols.
- Conducts or coordinates process validation execution for new products.
- Prepares validation summaries.
- Uses statistical tools to analyze data.
- Performs annual reviews of validation projects.
- Investigates and executes validation related Corrective and Preventive Actions.
- Performs validation related investigations as needed.
- Participates in regulatory inspections.

Qualifications

- Bachelor's degree required, preferably in a science or engineering related field
- Minimum of 2 years pharmaceutical industry experience in parenteral manufacturing
- Computer proficiency in Microsoft Word, Excel, and Outlook and the ability to use enterprise software (examples include: JDE, Pilgrim, Trackwise, etc.)

Physical / Safety Requirements

- Duties may require overtime work, including nights and weekends
- Use of hands and fingers to manipulate office equipment is required
- Position requires sitting for long hours but may involve walking or standing for periods of time.
- Must be able to gown for Grade C area