

****Senior Scientist, SAS (Melville, NY)****

This is a research position working on validation studies for regulated products. Through analytical testing, determinations must be made whether analytical methods are suitable to use for quality release testing as per FDA/ICH requirements. This process must be conducted on all new products to ensure they comply with corporate and global regulatory requirements. Validation testing includes performing standard test methods and developing new methods. Also responsible for maintaining data integrity via notebook review/approval, audit trail review/approval, performing software backups, creating and executing validation/forced degradation protocols, authoring and reviewing validation protocols and reports, ensuring system/user access is maintained and GDP is followed. Provides technical/analytical support to Global QA Laboratories. Must have excellent analytical chemistry skills, strong knowledge of compliance and cGMP, communication skills, excellent organizational skills, time management skills, be able to interact with senior management and formulation chemists.

-Maintaining data integrity via notebook review/approval, audit trail review/approval, performing software backups, creating and executing Performance qualification/validation/degradation protocols, authoring validation protocols and reports, ensuring system/user access is maintained and GDP is followed.

-Coordinates workflow based on corporate timelines. Organizes and approves data for the validation team. Reviews and approves validation reports.

-Provides assistance to Global QA and QAS Labs.

Qualifications - External

-Extensive knowledge of Analytical Instrumentation, Chemistry, Pharmaceutical regulations and Pharmaceutical Industry in general, especially focused on analytical validation. -Excellent written and verbal communication skills.

-Ability to manage many critical processes simultaneously.

- Ability to communicate results and important findings to internal and external departments and write technical reports for Governmental Agencies, Legal and Senior Management.

-Bachelor's Degree in Chemistry Related Field (Masters is preferred).

-3-5 Years Minimum Experience

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