NEOMED-LABS, Laval, Quebec
Software Validation Specialist

Job Description

NEOMED-LABS is a growing Contract Research Organisation (CRO) offering high quality immunology laboratory services to support vaccine clinical trials (www.neomedlabs.com).

We are currently seeking a highly motivated candidate with experience to fill the position of Validation Software Specialist. This position reports to the Associate Director, Operations Support and requires extensive knowledge of software and commercial laboratory equipment.

The primary role is to provide technical support validate laboratory computerised systems and equipment while ensuring compliance with internal procedures (e.g. GAMP5, 21-CRF-11, BPCL, BPL).

Main responsibilities

- Perform full validation of laboratory computerized systems (including custom developed software) and equipment;
- Write, review and execute software validation documentation (e.g. URS, FS, IQ/OQ/PQ) according to business needs and internal procedures;
- Coordinate interventions with manufacturers and ensure change control validation prior to release;
- Ensure calibration, maintenance, environmental monitoring and repairs in compliance with internal procedures.

Knowledge, skills and abilities

- Skilled to research complex documentation autonomously;
- Excellent English writing and problem-solving skills;
- Proficient with MS office tools (e.g. Word, Excel, Outlook);
- Ability to work methodically with a concern for precision and accuracy;
- Excellent team work, service oriented and organizational skills;
- Bilingual in English and French.

Qualifications

- Background education in life sciences or engineering;
- Minimum of two (2) years' experience at validating computerized systems and laboratory equipment for regulated use in the pharmaceutical industry;
- Form based application programming experience (e.g. #, VB.Net, VBA) would be an asset.