Senior Scientist (Scientist III)

The Company:

Ortho Clinical Diagnostics, Inc. (OCD) is a leading provider of in vitro diagnostic products and services, offering accurate, timely, and cost-effective solutions for screening, diagnosing, monitoring and confirming diseases. The company has approximately 3,800 employees around the world serving the global clinical laboratory and transfusion medicine community, and is committed to providing customers with products, services and process solutions to make labs more efficient in delivering the quality test results doctors and patients need.

OCD was recently acquired by global alternative asset manager The Carlyle Group as an independent, freestanding company. With new leadership and accelerated investment in research and development, OCD is well positioned for growth as a leading player in the global diagnostics market, tapping into rising demand for sophisticated medical diagnostic products and services worldwide.

The Position:

We are seeking a regular position as a Research & Development Senior Scientist to work in a team environment working on developing new assays for our VITROS analyzer systems. The successful candidate will be able to apply standard scientific and mathematical principles, theories, concepts, and techniques and will be responsible for leading a compliant development of a new assay on our VITROS chemistry analyzers while developing and maintaining an in-depth knowledge regarding our reagent technologies and the assay interactions with the VITROS systems and software. The job will consist of ensuring the assay development is completed within the Quality System according to the project schedule and will be responsible to lead and train others.

The Responsibilities:

- Functions as key technical leader on critical development projects ensuring timely commercialization of products that meet or exceed customer expectations. Leads a technical team and plans, designs test protocols, performs testing, analyses the experimental data, and summarizes the results aimed for the development of new VITROS in vitro diagnostic products or processes using established protocols and SOP's.
- Prepares technical reports, including quantitative analysis, and participates in scientific meetings and presents technical findings.
- Responsible for maintaining accurate records of work performed in accordance with cGMP and the procedures outlined in the Quality System. This includes Design History Files, other associated testing documentation, and claims papers for regulatory submissions.
- Defines and maintains world class best practices in the science of IVD assay and system design that allows them to impact business critical projects across all lines of business.
- Mentors lower level scientists for day to day direction, and reviews and approves report or memos from lower level scientists

The Individual:

- A minimum of a Bachelor's Degree in Analytical Chemistry, Clinical Chemistry, Organic Chemistry, Biochemistry or Physical Chemistry with 5-7 years industrial experience, 3-5 years with MS or 1-2 years with a Ph.D. in Analytical Chemistry, Clinical Chemistry, Organic Chemistry, Biochemistry or Physical Chemistry is required.
- Research experience and track record of product development or publications in the area of Cardiac, Metabolic or Infectious Disease is a plus
- Previous experience in experimental design and analytical analysis, including data evaluation and interpretation is required.
- Basic computer skills (MS Word, MS Excel) along with excellent verbal and written communication skills will be required. Experience in MiniTab or other statistical software is desired.
- Successful candidates will have made strong independent technical contributions that are substantiated by a track record of peer-reviewed publications, patents, and / or commercialized products.
- Candidates should have excellent written and oral communication skills and a demonstrated ability to work in an interdependent, collaborative environment.
- Experience in the IVD industry, with GMP/QSR, ISO and related regulations as well as Process / Design Excellence Green Belt or Black Belt training is preferred.
- Experience with evaluation and statistical analysis using methods such as the CLSI documents is preferred.
- Experience in identifying and resolving problems for IVD Medical Devices is preferred.
- This position will be based in Rochester, NY.

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