



*Position Title:* Sr. Director/Executive Director, Microbiology

*Department:* Clinical

*Reports To (title):* Vice President, Clinical Affairs

*Location:* King of Prussia, PA

*Date:*

Exempt     Non-Exempt

*Summary of Position:*

Individual is responsible for design and implementation of clinical microbiology programs required to support IND submissions, phase II-IV protocols, NDA and other regulatory submissions, and post-marketing commitments including surveillance.

Responsible for quality data and comprehensive data to support the microbiology section(s) including breakpoint for all anti-infective NDA and other regulatory filings.

The individual is responsible for providing basic science and microbiology expertise for competitive intelligence and due diligence reviews of new chemical entities or products.

Responsible for microbiology input to strategic planning and execution of external non-human research, publication planning and strategy, and competitive research strategy.

Responsible for antimicrobial susceptibility testing platform development.

A scientific resource capable of conducting high level scientific and strategic interactions with employees as well as external thought leaders. Possess the ability to expertly communicate concepts, ideas and information both in writing and via formal presentation.

Responsible for supporting drug development by strategically planning timelines and budgets for all aspects of antimicrobial susceptibility testing platform development, clinical trial support and regulatory filings.

*Position Responsibilities:*

- Design and execute clinical microbiology program(s) required to support phase II-IV protocols, NDA and MAA submissions and launch.
- Responsible for basic science/microbiology sections of regulatory submission documents for the EU, USA, and ROW.
- Responsible for basic science and microbiology of Health Agency negotiations and meetings: Scientific Advice, Pre-submission meetings, labeling negotiations.
- Responsible for scientific support and data generation for life cycle management: Periodic Safety Update Reports (PSURS), Pediatric Investigations Plans, supplemental indications Presentations and negotiations with antimicrobial susceptibility testing committees: Clinical Laboratory Standards Institute (CLSI), European Committee on Antimicrobial Susceptibility Testing (EUCAST), and US Committee on Antimicrobial Susceptibility Testing (USCAST).
- Responsible for clinical trial support including development of protocol, SAP and data quality review plans.

- Establish *in vitro* antibacterial studies and infection models with experts, initiate and monitor large international antibacterial surveillance programs.
- Initiate and drive Antimicrobial Susceptibility Testing Development.
- Provide basic science and microbiology support for competitive intelligence and due diligence reviews of new chemical entities or products.
- Accurately and regularly communicate the technical and business aspects of the project work being conducted to team.
- Support drug development by strategically planning timelines and budgets.

*Candidate Requirements:*

- 10+ years microbiology experience.
- Demonstrated pharmaceutical experience including NDA, MAA and other regulatory filings and interactions preferred.
- Demonstrated skills in managing scientific projects/programs.
- Demonstrated capability for scientific, creative and strategic thinking, championing ideas for positions, and ability to present scientific data and concepts effectively.
- Demonstrated comprehensive skills in establishing and maintaining collegial peer-to-peer relationships with a wide range of external thought leaders/investigators including physicians, pharmacists, and allied healthcare professionals.
- Ability to assess and respond to clinical information, scientific/medical concepts and intellectual property, and to integrate such information into the development of effective and relevant research projects.
- Ability to expertly communicate – orally, in writing and via formal presentation.
- Ability to resolve emerging issues using existing teams and/or an established network of expert consultants.
- Experience managing budgets.
- Sound knowledge of microbiology epidemiology, regulatory requirements, susceptibility testing and diagnostic microbiology.
- Good interpersonal skills with the proven ability to work in a matrix-team environment and the ability to lead internal and external microbiology activities.

*Additional Information:*

- Technology needs: Microsoft Office
- Travel requirements (%): 10%, as needed (domestic or international)