708 Quince Orchard Road
Gaithersburg, MD 20878
www.OpGen.com
Support 888.856.2748
Corporate 301.869.9683
Fax 301.869.9684

Director, Clinical Laboratory

OpGen is a precision medicine company using molecular diagnostics and informatics to help combat infectious disease. We are developing molecular information products and services for global healthcare settings, helping to guide clinicians with more rapid and actionable information about life threatening infections, improve patient outcomes, and decrease the spread of infections caused by multidrug-resistant microorganisms, or MDROs. Our proprietary DNA tests and informatics address the rising threat of antibiotic resistance by helping physicians and other healthcare providers optimize care decisions for patients with acute infections.

We seek a Director, Clinical Laboratory (DCL) to lead the operation and administration of the OpGen clinical laboratory and to participate in the next phase of development and commercialization of our Acuitas AMR Gene Panel rapid test and the Acuitas Lighthouse Software for antibiotic decision making. The DCL will be a subject matter expert for infectious disease laboratory diagnostics. He/she will have a strong working knowledge of clinical diagnostic methods for detection of MDROs including culture-based phenotypic microbiology, DNA-based rapid diagnostics and DNA sequencing. The DCL will develop ongoing professional relationships with laboratory professionals and clinicians to help achieve positive outcomes for patients, facilitate peer to peer education and scientific publication programs. The DCL is responsible for implementing all applicable regulatory and accreditation standards and leads OpGen's efforts for the design, validation, and delivery of clinical services and establishes our organizational commitment to quality and compliance. The DCL will provide medical and scientific expertise to help shape the company's product development, regulatory and commercialization strategies towards positioning OpGen as a leader in precision medicine.

The position is based in our Gaithersburg Maryland headquarters and will report to the Vice-President of Operations. He/she will interface with OpGen current and prospective customers, our Clinical Advisory Board (CAB) as well as other clinically focused working groups and external stakeholders including physicians, healthcare executives, and key opinion leaders.

Primary Activities:

- Manage our BSL2 laboratory for testing of third party clinical samples, internal product and verification/validation studies, and manufacturing quality control testing.
- Manage our biorepository and assist in sample acquisition efforts.
- Ensure that the appropriate laboratory equipment and supplies are selected, designed, and tested.
- Establish an effective quality management program. This includes the approval of Quality System controlled documents, metrics reports, encouraging efforts to improve laboratory processes and procedures, reviewing audits, implementing responses to CAPAs, establishing a quality control and quality assessment program, etc.
- Ensure that our laboratories are staffed with qualified personnel and that policies and procedures are established for monitoring pre-analytical, analytical, and post-analytical phases of testing. When necessary, providing remedial training or continuing education.
- Define the specifications for and manage the Laboratory Information Management System (LIMS) processes.
- Establish a validated laboratory testing system for all aspects of test performance to provide the high-

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quality results required for patient care and/or regulatory submission.
- Maintain productive relationships with accrediting and regulatory agencies.
- Participate in the development and execution of OpGen's publication strategy including authorship of journal publications, white papers and other contributions to the scientific and industry literature.
- Consult with the laboratory's clients on matters relating to test results and their medical significance to specific patient conditions.
- Serve as the Technical Supervisor, responsible for the scientific oversight of the Laboratory and ensure the safety of personnel and minimize the risk to operations.
- Create analytical and clinical validation plans for products seeking FDA 510(k) or PMA approval.

Qualifications:

- PhD, D(ABMM) and/or Doctoral degree in a biological or clinical laboratory science from an accredited institution
- Expert knowledge of molecular and microbiology
- At least 5 years of experience in a clinical laboratory, 2 in an overall management capacity.
- Meet the qualification requirements including education, experience, and certification, established by MDDOH and CLIA.

At OpGen you will find a vibrant culture, that values scientific and business excellence with the goal of improving human health. Please send your resume and any other pertinent information to the Senior Director of Human Resources at **arisdorfer@opgen.com.**

March, 2018