



## MICROPHAGE

MicroPhage Incorporated  
2400 Trade Centre Avenue  
Longmont, CO 80503

### **Quality Control/Assurance Associate**

Based in Longmont, Colorado, privately-held MicroPhage, Inc. develops innovative, easy-to-use diagnostic products for bacterial identification and antibiotic susceptibility/resistance testing using its proprietary Bacteriophage Amplification Technology (BAT™) platform. The U.S. Food and Drug Administration (FDA) granted 510(k) clearance for the KeyPath™ MRSA/MSSA Blood Culture Test – BT in May 2011 and we will initiate US sales in October of 2011. We have recently signed a partnership agreement with Cardinal Health to distribute and sell our product.

Currently doctors treat bacterial infections with antibiotics for 2-3 days before lab results guide better choices in therapy. Frequently, the initial therapy is sub-optimal or even inappropriate for the patient's condition. MicroPhage technology dramatically improves this paradigm by providing doctors with the results they need on day one. As MicroPhage expands its test menu there can now be imagined a day within our lifetime when physicians will be able to rapidly optimize antibiotic therapy for all patients and eliminate the days of watching and waiting. How would this change clinical practice? Outcomes? Mortality rates? Hospital economics? Frankly, we are just getting our arms around it ourselves, but we could use your help.

MicroPhage is poised for growth and we need to strengthen our Quality team to support our increased manufacturing scale. We are seeking an experienced Quality Control/Quality Assurance Associate ideally with experience in GCP and GMP environments.

### **Position Summary/Objective**

Under limited supervision performs tests and oversees results for raw material, in-process and finished product quality testing and/or release. Writes standard operating (SOPs) and assists with investigating and resolving assay failures and troubleshooting analytics and equipment. Leads and executes process/method validation studies. Ensures compliance with cGLP and cGMP standards and documentation related to product manufacture.

### **Essential Duties and Responsibilities**

1. Performs analytical testing on raw materials, in process and finished product per written procedures. Reviews data obtained for compliance to specifications and reports abnormalities.
2. Assist with the review of commercial drug product batch records and all supporting documentation to ensure approval of the commercial lot in a timely manner.
3. Writes and revises Standard Operating Procedures/analytical methods and performs method development. Compiles data for documentation of testing methods and procedures.

4. Leads Quality Control method development and method validation.
5. Assists in the defense of Quality Control data and programs with outside agencies. (FDA, ISO, etc.)
6. Manages and assists with analytical and microbiological testing.
7. Assists staff members with troubleshooting, investigating and resolving assay failures and product failures and closing out discrepancies.
8. Performs laboratory investigations, troubleshoots analytical methods and equipment. Submits results of investigations and discusses results with other staff members. Provides hands-on support in the lab to accomplish assigned tasks.
9. Assists in the area of Quality Control Quality Systems. Able to train staff on requirements.
10. Provides support on various other quality control issues as necessary, ensuring the precision, accuracy, and reliability of Company products.
11. Assist with the management of Change Control, Deviations, NCMRs and CAPAs.
12. Reviews documents impacting regulatory filings such as specifications, stability protocols, batch records, manufacturing formulas, test methods, validation protocols and reports, etc.
13. Maintain current knowledge of cGMP, ISO and related regulations.
14. Takes proper safety precautions to prevent accidents. Responsible for the safety of self, others, materials and equipment. Uses all required self-protective and safety equipment and follows all safety regulations, policies and procedures.
15. Additional duties as assigned.

#### **Required Competencies (Skills, knowledge, abilities)**

- Detailed knowledge of cGMP, cGLP and ISO standards; understanding of Quality Systems
- Experience reviewing Manufacturing Batch Records and associated supporting data required
- Proficient knowledge in the use of common lab equipment
- Ability to deal accurately with a high level of detail
- Solid oral, written communication skills and interpersonal skills
- Proficiency in the use of Microsoft office suite (Word, Excel, Power Point, Outlook)
- Experience performing Quality Control method development and method validation

#### **Education and Experience**

Bachelor's degree in life science and a minimum of 5 years of experience in Quality Assurance/Quality Control in a regulated industry; at least 5 years of experience with medical devices or biological diagnostics or equivalent education and experience.

#### **WORKING AT MICROPHAGE**

The work environment at MicroPhage is characterized by teamwork and collaboration. Employees are engaged and passionate about their work. The atmosphere is friendly, casual, and professional. We expect every single employee to have an impact on our success. MicroPhage offers a full range of benefits including insurance coverage for medical, dental and vision. The Company offers 401k participation and an opportunity for company stock options. Compensation is competitive and based on experience and qualifications.

**How to Apply**

If you believe you have the drive and the talent to make a significant contribution to our growing organization, we encourage you to submit your resume or CV, a cover letter describing how your background fits our needs, your salary expectations, and two professional references to [jobs@micro-phage.com](mailto:jobs@micro-phage.com). Please type **Quality Associate** in the subject line of your email. Applicant materials received by November 7, 2011 will be given priority attention. MicroPhage is an Equal Opportunity Employer.