

Job Description

Position Title:	Quality Control Analyst II
Reports To:	Quality Control Manager
Department:	Quality Control
Date Revised:	April 2013
FLSA Status:	Non-Exempt (hourly)

Summary:

The position will include routine testing of in-process and final container samples for the release of avian vaccines. The individual will be responsible for ensuring all methods are performed as written and filed with regulatory agencies.

Duties and Responsibilities:

1. Perform accurately all required tests for bulk antigens, final products, and raw materials, as well as other procedures necessary to support company and laboratory objectives under cGMP and GLP guidelines to meet specified timelines.
2. Operate and proactively maintain laboratory equipment. Ensure that equipment maintenance is properly documented in a timely manner.
3. Maintain accurate and concurrent testing records in accordance with USDA regulations, compare test results against prescribed parameters, and reports findings to the QC Manager and other departments as needed.
4. Assist with validating and troubleshooting assays.
5. Provide backup support for virology and microbiology assays for other QC analysts.
6. Occasional weekend and off-hour work may be required.
7. Other duties as assigned by the QC Manager.

Competencies:

1. Performs all duties, procedures, techniques, and completes paperwork with persistent focus on quality and safety. Supports a culture of quality by encouraging co-workers to be diligent in the performance of each task, continually striving for accuracy. Participate at the direction of the QC Manager to support research, production, and/or other departments to achieve company quality objectives.
2. Provides effective training of QC Analyst I's, as appropriate or assigned, confirming that they have been properly trained on the procedure at hand and all required training documentation has been completed. Understands and can effectively communicate the necessity for, and the effects of, each task performed.
3. Actively contribute to a team setting with the laboratory and potentially with other work teams to increase efficiency, solve problems and improve quality. Must be a team player; fostering positive productive relationships within the department and across departmental lines.
4. Open minded and positive in regard to change, with a focus on continual improvement.
5. Proficiently performs all procedures as specified, and trained for, by the company with proper technique. Understand and accurately performs all aspects of a specific area from set-up to completed paperwork with final results independently.

6. Records and reports all data accurately, honestly, legibly and within specified time frames.
7. Asks applicable questions of appropriate sources and continually seeks to understand the 'why' behind duties performed.
8. Performs duties according to established Standard Operating Procedures (SOP's) and company safety procedures. Assists with maintaining SOP's; uses proper change control procedures when drafting or recommending updates.
9. Demonstrates initiative by pro-actively identifying issues, obstacles, opportunities, possible solutions and the next step of action. Demonstrates initiative to take on new responsibilities and assist in other laboratory areas.
10. Consistently strives to produce appropriate volume of work with high quality results.

Qualifications:

Bachelor of Science degree in Virology, Microbiology, Bacteriology, Biology or related field with a minimum of four (4) years of laboratory experience in biotechnology and/or aseptic processing required. Advanced knowledge of virology and tissue culture methods required. Understanding of Good Laboratory Practices (GLP) and good aseptic technique required. Must be able to understand and apply cGMP requirements. Understanding of and ability to ensure compliance with USDA and EU guidelines is required. Good documentation practices as well as the ability to follow and comprehend a written procedure is a requirement. Individual must have a proven track record of working in a team environment and handling multiple tasks simultaneously and complete tasks according to deadlines and specified time frames. Must demonstrate flexibility, adaptability and initiative. Must have excellent written and oral communication skills, excellent planning and organizing skills, as well as proficiency in MS Word and Excel. Must be quality minded, detailed oriented, conscientious and responsible. Quality Management System experience desirable (ISO 9001-2008). Working knowledge of Code of Federal Regulations or European Pharmacopeia desired.

***Note:** All LAHI job descriptions are guidelines to assist employees in awareness of qualifications and performance expectations for their respective positions. It is not possible or desirable to commit every detailed aspect of each job to a written description. Each employee is expected to continually improve their knowledge and understanding of their job requirements and to use this information to increase insight as to the scope of their responsibilities. Job descriptions cannot be used as an argument to refuse work assignments.*

Incumbent Signature

Date