

ENTURIA INC.**JOB DESCRIPTION**

JOB TITLE: PRODUCT DEVELOPMENT MICROBIOLOGY
LAB LEAD

LOCATION: El Paso, Texas

DEPARTMENT: Product Development

REPORTS TO: Director, Product Development

<i>REVISION SUMMARY</i>	
CAF NUMBER	2008-05-65
REVISION	A
DATE	5/28/08
SUMMARY OF CHANGE	NEW

SUMMARY:

See duties and responsibilities.

DUTIES AND RESPONSIBILITIES:

1. Responsible for Method Development and Methods Validation in the area of microbiology and materials as related to new products.
2. Responsible for development and execution of Design of Experiments (DOE) for new product Synthesis Trials.
3. Supports scale-up transitions from laboratory processes to pilot plant to production.
4. Responsible for overall Regulatory Compliance in the area of Microbiology and Formulation for new products.
5. Responsible for microbiology support of Stability Study Programs for Product Development projects as well as routine testing.
6. Responsible for sampling and testing of existing and new raw materials.
7. Responsible for formulated product testing and standardization and maintenance of test solutions.
8. Able to provide strategic input on Microbiology research and compliance programs to support new product development.
9. Performs Protocols, Engineering test, hypothesis testing and statistical evaluations.
10. Leads troubleshooting efforts.

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11. Performs contract Sterilization Audits and Internal Audits as assigned.
12. Responsible for training and mentoring microbiology staff on industry and company best practices.
13. Provides leadership in assuring all lab personnel follow Standard Operating Procedures, as well as other company policies and procedures, and GMP's.
14. Creates and updates procedures for Laboratory functions through documentation process.
15. Maintains and implements efforts in housekeeping, as well as safety programs.
16. Must have awareness and respect of all company policies and safety rules.
17. Responsible for the completion of the appropriate documentation, i.e. batch records, logbooks, and forms.
18. Communicates with lab staff on schedules, project status, key constraints and safety issues.
19. Responsible for new product concept feasibility and investigation.
20. Must be willing to interact with all other departments to promote open communication and assure departmental alignment.
21. Daily task and testing prioritization for self and other group members.

SUPERVISORY RESPONSIBILITIES:

Direct supervisory responsibility of laboratory microbiology staff team members and input on supervised associates overall performance. This role will not be responsible for performance reviews.

EDUCATION/CERTIFICATION:

BS, MS or PhD in Biology, Biochemistry, Microbiology, or a related field.

PHYSICAL DEMANDS:

No unusual physical requirements.

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EXPERIENCE:

Basic principles of microbiology involving cell culture, growth and production. Education and experience requirements as follows:

B.S.: 4 or more years of experience

M.S.: 2-4 years of experience

Ph.D.: 0-2 years of experience

COMPUTER SKILLS:

Computer literate.

Basic commercial software packages, MS-Word, MS-Excel and Chemstation Software.

OTHER SKILLS:

1. Must have good written and oral skills, and the ability to organize and follow-up.
2. Must be a team player.
3. Must have an outstanding record in attendance, punctuality and discipline.
4. Must champion safe and efficient laboratory practices by setting the example.