Position Title: Scientist, Quality Control Compliance Microbiology
Location: Summit West, S-12

PURPOSE AND SCOPE OF POSITION:

The Senior Scientist QC Compliance Microbiology will work both independently and with the team overseeing all of the QC microbiology related compliance records across Deviations, CAPA’s and Change Control. This role will be primarily responsible for providing technical assessments in relation to product impact, disposition assessments, root cause analysis, and hypothesis driven investigational testing plans. In addition, this role will work closely with the Lab Excellence team on areas for improvements.

This position is part of the Summit Quality Control Compliance Team, which is comprised of two pillars: Compliance and Continuous Improvement. While this is a site-based role, collaboration across other sites in the CTDO network and the BMS Global network is essential.

REQUIRED COMPETENCIES: Knowledge, Skills, and Abilities:

- Carry out responsibilities in accordance with the organization’s policies, procedures, and state, federal and local laws.
- Ensure compliance with current Good Manufacturing Procedures (cGMP), USP, EU and other global regulatory requirements at all times.
- Follow directions properly, work cooperatively as an individual contributor and as a team member.
- Communicate effectively with QC peers, cross-functional peers and management.
- Must have strong microbiological technical skills to provide assessments in relation to product impact, disposition assessments, root cause analysis, and hypothesis driven investigational testing plans.
- Must have strong authorship and be able to critically review investigations, interpret results and generate technical conclusions consistent with Quality risk management principles.
- Must be able to routinely recognize quality issues and interpret problems, as well as propose solutions for complex issues.
- Must understand continuous improvement and be able improve the compliance and efficiency of the quality system.
- Must be able to effectively prepare and convey data analysis to management and others within the group with clarity and accuracy.
• Must be self-directed, complete routine tasks independently and be confident in making decisions in respective subject matter area, consulting with management for decisions outside of established processes.

• Requires minimal direction to complete more complex tasks.

• Comfortable providing input/guidance to others within the department and across the organization in deviations technical writing.

• Knowledge of problem-solving methods used to perform Root Cause Analysis

• Propose solutions for issues and work with management to resolve.

• Able to prepare written communications and communicate problems to management with clarity and accuracy.

• Able to support internal and health authority inspections of facility.

• Author and revise controlled documents such as Standard Operating Procedures and Controlled Forms. Author non-routine Protocols/Validation Plans/ reports as needed.

• Support investigations and CAPAs associated with QC Department.

• Support data trending and tracking of results and draw conclusions from said data.

• Take ownerships/accountability of assigned tasks and come up with solutions/improvement suggestions.

• Perform all other duties as assigned by Management.

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<tr>
<th>Education and Experience:</th>
<th>Requires Bachelor’s degree in Microbiology, Molecular Biology, or related discipline. Minimum 3 years of experience working in a regulated manufacturing environment.</th>
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<td>An equivalent combination of experience/education is acceptable</td>
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**DUTIES AND RESPONSIBILITIES:**

- **Identify opportunities for operational improvement in the Quality Control department for Deviations, Corrective and Preventative Actions and Change Control relative to CTDO and Summit - S12 goals.**
- **Responds to challenges and additional workload in a professional and objective manner.**
- **Ability to multitask, prioritize workload, document properly and interpret data accurately.**
- **Collaborate with other Site and network Operational Excellence team members to ensure initiatives external to the S12 site can be leveraged to obtain intended benefit of those external initiatives.**
- **Excellent writing and presenting skills.**
- **Develop and implement standard operating procedures, work practices and guidance’s.**
- **Other responsibilities as assigned by management**

**WORKING CONDITIONS (US Only):**

- **Equipment Usage During Work Period: Computer 70%; Phone and Electronic Devices 30%.**
- **Sitting at a computer terminal for an extended period.**
- **Requirement to work in a conference room / meeting environment for moderate periods of time.**
- **Occasional periods in labs or production area, requiring some level of gowning.**
- **Light to moderate lifting.**
- **Regular, predictable attendance is required, plus flexibility with schedule (weekends, holidays, extended hours) as business demands dictate.**
- **Moderate noise i.e., business office with computers, phone, and printers.**

This job description is intended to describe the general nature and level of work being performed by the person assigned to this position. The primary duties and responsibilities are intended to describe those functions that are essential to the performance of this job. This job description does not state or imply that the above are the only duties and responsibilities assigned to this position. There are other duties and responsibilities that are considered incidental or secondary to the overall purpose of this job. Employees holding this
position will be required to perform any other job-related duties as requested by management.

This is the end of the Official Use document

REFERENCES AND ASSOCIATED DOCUMENTS:

WP-010288    S12 Job Description Process
**JOB DESCRIPTION REVISION HISTORY:**

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<th>Change Description</th>
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<td>• New Document.</td>
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**TEMPLATE REVISION HISTORY:**

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<td>1.0</td>
<td>• New Document.</td>
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<tr>
<td>See Effective Date</td>
<td>2.0</td>
<td>• Added guidelines to the Position Title, and Location, Purpose and Scope of Position, the Required Competencies, and to the Duties and Responsibility sections. Changed the “red” font in the Working Conditions section to “blue” font to match the rest of the document.</td>
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