Job Description

Position: Quality Assurance (QA) / Corrective Action Preventative Action (CAPA) Analyst I, II
Department: Quality Assurance
Reports To: Director, Quality Assurance /Regulatory Affairs
FLSA Status: Full time salaried employee

POSITION SUMMARY:

The Quality Assurance (QA) / Corrective Action Preventative Action (CAPA) Analyst I, II will assist in the daily Quality Assurance (QA) and Corrective Action Preventative Action (CAPA) activities at Biocoat, Inc. Activities include daily operational support of the Quality Management Systems (QMS). Additional responsibilities include quality oversight, maintenance, and functional operation of quality related activities. The Quality Assurance Analyst I, II / CAPA Analyst reports to the Director, Quality Assurance / Regulatory Affairs.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Responsibilities include, but are not limited to:

- Administration and delivery of Quality Assurance training.
- Review batch records and supporting documents for production activities.
- Review, create, and facilitate investigations: perform root cause analysis, perform risk analyses & effectiveness monitoring and close Corrective and Preventive Actions (CAPA).
- Perform audits (internal) as required.
- Support and facilitate Client audits as necessary
- Administration of QMS documentation.
- Author and review quality procedures, templates, forms, and reports.
- Develop procedural and work instructions as necessary.
- Oversee, investigate, and resolve customer complaint processes.
- Compile data and provide presentation level metrics reporting for Management Reviews.
- Coordinate material review board meetings as required.
- Maintain and report Quality System metrics.
- Other duties as assigned by Director.
- Ensures interactions are consistent with company values and treats others with dignity and respect.

QUALIFICATIONS & REQUIREMENTS:

- Bachelor's degree in a Scientific, Engineering, or Life Science discipline from an accredited secondary education institution. Relevant experience may be considered in lieu of education at the discretion of hiring manager.
- 2 to 5 years relevant QMS experience
- Minimum of 2 to 5 years of relevant pharmaceutical or medical device manufacturing experience in a GMP environment preferred
- Familiarity with regulatory compliance / regulatory affairs preferred
- ISO 13485/ 21 CFR 820 knowledge highly desirable.
- Ability to work proficiently in a regulated manufacturing setting.
- Solid interpersonal skills required.
  The conditions herein are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential job functions.

Physical Requirements
Physical Demands-Stooping, turning, bending, squatting, kneeling and the ability to lift up to 30 pounds; constant/repetitive standing; requires normal, correctable vision and hearing, and the ability to accurately discern color as necessary to perform job functions.

Disclaimer
This job description is not intended to be construed as an exhaustive list of responsibilities, duties, or skills required for the position. This position may be changed or assume additional duties at any time. The employee may be requested to perform different or additional duties as assigned.