JOB DESCRIPTION

Position: Quality Assurance Analyst I, II
Department: QA
Reports To: Director, QA/RA
FLSA Status: Full time salaried employee

POSITION SUMMARY:

This position will assist in the daily Quality Assurance activities at Biocoat, Inc. Activities include daily operational support of the QMS system. Includes Quality oversight, maintenance, and functional operation of quality related activities. The QA Analyst I, II reports to the Director, QA/RA.

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).
- Demonstrated proficiency in leading audits, both internal and external. Developing reasonable, sound responses and when appropriate acting upon those commitments with limited instructions.
- Administration of QMS documentation.
- Author and review quality procedures, templates, forms, and reports.
- Develop Standard Operating procedures 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.

QUALIFICATIONS & REQUIREMENTS:

- Minimum – Bachelor's degree in a Scientific/Engineering/Life Science discipline from an accredited secondary education institution.
- Relevant experience may be considered in lieu of education. 3 years On the Job equates to Life Science degree.
- 3 to 5 years of relevant pharmaceutical / medical device manufacturing experience in a GMP environment is preferred.
- Demonstrated ISO 13485/ 21 CFR 820 knowledge highly desirable.
- Regulatory Affairs and International MDR/MDD expertise is considered highly desired.
- External certification, (CQA,CQE, RAC, etc.) is highly desirable, or at a minimum, clear path to achievement either thru advanced degrees or training.
- Ability to work proficiently in a regulated manufacturing setting.
- Other duties as assigned by Director.