

1930 California Avenue - Corona, CA 92881 - Phone: (951) 547-7000; Fax: (951) 547-7001

JOB TITLE: QUALITY ASSURANCE / DOCUMENTATION RECORD REVIEWER

POSITION SUMMARY:

The Quality Assurance & Documentation Record Reviewer is primarily responsible for:

- Inspecting manufacturing operations for compliance with current Good Manufacturing Practices (cGMPs) and Good Documentation Practices (GDPs), and
- Promptly and accurately reviewing production batch records (PBRs), quality control records, and all logs to determine compliance with Good Manufacturing Practices, Good Documentation Practices, and established company procedures.

MAJOR FUNCTIONS & RESPONSIBILITIES:

- Assemble, promptly and accurately review manufacturing batch records and daily production paperwork and identify product records that do not meet product release requirements.
- Assist with preparing and issuing batch records for manufacturing, packaging and labeling products.
- Assist with preparing in-process labels for manufacturing and packaging operations.
- Audit quality control release reports for completeness and compliance to specifications.
- Manage all production and quality control logbooks (ordering new logbooks and sending completed logbooks to document control coordinator with complete tracking record).
- Assist in archiving all manufacturing records, quality control lab records and logs once products are released; and retrieving documents and records from the archive upon request.
- Communicate with document control coordinator for new batch records, logbooks, official documents, etc.
- Create/review certificates of analysis, certificates of conformance, certificates of continued quality guarantee, etc.
- Provide support during regulatory and other audit-related activities.
- Control inventory of reserve (retain) samples and maintain databases (as directed).
- Send samples to third party laboratories and customers and process test results.
- Perform other duties as assigned by the Supervisor, Manager and/or Quality Systems & Regulatory Compliance Department management.

REQUIRED EDUCATION / WORK EXPERIENCE / SKILLS:

- A bachelor degree (Bachelor of Science, Bachelor of Art) and at least 1 year of work experience as Quality Assurance Inspector/Auditor and/or Documentation Reviewer for industries manufacturing foods, dietary supplements, personal care and/or pharmaceutical products.
- An associate degree and a minimum of 3 years of work experience indicated above may be accepted in lieu of a bachelor degree and one year (at least) of work experience.

- Familiarity with Quality Assurance in manufacturing and packaging of food & beverage products, nutritional supplements, pharmaceutical products, and/or personal care products,
- Knowledge of one or more of the following is desirable: FDA regulation for food & beverages / dietary supplements / pharmaceutical products, GMPs, GDPs, Hazard Analysis & Critical Control Points (HACCP), Safe Quality Foods (SQF), and/or document control.
- Ability to add, subtract, multiply, divide in all units of measure, using whole numbers, common fractions and decimals.
- Well-organized, detail oriented, and strong written and verbal communication.
- Basic computer skills (Microsoft Word and Excel).

OTHER REQUIREMENTS:

• Extended hours of sitting and reading/reviewing written documents.