



JOB PLACEMENT STANDARD FORM

Recruiter: Sharon Amler
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Senior Manager, Third Party QA-Steriles (1/13/12):

Northern, NJ-Local candidates

Responsibilities:

Responsible for the management, direction, and administration of the QA oversight of contract manufacturing organizations (Auditing/Inspection, APR's, Deviation and Change Management and Batch Release).

- Assuring compliance with all cGMP, FDA, DEA, and OSHA regulations, as well as all applicable federal, state, and company compliance guidelines, standards and objectives.
- Primary signature authority for all applicable site/corporate controlled documents, including Batch Record review and release, protocols, procedures and Annual Product Reviews.
- Responsible for all CMO Support functions including Batch Record review and release, Annual Product Reviews, Deviation and Change Control reviews.
- Direct management of exempt and non-exempt personnel, including staffing, organization, and budget, if applicable.
- Maintain direct and frequent contact and coordination for both existing and new product relationships.
- Management of Quality Agreement Obligations for compliance and/or update, as needed.

Requirements:

Bachelors Degree Required

- Minimum 10-15 years experience working in a QA and/or manufacturing environment with a **minimum of 7 years sterile product experience**
- Current knowledge of cGMP's in the pharmaceutical industry.
- Ability to coach and manage direct and indirect relationships through demonstrated management experience and strong negotiation skills.
- Must possess excellent verbal and written communication skills.
- Experience using Microsoft Office applications, including Word and Excel, and data entry experience is a plus.
- Ability to develop, direct, and manage simultaneous multiple priorities and projects.
- Ability to prioritize issues and work by application of critical thinking and risk-based decision making.
- Experience with product complaints preferred.
- This position has direct responsibility for key contractor in several geographic locations both domestic and international. This position will require up to 20% travel.

Apply:

For detailed job descriptions, please visit our website at www.arcstaff.com and search nationwide listings from ALTERNATIVE RESOURCES COMPANY.

Other Available Positions:

ANALYTICAL R&D

Senior Director, Analytical R&D and QC, California
Principal Scientist, Analytical R&D, New York
Senior Scientist, Analytical R&D, New York

BIOANALYTICAL & PHARMACOKINETICS& DRUG METABOLISM

No current openings

BIOSTATISTICS

No Current Openings

BUSINESS DEVELOPMENT/LICENSING

Business Intelligence Manager-Senior Manager, New Jersey

CONTRACT MANAGEMENT

Government Pricing Analyst, New Jersey

CLINICAL RESEARCH

Clinical Operations Manager, New Jersey

DOCUMENTATION

No Current openings

DRUG SAFETY

Senior Drug Safety Associate, New York

FORMULATION

Manager, Formulations, New York

HEALTH ECONOMICS AND OUTCOMES

No current openings

HUMAN RESOURCES

Human Resources Manager, New York

IT

Manager of Systems Architecture, New York

IT Business Analyst, New Jersey

LEGAL/COMPLIANCE

Director of Commercial Compliance, New Jersey

MARKETING, SALES AND TRAINING

Brand Managers, OTC, New York

Senior Communications Specialist III, New York

MEDICAL AFFAIRS

Regional Scientific Manager, Boston, Massachusetts

(Boston, MA is preferred, CT, RI, MA, VT, NH or ME)

Medical Science Liaison, Great Lakes

(Territory: MI, WI, IN, OH & KY. Residency requirements include MI, WI, IN, OH, KY, MN, MO & IA)

PACKAGING

Manager Package Development, New York

PRODUCT & PROCESS DEVELOPMENT

No current openings

PROJECT MANAGEMENT

Associate Director Development Project Management, New York
Planning Coordinator II/III, Project Management, New York

QUALITY CONTROL (QC)

No Current Openings

QUALITY OPERATIONS (QA)

Director of Quality Assurance, California
Senior Manager – GLP Quality Assurance, New York
Senior Manager, Third Party Quality Assurance, New Jersey
Manager, Quality Assurance, California
Auditor - Senior Auditor, Quality Systems, New Jersey
Quality Specialist, Quality Systems/Quality Management, New York

REGULATORY AFFAIRS

Associate Director, Development Regulatory Affairs, New York
Associate Director – Promotional Review, New York
Global Project Lead, Regulatory Affairs – Early Development, New Jersey
Senior Manager, Regulatory Affairs (CMC), New Jersey
NDA/ANDA Regulatory Affairs Project Manager, Michigan

SUPPLY CHAIN

No current openings

Recruiters:

It is the sole responsibility of the recruiter or hiring manager for accuracy of each job position. Recruiter is also responsible to clearly state how the prospective candidate should apply for job position and if made possible reply to the recruiter.

ASQ Long Island:

At ASQ Long Island, we are happy to help recruiters post their job vacancies on our website for 45 days maximum as we feel this is ample time to advertise, interview & hire for job positions. By sending a job description to ASQ Long Island, it is considered permission to post on our website. The job posting data received by ASQ Long Island MUST complete our job placement standard form with contact information for recruiter as well as job application instructions. ASQ Long Island is also allowed to proof read job description for objectionable content. ASQ Long Island also reserves the right to not place a job posting on our website for any reason. ASQ Long Island also reserves the right to charge recruiters for this service in the future.

Applicant:

At all times, ASQ Long Island absolutely requests each applicant to NOT contact ASQ nor its members while applying for a job position on our website. Please contact the recruiting agency or hiring manager directly for additional information. It is the sole responsibility of the applicant to

research the job position on their own and find out if this job position is suitable for them. ASQ Long Island asks each prospective candidate to follow the specific application procedures listed by each job position. ASQ Long Island does not endorse any of the positions listed on our website at anytime.