Mary Joy,

I am reaching out to you regarding an exciting Senior role for an **Associate Director, Biostatistics**, for a steadily-growing branded pharmaceutical company in the Mercer County, NJ area (relocation will be provided).

I have included below the description of the role (**as well as a list of other searches we are working on nationwide**) for your review. Please let me know if you or someone you know may be interested.

***PLEASE network this email to others in the industry. Networking is a powerful tool often the means by which many find their next great career move. Thank you so much for your time and I and look forward to hearing back.***


Thank you!
Haylee J. Bell
Associate Director, Pharmaceutical Recruitment
Alternative Resources Company
hbell@arcstaff.com
www.arcstaff.com

**Associate Director Biostatistics**

**Overview**

Provides statistical input in the clinical development plan and protocols and conducts statistical analyses and summary of clinical studies and integrated database to help advance the drug development process. This is a strategic and critical role in effectively and efficiently developing the process for approval of drug products.

**Responsibilities**

60%

1. Protocol development
   - Provides statistical analysis plan, including study design, sample size, primary and secondary endpoints, and statistical analysis method.
   - Reviews protocol outlines and protocols.
2. Produces randomization codes.
3. Reviews CRF.
4. Reviews and approves database structure and edit-check specifications.
5. Reviews and approves other clinical documents, such as clinical operation manual, investigator brochure (I), etc.
6. Develops final tables and listings (and figures) for final study report (FSR).
   - Develops Table of Contents (TOC) and Tables & Listings templates.
   - Develops a detailed Statistical Analysis Plan (SAP) to document technical considerations.
   - Provides specs to SAS programmers for generating analysis datasets.
   - Programs efficacy analysis and produces final efficacy tables and figures.
   - Reviews final tables, listings, and figures.
7. Develops tables and listings (and figures) for other regulatory submissions.
   - Performs statistical analyses for PK/PD parameters.
   - Provides safety tables and listings for IND annual reports and PSUR.
   - Provides tables and listings for FDA meeting briefing packages.
   - Performs exploratory analyses.
   - Performs statistical analyses for marketing and Phase IV studies.
   - Performs statistical analyses for abstracts, posters and publications.
8. Develops final study report (FSR).
   - Provides Statistical Methods section.
   - Summarizes Efficacy Results.
   - Reviews FSR.
9. Handles FDA or other regulatory agencies’ contracts and regulatory meetings.
   - Drafts response to questions from regulatory agencies.
   - Participates in preparing FDA briefing packages.
   - Attends meetings with Regulatory Agencies.
   - Interfaces with FDA statistical reviewers and serves on the rapid response team to address inquiries during the NDA review.
10. NDA submissions
    - Provides Integrated Summary of Efficacy (ISE) and Integrated Summary of Safety (ISS) tables.
    - Reviews ISS and ISE reports.
- Prepares briefing packages for FDA Advisory Meetings.
- Participates in responding to Advisory Committee questions in NDA defense.

40%

- Provides statistical inputs on Clinical Development Plan regarding primary efficacy end point, go/no-go decision criteria, size of studies, and statistical methodologies.
- Discusses strategies with Global Clinical Development and Regulatory Affairs regarding study design and complex analysis issues, FDA issues, and general drug development.
- Reviews clinical, statistical, and regulatory literature for current clinical trial results, regulatory trends and new statistical methods to be applied on his/her assigned therapeutic area.
- Represents clients (internal and external partners) at FDA meetings, FDA advisory boards, or other scientific meetings.
- Evaluates new statistical methodologies and software and their potential applications in our study design and analysis.
- Serves as the Biometrics project team leader regarding the statistical analysis, tables and listings, data collection and quality, and overall timeline. If any potential issues arise within Biometrics functions, advises VP of Biometrics for action.
- Assists in departmental planning and resource allocation and mentoring staff. Provides support for administrative duties as needed to the Senior Director.
- Assists in proposal development, FTE allocation, budget projections, and corporate presentations.
- Provides technical supervision over other biostatisticians assigned to his/her therapeutic area and assigns them the statistical tasks.
- Takes full responsibility in managing biostatistical tasks (as listed below) for one therapeutic area and provides strategic technical support to other clinical projects.
- Provides technical direction to supporting statisticians working on projects on a day-to-day basis.

**Requirements:**

**Knowledge**

- Understands the company's products, the competition, and the pharmaceutical industry in general.
- Demonstrates a competent knowledge of the company's work tools, processes, and policies.
- Maintains a current awareness of new drug developments and statistical methodologies in the business.
- Requires a strong working knowledge of applicable U.S. regulatory requirements and NDA preparation for submissions.
Skills

• In-depth knowledge of statistical principles, applications, and SAS programming software.
• Strong computer skills with demonstrated experience in working with the Microsoft suite of programs (Word, Excel, PowerPoint, and Outlook).
• Knows how/when to apply organizational policy or procedures to a variety of situations.

Education and Related Experience

• PhD in Statistics or Biostatistics
• Minimum 12 years of experience in the pharmaceutical industry including 3 - 4 year in supervisor role.
• Requires 10% of travel.

Nationwide listings from ALTERNATIVE RESOURCES COMPANY
(For detailed job descriptions, please visit our website at www.arcstaff.com)

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QUALITY OPERATIONS (QA)

Director Quality Assurance, Quality Operations CA
Associate Director, Quality Assurance, Compliance CA
Senior Manager – Document Administration & Validation NY
QA Operations Manager NY
Manager, Quality GCP NY
Quality Systems Auditor – Senior Auditor NY/NJ
Compliance Specialist NJ
Complaint Specialist (Medical Devices) NJ

REGULATORY AFFAIRS

Senior Director to VP, Head of Regulatory Affairs NJ
Associate Director, Global Regulatory Affairs MI
Head of Regulatory Review (Remote working Opportunity!) MI

VALIDATION

Validation Specialist (Cleaning Validation) NY

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