Job opportunities at the Division of Quantitative Methods and Modeling (DQMM), Office of Research and Standards/Office of Generic Drugs at the FDA's Center for Drug Evaluation and Research.

1. **Junior/Senior Reviewer, Quantitative Clinical Pharmacology.** This position offers a unique combination of regulatory assessment and research opportunities.

   The incumbent will:

   - Lead and provide quantitative method support for development of regulatory guidance and assessment of abbreviated new drug applications (ANDAs), citizen petitions, controlled correspondence, and pre-ANDA meetings.
   - Provide consults on complex issues in generic drug review and product life cycle management related to quantitative methods, modeling, and simulation.
   - Apply modeling and simulation tools to support the development of new quality and bioequivalence standards or guidance documents for generic drug approvals.
   - Serve as FDA project officer and provide scientific oversight on collaborative modeling and simulation projects with external experts in the field. Please refer to FDA GDUFA sponsored modeling and simulation grants and contracts for more information.
   - Plan and coordinate generic drug regulatory activities (e.g. evaluating the feasibility of the initial plan, monitoring and adjusting the conduct of a study, and implementing research outcomes into new regulatory policy or guidance).
   - Develop propositions for study, create new projects and procedures, conduct satisfactory quality control on several different types of documents (e.g. review, consult, and communication documents), and prepare scientific texts and technical references.
   - Maintain continuing liaison both internally and externally, such as briefing the Division Director/Deputy and the team on all scientific interpretations and analyses, represent the discipline to professional and academic communities, provide consultations, opinions, and endorsements regarding the scientific discipline.

   Requirements:

   - PhD in clinical pharmacology, pharmacokinetics (PK), pharmacometrics, engineering or other suitable post-graduate qualification.
   - 3-15 years of regulatory/industry experience in quantitative clinical pharmacology, and/or clinical pharmacokinetics/pharmacodynamics (PK/PD), and/or pharmacometrics.
   - Excellent written and verbal communication skills.
   - Demonstrated presentation skills.

2. **Oak Ridge Institute for Science (ORISE) fellows.** DQMM has multiple openings for trainees to participate in research activities that support our mission of providing high quality generic drugs to the American public. Many of the outstanding scientists/researchers trained in DQMM have now joined new and generic drug companies, clinical research organizations (CROs), consulting firms, and other offices within FDA (e.g. Office of Clinical Pharmacology, Office of Bioequivalence, Office of Pharmaceutical Quality, and Office of Surveillance and Epidemiology).

   Under the guidance of a mentor, the ORISE fellow(s) will:
   - gain knowledge about the use of modeling and simulation tools for bioequivalence assessment.
   - learn to effectively share the results of their research by preparing scientific texts, technical references, and posters and presentations at conferences.
   - collaborate with cross-disciplinary teams and liaise both internally and externally (e.g. , presenting results at team briefings, workshops, etc.).
   - be given opportunities to publish results in peer-reviewed scientific journals.

   <u>Requirements:</u>
   - PhD in pharmaceutical sciences, clinical pharmacology, pharmacokinetics, pharmacometrics, engineering, statistics, data science, or other suitable post-graduate qualification.
   - PhD received within the last 60 months.
   - Excellent communication skills and critical thinking.
   - Demonstrated presentation skills.

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