

**Perrigo New York, Inc.  
Job Description**

**Job Title:** Senior Scientist– PK Studies  
**Department:** Clinical Affairs / Scientific Affairs  
**Reports To:** Director, Clinical Affairs  
**FLSA:** Exempt  
**Grade:**

**SUMMARY:** Reporting to the Director of Clinical Affairs, this position will focus on supporting our Consumer Health Care, Rx Generic and Proprietary Pharmaceutical business. The position will work closely with Product Development scientists in Michigan, Israel and New Jersey in the selection of test products for BE studies. The individual will develop PK models to predict desired in vitro profiles, and develop BE protocols in collaboration with CRO for testing. This position will select CROs for conducting BA/BE studies and coordinate efforts with AR&D to evaluate method validation packages from CROs to assure compliance with regulatory requirements.

This position will act as an advisor in clinical drug development and CRO outsourcing and provide expert consulting services in the area of Phase I-III clinical PK program development.

**ESSENTIAL DUTIES AND RESPONSIBILITIES** [other duties may be assigned]

- Design clinical PK trials/protocols for pharmaceutical drug products.
- Select and recommend CROs for bio study projects based on various factors.
- Assist formulation scientists in development and selection of appropriate formulation for bioequivalence studies
- Coordinate activities with ARD to review bio-analytical methods validation report
- Develop and manage timeline for bio studies with CRO
- Maintain an current knowledge of strength, cost-effectiveness, and suitability of CROs
- Provide program development for complex Phase I – III clinical PK programs.
- Develop strategic processes to expedite drug development to proof-of-concept.
- Assists Perrigo in the development of complex Phase I or II/III PK/Clinical Pharmacology RFP's and assessment of CRO proposals and assists with sponsor – CRO negotiations.
- Clinical development of pharmaceutical drug products, modeling and population PK analyses.
- Assist management in drug development strategies.
- Assist CA management in review of bio study reports for inclusion in ANDAs and NDAs.
- Assist Regulatory in preparation of pre-IND or pre-NDA meeting package
- Assist in due diligence for potential acquisition of products
- Evaluate of in-license pharmaceutical candidates
- Assess qualitative and quantitative composition of in vivo product performance.
- Design and execute PK and I/S/A studies for transdermal product

- Assess bioanalytical laboratories and deliverables including assay development/validation and bioanalytical reports for compliance with FDA regulatory guidances.
- Author PK analysis plans and PK/PD reports
- Participate in product development meetings, prepare/deliver presentations
- Train other clinical research associates
- Contribute to SOP development, PK guidelines, and report formats
- Prepare and/or publish manuscripts for scientific journals
- Attend professional conferences and meetings
- Attend off-site regulatory agency (FDA) meetings
- Assist formulation scientists in development and selection of appropriate formulation for bioequivalence studies

## QUALIFICATIONS

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, education, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- PhD in Pharmacokinetics and/or Biopharmaceutics.
- Prior experience: At least 3 + years experience required. Previous experience working in the generics industry highly preferred.
- Demonstrated ability to work both independently and in a team environment and exhibit initiative.
- Computer Literate with knowledge of Word, Excel, and Powerpoint.
- Demonstrated ability to manage and prioritize multiple projects.
- Exhibit effective/professional written and verbal communication skills required.
- Demonstrate knowledge and mastery of regulations, federal and clinical guidances.
- Superior organizational skills and very detailed oriented.

## EDUCATION and/or EXPERIENCE

- PhD in Pharmacokinetics and/or Biopharmaceutics.
- Preferred Certifications and/or membership of Professional Associations.
- Preferred experience in Dermatology and working within the Pharmaceutical industry.

## CERTIFICATES, LICENSES, REGISTRATIONS

- Certification in scientific field or with professional associations preferred.

## LANGUAGE SKILLS

- English required

## MATHEMATICAL SKILLS

- Knowledge of statistics is helpful though not required.

## REASONING ABILITY

### **WORK ENVIRONMENT**

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

### **PHYSICAL DEMANDS**

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Approved: \_\_\_\_\_

Beatriz North, MPH, CCRA  
Director, Clinical Affairs  
Scientific Affairs, PERRIGO New York

Date: \_\_\_\_\_

Version 1.0