Opportunity Title: Transdermal Drug Release Fellowship - CDER
Opportunity Reference Code: FDA-CDER-2016-0107

Organization U.S. Food and Drug Administration (FDA)

Reference Code FDA-CDER-2016-0107

How to Apply A complete application consists of:

- An application
- Transcripts – Click here for detailed information about acceptable transcripts
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- Two educational or professional references

All documents must be in English or include an official English translation.

If you have questions, send an email to FDArpp@orau.org. Please include the reference code for this opportunity in your email.

Description A research opportunity is available in the Office of Pharamaceutical Quality/Office of Testing and Research at the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

The therapeutic advantages including extended systemic drug exposure, simplified dosing regimen, and avoidance of first-pass metabolism have generated great market potential for transdermal drug delivery systems (TDDS). However, complex formulation designs and manufacturing processes of TDDS present a significant challenge in in vitro evaluation of product performance. In vitro skin permeation tests (IVPT) have been developed to understand the efficiency of drug permeation through the skin over a prolonged period of TDDS application. However, inherent variations of the skin tissue make it very difficult to obtain reproducible in vitro permeation data that are relevant for product's in vivo behavior. Furthermore, high variability also creates complications for direct comparison of in vitro permeation data among different products. On the contrary, in vitro drug release tests (IVRT) provide less variation in obtaining reproducible data; but currently they are only used for product quality control of TDDS. The availability of scientifically sound and clinically relevant IVRT methods for evaluation of the performance of TDDS is still an unchartered territory, given that the correlation between the in vitro drug release and in vivo drug absorption is not yet established for TDDS.

The outcome of this study is expected to be beneficial for both Industry and FDA to reduce development time, cost, and regulatory burden. It can also assist in establishing linkage for certain scale-up and post-approval changes (SUPAC) such as formulation, equipment, process, and manufacturing site change that may otherwise require in vivo bioequivalence study.

The participant will engage in the following activities:

- Developing bio-relevant in vitro release test and obtaining in vitro drug release profiles of TDDS products using dissolution apparatus or diffusion cells suitable for TDDS products.

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- Collecting clinical data of the same TDDS from product labels and other publications for deconvolution into in vivo drug absorption data.
- Constructing IVIVC models between the in vitro release and in vivo absorption data, and establishing IVRT methods through the IVIVC model validation process.

This program, administered by ORAU through its contract with the U.S. Department of Energy to manage the Oak Ridge Institute for Science and Education, was established through an interagency agreement between DOE and FDA. The initial appointment is for 6 months, but may be renewed upon recommendation of FDA contingent on the availability of funds. The participant will receive a monthly stipend commensurate with educational level and experience. Proof of health insurance is required for participation in this program. The appointment is full-time at FDA in the Silver Spring, MD area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

Qualifications

A doctoral, medical, or other qualified scientists holding advanced degree(s) in Clinical Pharmacology, Pharmaceutical Sciences, Chemistry, or Engineering received within the last 5 years. Candidate with a master's degree and relevant experience will also be considered. Experience in conducting drug release studies and in using Phoenix WinNonlin and/or GastroPlus software is preferred.

Eligibility Requirements

- **Degree:** Master's Degree or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Chemistry and Materials Sciences** (1 👁)
  - **Engineering** (1 👁)
  - **Environmental and Marine Sciences** (1 👁)
  - **Life Health and Medical Sciences** (45 👁)