

**Opportunity Title:** Anti-infectives PK/PD (Clin Pharm/Pharmacometrics)

Fellowship - CDER

**Opportunity Reference Code:** FDA-CDER-2018-0209

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

**Reference Code** FDA-CDER-2018-0209

**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](mailto:FDArpp@orau.org). Please include the reference code for this opportunity in your email.

**Description** It is critical to determine PK/PD indices for anti-infective drugs in animal studies, which are currently utilized to support dose selection in clinical efficacy trials and to inform susceptibility breakpoints for anti-infective drugs. A category of “Time-dependent and concentration-enhanced PD” has been well recognized for anti-infective drugs exhibiting a combination of time- and concentration-dependent killing features. However, no appropriate PK/PD index is available to support dose selection and inform susceptibility breakpoint for these anti-infective drugs.

The objective of this project is to determine a PK/PD parameter candidate most appropriately for anti-infective drugs in the “Time-dependent and concentration-enhanced PD” category.

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 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, Maryland, area. Participants do not become employees of FDA or the program administrator, and there are no fringe benefits paid.

**Qualifications** A degree in pharmaceutical science or a scientific or medical field received within the last five years. Students currently pursuing a Doctoral degree in the designated areas are also encouraged to apply.

Additionally,

- Experience and/or knowledge in microbiology is desired.
- Experience in modeling and simulation software (e.g., NONMEM, SAS, Splus/R, Phoenix, etc.), and knowledge of PK/PD modeling principles and statistics is also desired.
- Good written and oral communication with a publication history in peer



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reviewed journals.

**Eligibility  
Requirements**

- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree received within the last 60 month(s).
- **Discipline(s):**
  - **Computer, Information, and Data Sciences** ([1](#)👁)
  - **Life Health and Medical Sciences** ([3](#)👁)