Opportunity Title: FDA 2D NMR Spectral Comparison Faculty Fellowship
Opportunity Reference Code: FDA-CDER-2019-0433

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

Reference Code FDA-CDER-2019-0433

How to Apply A complete application consists of:

- An application
- Statement of Research Interests
- Salary Certification
- A current resume/CV, including academic history, employment history, relevant experiences, and publication list
- One educational or professional recommendation. Your application will be considered incomplete, and will not be reviewed until one recommendation is submitted.

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

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

Application Deadline 12/31/2019 3:00:00 PM Eastern Time Zone

Description A faculty research opportunity is currently available with the Office of Pharmaceutical Quality/Office of Testing and Research, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) located in Silver Spring, Maryland.

This project in the Office of Pharmaceutical Quality/Office of Testing and Research will establish a scientific basis not only for regulatory decisions in approving biosimilar or manufacture changes, but also, in combination with other literature findings, for a granular level of understanding of how minor afucosyl glycans can modulate mAb function and efficacy, critical for the development of the new generation of “bio-better” mAb products (Mossner E. et al. Blood, 2010). The gained knowledge of minor glycan control will greatly facilitate the drafting of mAb product specific guidance for sponsors who might not have resources to explore all possible analytical methods. The developed regulatory analytical methods can be transferred to the surveillance laboratories in the Agency’s Office of Regulatory Affairs (ORA) to ensure safe medicine for the public. Finally, the research outcomes will be discussed and documented through internal meetings and technical reports, and disseminated through scientific conferences, public workshops and peer-reviewed publications.

Under the guidance of a mentor the participant will have the opportunity to learn various analytical methods to meet regulatory requirements, specifically examining state-of-the-art methods related to glycosylation of mAb products in submission, including biosimilar and novel mAb products.

***Although the application deadline is December 31, applications will be reviewed on a rolling-basis.**

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 three 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 part-time (8 hours per week) at FDA in the Silver Spring, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related

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benefits.

Completion of a successful background investigation by the Office of Personnel Management is required for an applicant to be on-boarded at FDA. OPM can complete a background investigation only for individuals, including non-US Citizens, who have resided in the US for a total of three of the past five years.

FDA requires ORISE participants to read and sign their FDA Education and Training Agreement within 30 days of his/her start date, setting forth the conditions and expectations for his/her educational appointment at the agency. This agreement covers such topics as the following:

- Non-employee nature of the ORISE appointment;
- Prohibition on ORISE Fellows performing inherently governmental functions;
- Obligation of ORISE Fellows to convey all necessary rights to the FDA regarding intellectual property conceived or first reduced to practice during their fellowship;
- The fact that research materials and laboratory notebooks are the property of the FDA;
- ORISE fellow's obligation to protect and not to further disclose or use non-public information.

Qualifications

The qualified candidate must be a full-time faculty member at an accredited U.S. college or university, with a doctoral degree in mathematics or statistics, and carry an academic title of assistant, associate or full professor.

Knowledge of multi-dimension and multivariate data analysis; numerical modeling; NMR spectral comparison; and quantitating statistical results is preferred.

Eligibility Requirements

- **Degree:** Doctoral Degree.
- **Discipline(s):**
  - **Mathematics and Statistics** (10 👁)

Affirmation

I am a full-time faculty member at an accredited U.S. college or university, with a doctoral degree in mathematics or statistics, and carry an academic title of assistant, associate or full professor.