

**Opportunity Title:** Quality Standards for Drug Products Fellowship - FDA CDER

**Opportunity Reference Code:** FDA-CDER-2019-0336

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

**Reference Code** FDA-CDER-2019-0336

**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** An opportunity is available at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER) in Silver Spring, Maryland.

The Office of Pharmaceutical Quality (OPQ) Scientific Staff (SS) will address one of the main challenges in regulation of new, biologic, and generic drugs, the establishment of adequate quality standards. This involves, among other things, identification of critical attributes of drug substance and formulation, critical process parameters and their interactions, development of control strategies, and consideration of variables and challenges faced in manufacturing facilities. This issue is particularly evident for drug products containing complex drug substances, complex dosage forms (e.g., modified release drug products) and drug-device combination products. Such an improved understanding will support guidance and policy development needed for ensuring high quality of drugs across their life cycles.

Under the guidance of a mentor the participant may be involved in:

- conducting a data search in literature and the Food and Drug Administration (FDA) databases to collect quality data on a number of drug products
- identifying critical formulation and manufacturing process variables affecting the quality of drug products
- identifying a series of critical quality attributes, and developing test procedures and acceptance criteria based on these attributes
- establishing quality standards to facilitate product development, manufacture, and review of drug products

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 one year, 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, Maryland, area. Participants do not become employees of FDA, DOE or the program administrator, and there are no employment-related benefits.

The Homeland Security Presidential Directive-12 (HSPD-12) mandates a background check be completed for both U.S. Citizens and foreign nationals. Foreign nationals must have resided in the U.S. for at least three (3) of the past five (5) years in order for FDA to be able to complete a



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background check.

**Qualifications** The qualified candidate should have received a bachelor's degree or higher in clinical pharmacology, pharmaceutical sciences, chemistry, chemical engineering, or engineering/material science. Degree must have been received within the last 5 years of the appointment start date.

Experience in pharmaceutical formulation and analytical characterization methods is desired.

- Eligibility Requirements**
- **Degree:** Bachelor's Degree, Master's Degree, or Doctoral Degree.
  - **Discipline(s):**
    - **Chemistry and Materials Sciences** (2👁)
    - **Engineering** (3👁)
    - **Life Health and Medical Sciences** (1👁)

**Affirmation** I have received a bachelor's, master's or doctoral degree within the past five years, or are currently pursuing a master's or doctoral level degree.