

Request for Applications Fellowship in Microbial Assay Transition sponsored by the U.S. Pharmacopeial Convention

The U.S. Pharmacopeial Convention (USP) has established a fellowship program for early career scientists and researchers who wish to contribute to the improvement of the quality control of antibiotic products. This will have a significant impact on the critical medicines throughout the world. This Request for Applications (RFA) seeks qualified candidates with advanced degrees who wish to conduct research and receive valuable experience with pharmaceutical quality control technology and techniques.

The Fellowship in Microbial Assay Transition will foster the research, scholarship, and careers of individuals who are poised to work with academia, government, and industry to advance knowledge about the quality control of medical products. Fellows will have the opportunity to develop and demonstrate skills in a broad range of pharmaceutical science areas including development and validation of HPLC assays, synthesis and/or isolation of impurities, performing microbiological assays, characterization of reference standards, and statistical comparison of results, as well as interactions with USP and other stakeholders.

With more than 200 years history, USP establish quality standards to help manufacturers deliver on their promises of safe products, while building confidence among healthcare practitioners, patients, and consumers. The research we are proposing has potential for significant impact in these aspects of USP's mission.

Research

The main objective of this project is to transit selected antibiotic products from microbial assay to the use of more accurate and cost-effective physiochemical techniques. A number of antibiotics still use microbial assay described in USP General Chapter <81> to test the potency as the official compendial methods in USP-NF. Microbial assays are highly variable and require specialized equipment and skills. This results in barriers to the availability of important medicines and may impact product quality and therefore the trust of practitioners and patients.

USP General Chapter <1223.1> outlines the approach for the transition from the microbial assay to the physiochemical method for antibiotics. The work could include the following activities.

- Obtain representative antibiotic product batches from different manufactures
- Develop an HPLC method that resolves impurities in these batches
- Identify major impurities that could have contribution to the microbial activity
- Isolate/purify or synthesize a pure sample of each major impurity
- Characterize each isolated major impurity as a reference standard
- Generate comparative microbial activity (relative response factor) between the main component and each pure major impurity by following USP General Chapter <81>
- Test the relative response factor by comparing the microbial assay (against the current USP RS) and the computed assay using the HPLC purity data after applying the relative response factor for a sufficient number of antibiotic product batches



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- Apply statistical analysis when comparing the assay results obtained by the two methods
- Validate the HPLC method for specificity, linearity, precision, accuracy, robustness and stability indicating.

Fellows will be expected to analyze data and report results to USP. Data may be used to support USP monograph revisions and will help USP enhance the quality of antibiotics which are play a critical role in protecting public health, leading to a world where everyone trusts the medicines that improve and save lives.

Fellowship Activities

The fellows will work with USP to advance medicines quality. Key activities and training outcomes include:

- Conduct the research activities on selected antibiotic product
- Develop skills and knowledge in a broad range of pharmaceutical science areas and strengthen the ability of solving problems in real-world
- Collaborate with scientists from USP on research initiatives
- Present on USP BIO4 Expert Committee meetings
- Experience learning opportunities with USP (e.g., direct interactions with staff, giving or attending presentations, attendance at select meetings)

Candidate Qualifications

Ideal candidates will have laboratory facility equipped with necessary analytical instruments and demonstrate a strong interest in quality control of pharmaceutical products through their professional and educational backgrounds. Candidates should be enthusiastic, self-motivated individuals who have a deep desire to develop their careers at the pharmaceutical science areas.

Specifically, candidates should possess the following qualifications:

- Advanced degree in a related scientific field (e.g., MD, MPH, MS, PhD)
- Ability to write and communicate clearly and thoughtfully
- Experience and comfort working in a research setting
- Demonstrated capacity to work independently and collaboratively

Location and Duration

The fellow will work full time at their laboratory facility. The fellow will be awarded an initial one-year term, with a one-year extension upon successful completion of the first year. Success will be defined by pre-specified milestones and deliverables, which the fellow will establish with program directors from USP. The anticipated start date of the first year will be on or before February 1, 2022.

Application Criteria & Key Dates

October 31, 2021 – Application Due

Required Application Elements

1. Letter of intent (LOI), including the applicant's name, highest degree and conferring institution, and contact information (i.e., email address, mailing address, and phone number)
2. **Curriculum Vitae** (5 page maximum)



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- 3. Personal Statement** (500 words maximum) describing professional background, interest in medicines quality, and how the fellowship aligns with long-term career goals.

Optional Application Elements

- 1. Scientific Publications or Other Writing Samples** (2 publications maximum).
- 2. Letters of Recommendation.**

Submitting an Application

Submit the materials listed via email to uspbiologics@usp.org by October 31, 2021 with “USP Fellowship Application-Microbial Assay Transition” as the subject line. We will notify applicants to confirm letters have been received.

Conditions

This fellowship is supported by the USP. USP will require the fellow to complete annual disclosure forms listing financial and other interests that they, their spouses or minor children, or organizations in which they are involved (as a partner, employee, board member, etc.), have a financial interest that may give rise to real or apparent conflicts with the work of the fellowship.

Contact Information

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