

Visiting Scientist Program

Call for Candidates

Project Area: Global Biologics

Project Title: *Identification of Gaps and Potential Solutions for Effector Function Assays for Monoclonal Antibodies*

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Objective: In the format of the Visiting Scientist Program, USP is looking to host a visiting scientist at the U.S. site near Washington DC for a short-term, approximately 3 months long, regulatory science project.

Project Description: Monoclonal Antibodies exert their therapeutic effect through different mechanisms, including antibody-dependent cellular cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), complement-dependent cytotoxicity (CDC) and Fc-mediated apoptosis. A variety of different assay formats are used for assessing effector function, including both animal-based and cell-based assays. A variety of different cell-based assays are used, using different cell lines (primary and engineered), different readouts (reporter genes, enzymes, or ATP) and different labels or probes (fluorescence, radioactivity). The goal of this project is to identify gaps in the comparability of different assays and propose standards that can help improve assay consistency and comparability. Project will support ongoing collaborations with regulatory agencies.

The objectives of the project are to:

- identify opportunities for performance standards for effector function assays, which have been suggested at multiple roundtables and industry meetings.
- build on and complement the guidance provided in <1108> Assays to Evaluate Fragment Crystallizable (Fc)-mediated Effector Function, which has recently been published in Pharmacopeial Forum (PF).

The Ideal Candidate:

- Is familiar with commonly used assays to evaluate effector function
- Has awareness of relevant regulatory guidances and standards
- Is a current regulatory, academic, or industry scientist in good standing
- Possesses solid English communication skills [verbal and written], as is required for US J-1 visa application
- Able to travel to the United States
- Able to take a short-term project at USP's U.S. site located in Rockville, Maryland

Process and Support: Participants are selected via a competitive nomination process. If selected, ***housing, stipend, visa, and other support will be provided*** for the duration of the project.

Next steps: If interested, please submit a Curriculum Vitae (CV) in English, a 250-400 word statement, also in English, describing your background and interest in this project, and your passport scan.

Please send all materials and inquiries to Ms. Helen Kharab (hk@usp.org).

The United States Pharmacopeia (USP) is a standards setting organization committed to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's Visiting Scientist Program (VSP) brings scientists to collaborate side-by-side with USP scientists and staff to advance the science of public quality standards and related activities. Find out more about us at usp.org.