



University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)

Visiting FDA Scientists Program - 2019

Request for Proposals

This announcement is a Request for Proposals for M-CERSI Visiting FDA Scientists Program, a new program in 2018-19. The mission of M-CERSI is to foster the development of regulatory science – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products. M-CERSI intends to have seven (7) Visiting FDA Scientists. M-CERSI will provide the UM collaborator up to \$5,000 per visiting scientist in order to conduct collaborative regulatory science research. Funds are for expenses at UM and not provided to the FDA employee. A visiting scientist must be an FDA employee (includes members of the USPHS). FDA staff that enter the program must visit UM at least three times, over at least one month but not longer than nine months. Funds are intended to cover the cost of research related materials and supplies, as well as graduate student or post-doctoral fellow salary support at UM if needed, in line with visiting scientist activities.

The aims of the Visiting FDA Scientists Program are to:

1. Address an area of regulatory science identified by FDA (see [FDA Center/Office Regulatory Science Research Priority Areas for CERSI Program](#)) through research;
2. Provide professional development to FDA staff via access to UM facilities;
3. Provide professional development to UM faculty, staff, and students; and
4. Promote collaborative research between FDA staff and UM faculty, staff, and students.

Not all successful applications need to fulfill all of these aims. Proposals will be scored based upon the above four aims of the Visiting FDA Scientist Program, along with feasibility of the proposed research.

The deadline for applications from FDA staff is **April 1, 2019**. Early applications are encouraged. Applications must include a proposed UM faculty member. All full-time faculty members having primary academic appointments within the Baltimore or College Park campuses of the University of Maryland are eligible. Additional information about UM is below.

FDA staff who participate in the program must visit UM at least three times, over at least one month but not longer than nine months. Research may take place in many forms, such as:

- FDA staff mentoring a graduate student;
- FDA staff performing investigations in collaboration with UM faculty;
- FDA staff learning the use of certain equipment

Some research plans may only require one month to address the research question. Other plans may require nine months to address the research question. Proposed research must include a well-defined intended outcome or question-to-be-addressed, foster the development of regulatory science, and

relate to FDA [Center/Office Regulatory Science Research Priority Area\(s\) of CERSI Program](#). Proposed research also needs to be focused, given the scope of resources. Development of a research plan for a Visiting FDA Scientist Program application is strongly encouraged. Please contact Dr. Polli (jpolli@rx.umaryland.edu) and Dr. Bentley (bentley@umd.edu), with a cc: to Ms. Blum-Kemelor (Donna.Blumkemelor@fda.hhs.gov) regarding answers questions about preliminary ideas. Useful attachments and websites include:

- Summary of Baltimore and College Park campuses of the University of Maryland (page 3)
- www.umaryland.edu/academics/schools-and-programs
- www.umd.edu/colleges-and-schools
- Current M-CERSI projects are listed at: <https://cersi.umd.edu/projects>
- A list of example UM research capabilities is available at: <https://cersi.umd.edu/research-capabilities>

Application and review. See below application on page 4, which should include responses to noted questions and a two-page maximum description of proposed research plan, with at least one literature reference. A research plan should include a research objective, methods, a timeline, as well as any professional development benefits. Applications should include a brief description of the roles and expected responsibilities of proposed Visiting FDA Scientist and UM faculty and/or graduate student or post-doctoral fellow. Applications must include a proposed UM faculty member. A budget is required. Each application will be assessed within one month of receipt. Proposals will be scored based upon the above four aims of the Visiting FDA Scientist Program (see above page), along with feasibility of proposed research. Applicants should not expect critiques of their proposals.

Applications should be submitted as a single PDF file by **April 1, 2019** to: aanonsen@umd.edu, with cc: to: Donna.Blumkemelor@fda.hhs.gov.

Conditions of the award. Awards are made to the UM faculty member and are not transferable without prior approval by Drs. Bentley and Polli. The visiting scientist and UM faculty member are expected to provide a one-page final report within 30 days of last visit completion. Funds should be budgeted for completion over the award period. Funds are intended to cover the cost of research related materials and supplies, as well as graduate student or post-doctoral fellow support at UM if needed, in line with visiting scientist activities. Expenses not allowed include: travel, housing, and food expenses; salaries for PIs and any co-PIs, secretarial support; general telephone services and postage; purchase of laboratory or office furniture; dues and memberships in scientific societies.

About M-CERSI

M-CERSI is an FDA-sponsored center at the College Park and Baltimore campuses of the University of Maryland (www.cersi.umd.edu). The mission of the Center is to foster the development of regulatory

science – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.

Summary of Baltimore and College Park campuses of the University of Maryland

UMB is the Baltimore campus of the University of Maryland. This 71-acre research and technology complex encompasses 67 buildings near the Inner Harbor. UMB is Maryland's only public academic health, human services, and law center. Seven professional and graduate schools train the majority of the state's physicians, nurses, dentists, lawyers, social workers, and pharmacists. The ever-growing University of Maryland BioPark promotes collaborative research opportunities and bioscience innovation. Sponsored research totaled \$556 million in Fiscal Year 2017. UMB consists of 6,500 students and 8,000 faculty members and staff. Many faculty have appointments in our hospital partners, the University of Maryland Medical Center (UMMC) and the Baltimore VA Medical Center (BVAMC). UMB, UMMC, and BVAMC are geographically contiguous and intimately connected in terms of physical facilities, as well as practice and research. Also on the UMB campus is R Adams Cowley Shock Trauma Center, the UM Institute of Human Virology, and the Institute of Genome Sciences. UMB Graduate School Baltimore (SGB) offers 31 masters and/or PhD degree programs in health, physical, biomedical, medical, and social sciences, as well as joint degrees programs, including the MD/PhD, DDS/PhD, PharmD/PhD, MD/BIOE, MD/MPH, MD/MPP, MD/MBA, and DDS/MS. The SGB is the largest professional school in Baltimore.

The University of Maryland Medical System (UMMS) has 16 hospitals and almost 150 other community offices throughout Maryland. University of Maryland Medical Center (UMMC) is the flagship academic medical center at the heart of UMMS. UMMC consists of the 757-bed University campus, located in downtown Baltimore, and the 170-bed UMMC Midtown Campus one mile north. UMMS statistics for 2017 were: 2,252 licensed beds, 109,414 hospital admissions, 1,447,357 outpatient visits, 374,853 emergency visits, and 65,301 outpatient surgical cases.

UMCP is the University of Maryland, College Park. Located in College Park, less than ten miles from the FDA Silver Spring campus, and even closer to the FDA Center for Food Safety and Nutrition, UMCP is a major public research university, currently ranked 18th among public research universities by US News and World Report, and the flagship campus of the University System of Maryland (USM). Sponsored research totaled more than \$550 million in Fiscal Year 2017. Its 1500-acre campus is home to 25,000+ undergraduate students and ~10,000 graduate students who are enrolled in over 100 undergraduate and over 100 graduate academic programs, administered by 14 Colleges and Institutes. Many of UM's programs, particularly in engineering; computer science, mathematics and natural sciences; agriculture and natural resources; public health; and public policy have great relevance to the current challenges that the FDA faces in transforming itself into a "science based, science led" regulatory agency.



Application for
University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)
Visiting FDA Scientists Program

1. Visiting FDA Scientist name:
2. Visiting FDA Scientist contact info, including Center/Office and email address:
3. Name of Visiting FDA Scientist's Supervisor (who approved application):
4. FDA Center/Office Steering Committee member* informed regarding this submission:
5. Proposed UM faculty member name (one name):
6. UM faculty member contact info, including email address:
7. Title of proposed research:
8. Anticipated start/end dates (approximate; must be between 1-9 months in duration):
9. Total budget amount (in dollars, only direct costs):

10. Please attach a description of proposed research (maximum 2 pages) with at least one reference. Description must include a brief description of the roles and expected responsibilities of proposed Visiting FDA Scientist and UM faculty and/or graduate student or post-doctoral fellow.
11. Please attach a budget.

An application (this completed page, plus two-page maximum description of proposed research) is due **April 1, 2019**. Applications must include a proposed UM faculty member (Item #5). A budget is required (Item #11). Applications should be submitted as a single PDF file by **April 1, 2019** to: aanonsen@umd.edu, with cc: to Donna.Blumkemelor@fda.hhs.gov.

* Please indicate the name of the CERSI FDA Steering Committee member that the applicant has shared their intent to apply, along with approximate date of concurrence. See this document for the latest lead CERSI Steering Committee members for FDA Centers and Offices:
<https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM628886.pdf>.