



Post-doctoral Fellowship Opportunities at the Food and Drug Administration (FDA)

Anuradha Ramamoorthy, Ph.D.
Office of Clinical Pharmacology, FDA
ASCPT Career Bootcamp, 2016

Post-doctoral Fellowship Programs at the FDA

- The FDA offers many exciting paths to learn about regulatory science
 - ORISE fellowships
 - Commissioners' fellowships
 - Other fellowship mechanisms
- Link: <http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/default.htm>



ORISE Fellowship Program

- FDA wide; applicants can be post-doctoral, pre-doctoral, faculty, or summer research participants
- Provides practical research training in regulatory science
- Link to further information:
<http://orise.orau.gov/fda/applicants/eligibility.htm>
<https://www.zintellect.com/Posting/AcademicLevel> (search for FDA, clin pharm, etc.)



FDA photo by Michael J. Emmerth

ORISE Fellowship Program

- Temporary appointment (a total of 5 years), Contractors (non-FTEs)
- Monthly stipend (amount determined based on educational level, past experience, years in position, scientific contributions, etc.)
 - Project specific travel and training funds
 - May not include benefits package (nor earned annual or sick leave)
- U.S. citizenship not typically a requirement



© photo by Michael J. Esmarth

ORISE Fellowship Program

- Refer to the website for information on:
 - How to apply (application form, transcripts, resume, references)
 - Description of the specific projects
 - Qualifications (degree requirement, specific experience or knowledge of software)
 - Interview, etc.

All  Showing 1 to 41 of 41 Opportunities (filtered from 539 total Opportunities)

▲ Opportunity	↕ Reference Code	↕ Posted
Analgesic Disease Modeling Fellowship - Center for Drug Evaluation and Research	FDA-CDER-2015-0049	6/30/2015
Analytical Method for Salt/Free Base Measurement Fellowship - CDER	FDA-CDER-2015-0110	9/21/2015
Anti-infectives PK/PD (Clin Pharm/Pharmacometrics) Fellowship - CDER	FDA-CDER-2015-0069	7/13/2015
Anticoagulant Exposure-Response Analysis Fellowship - CDER	FDA-CDER-2016-0026	1/5/2016
Clinical Outcome Surrogates in Mucopolysaccharidosis Syndromes Fellowship - CDER	FDA-CDER-2016-0032	1/11/2016
Clinical Pharmacology Fellowship - CDER	FDA-CDER-2015-0104	9/14/2015
Data Analysis Fellowship - CDER	FDA-CDER-2016-0021	12/9/2015
Data Science Fellowship - Center for Drug Evaluation and Research	FDA-CDER-2015-0057	6/30/2015
Emerging Pharmaceutical Manufacturing Technology Fellowship - CDER	FDA-CDER-2015-0046	6/24/2015
Exposure-Response Fellowship - Center for Drug Evaluation and Research	FDA-CDER-2015-0079	8/5/2015
Immunobiology Fellowship - Center for Drug Evaluation and Research	FDA-CDER-2015-0083	8/19/2015
Improved Understanding of Bioprocessing Analysis Fellowship - CDER	FDA-CDER-2015-0043	6/10/2015
MCM ORISE Fellowship - CDER	FDA-CDER-2015-0121	9/30/2015
Mechanistic Drug Safety Fellowship	FDA-CDER-2015-0124	10/5/2015
Model based assessment of endpoints in IBD Fellowship - CDER	FDA-CDER-2016-0022	11/30/2015
Modeling and Simulation Fellowships - CDER	FDA-CDER-2015-0105	9/14/2015
Nanotechnology Post-Doctoral Fellowship--FDA	FDA-NCTR-2015-0073	7/23/2015

Source: Snapshot of opportunities (from zintellect) as of 01/25/2016

Commissioner's Fellowship Program

- 2-year fellowship; annual announcement (refer website for key dates)
- Combines rigorous regulatory science training and a scientific, policy, or regulatory research project
- Graduate-level coursework



Commissioner's Fellowship Program

- Some statistics:
 - 8th year of the program
 - 182 Commissioner's Fellows have graduated
 - 76% continued to work at FDA after completing the program
 - 184 publications produced based on fellowship work, 245 regulatory science presentations, and countless reviews authored or co-authored
 - 26 fellows have received Center or FDA Honor Awards



Acknowledgement: Drs. Dionna Green and Gil Burckart
Source: NIH Fellow Flash (Feb. 2016)

Commissioner's Fellowship Program

- Applicants must have Doctoral level degree (or Bachelor's or Master's degree in an engineering discipline)
- FDA employee
- Competitive salaries and travel funds
 - Benefits package (including health insurance, retirement, paid vacation leave and sick leave)
- Specific citizenship requirements (refer website)
- Refer to the website for information on:
 - How to apply (application form, transcripts, resume, references)
 - Description of the specific projects
 - Qualifications (degree requirement, specific experience or knowledge of software)
 - Interview, etc.





Commissioner's Fellowship Program

For this year:

- Applications accepted: 04/01 to 05/12 (5 pm EST)
- Recommendation letters: 05/27 (5 pm EST)
- Interviews: June-July
- Applicants Notified: July-August
- Program Start Date: October
- Link:

<http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFellowshipProgram/default.htm>

- [Ram Tiwari, Ph.D.](#) (*Center for Drug Evaluation and Research - CDER*)
- [Wenming Xiao, Ph.D.](#) (*National Center for Toxicological Research - NCTR*)

Support New Approaches to Improve Product Manufacturing and Quality

- [Christine Karbiwnyk, Ph.D.](#) (*The Office of Regulatory Affairs - ORA*)
- [Steven Oh, Ph.D.](#) and [Mohammad Heidaran, Ph.D.](#) (*Center for Biologics Evaluation and Research - CBER*)

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

- [Eugene Civillico, Ph.D.](#) (*Center for Devices and Radiological Health - CDRH*)
- [Brian Erkkila, Ph.D.](#) and [Susan M. Chemerynski, ScD, M.P.H.](#) (*Center for Tobacco Products - CTP*)
- [Aric Kaiser, M.S.](#) (*Center for Devices and Radiological Health - CDRH*)
- [Christopher Leptak, M.D., Ph.D.](#) (*Center for Drug Evaluation and Research - CDER*)
- [Markham Luke, M.D., Ph.D.](#) (*Center for Devices and Radiological Health - CDRH*)
- [Michelle Moore, Ph.D.](#) (*The Office of Regulatory Affairs - ORA*)
- [Thilak Mudalige, Ph.D.](#) (*The Office of Regulatory Affairs - ORA*)
- [Carolyn Yong, Ph.D.](#) and [Becky Robinson, Ph.D.](#) (*CBER and CDRH*)

Implement a New Prevention-Focused Food Safety System to Protect Public Health

- [Yi Chen, Ph.D.](#) (*Center for Food Safety and Applied Nutrition - CFSAN*)
- [Nakissa Sadrieh, Ph.D.](#) (*Center for Food Safety and Applied Nutrition - CFSAN*)
- [Sherri Turnipseed, Ph.D.](#) (*The Office of Regulatory Affairs - ORA*)
- [Donna Williams-Hill, Ph.D.](#) (*The Office of Regulatory Affairs - ORA*)

Other Fellowship Opportunities at FDA

Interagency Oncology Task Force (IOTF) Fellowship

- NCI (NIH) and FDA joint fellowship program
- 2-5 year fellowship (depends on training track)
- Combines training in cancer-related research and research-related regulatory review
- Offers 4 training tracks (oncology, clinical oncology, clinical oncology for board certified oncologists and cancer prevention)
- Applicants must have Doctoral level degree (Ph.D., Master's degree, or equivalent)
- Non-FTEs (CRTA funding mechanism)
- Competitive salaries and travel funds
 - Benefits package (health insurance, paid vacation leave and sick leave)
- Link: <http://iotftraining.nci.nih.gov/>



Other Fellowship Opportunities at FDA

Regulatory Pharmaceutical Fellowship

- 2 years fellowship
- FDA-Academia-Industry joint fellowship program
- Applicants must have Pharm.D. degree
- Competitive stipend and benefit package
- Reimbursement for relocation and professional travel expenses



• Link: <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm162733.htm>

Student, Fellowship, and Senior Scientist Programs

- FDA offers many paths to learning about the exciting field of regulatory science
- Programs offered through different centers and offices
- Link:
<http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/default.htm#student-programs>

