Educational Opportunities at FDA-CDER for NIH Clinical Research Fellows

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Disclosure

• Dr. Juan Lertora is a full-time employee of the National Institutes of Health (NIH) since July 2006.

• The content of this presentation does not represent official positions of the NIH or the NIH Clinical Center.

• Dr. Lertora has no conflicts to disclose.
A program developed to provide clinical research fellows at the NIH with a short-term rotation at the FDA that includes:

- Tutorials on filing an Investigational New Drug Application (IND) and other relevant FDA regulations.
- Tutorials on therapeutic area-specific drug development guidelines.
NIH CC Fellows’ Rotation at FDA-CDER

• Rotations are for a *minimum of 8 weeks.*
• Rotating NIH fellows are *assigned to a mentor at FDA,* based on stated area of interest.
• Rotations are *elective* and need approval by the NIH Fellowship Program Director.
• Rotations are *coordinated by the Clinical Pharmacology Program* - NIH CC.
FDA-CDER
Office of Clinical Pharmacology

Larry J. Lesko, Ph.D. (former Director)
Shiew-Mei Huang, Ph.D., Deputy Director
Gilbert J. Burckart, Pharm.D.,
Program Coordinator for NIH/CC fellows rotating at OCP/CDER.
FDA-CDER
Office of New Drugs (OND)

John K. Jenkins, M.D., Director
Sandra L. Kweder, M.D., Deputy Director
Susanne Walker, Ph.D.,
Associate Director for Learning and Career Development
Christopher Leptak, Medical Officer
Educational Activities at FDA

• Review of pre-clinical and clinical data on investigational drugs.
• Specialized therapeutic team meetings.
• IND “30-day” safety review - approvals.
• Meeting with sponsors.
• Educational online modules and courses at FDA.

Note: A signed confidentiality agreement is required given the proprietary nature of information discussed at these meetings.
NIH CC Fellows Rotating at FDA-CDER

- Ten (10) fellows (NCI, NIMH, NIDDK, CC) have completed rotations at CDER since 2008.
- Two (2) fellows (NINDS) are currently in the program.
- Three (3) fellows were subsequently hired by the FDA-CDER as Medical Officers.
- Feedback from fellows has been very positive.
FDA-CDER-OCP
Educational Opportunities

• “Overall, this rotation provided a solid foundation for experiential learning about the drug approval process performed by the FDA. It was an excellent opportunity to both network with individuals at the FDA and learn more about this complicated process”

Kristin Busse, Pharm.D.
Research Fellow (2006-2008)
NIH Clinical Center