Career Opportunities at the FDA

Dionna Green, MD and Rita Humeniuk, PhD
Office of Clinical Pharmacology (OCP)
Office of Translational Sciences (OTS)
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Rutgers iJOBS Seminar
05/06/2015

Outline

• Overview of FDA
• Drug Development
• Career Opportunities for Ph.D.s, M.D.s and Engineers
• Pay and Benefits
• Professional Development & Moving Up in FDA
• Fellowships & Rotations at FDA
• Research at FDA
• Contact information
CAREER OPPORTUNITIES AT THE FDA

Rita Humeniuk, Ph.D.

What does FDA do?

✓ Assure the safety, effectiveness and security of human and veterinary drugs, vaccines and other biological products, medical devices, our food supply, cosmetics and radiation-emitting devices
✓ Regulate tobacco products
✓ Advance Public Health by helping speed innovations that make products more effective, safer and more affordable
✓ Help the public get accurate, science-based information about these products
What does CDER do?

- Oversee drug development:
  New drugs, Over-the-counter drugs, Generic drugs, Biologics, and Biosimilar products
- Oversee post-marketing safety and promotion
- Oversee drug quality throughout lifecycle
- Promote and protect public health
Office of Clinical Pharmacology (OCP)

Department of Health and Human Services

FDA

CDER

OTS

Office of Translational Sciences

Office of Biostatistics

OB

OCS

Office of Clinical Pharmacology

DCP-Division of Clinical Pharmacology
DPM-Division of Pharmacometrics
GG-Genomics Group
DARS-Division of Applied Regulatory Science
OCS-Office of Computational Science

Multi-Disciplinary Review Team

Sponsors

Project manager

Quality/CMC

Clinical Pharmacology

Medical

Preclinical Pharm/Tox

Statistics

Decision: Safe & Efficacious?

Some products may require additional disciplines such as microbiology and virology
My Path to the FDA

- Science Driven Drug Development
- Preclinical/Translational Research
- Clinical Pharmacology Intro

Value-Driven Career Choices … Progressive Career Pathways

Career Opportunities at FDA for Ph.D.

- Attorney Positions at FDA
- Biologist Positions at FDA
- Chemist Positions at FDA
- Consumer Safety Officer Positions at FDA
- Engineer Positions at FDA
- Information Technology Positions in FDA
- Medical Officer Positions at FDA
- Microbiologist Positions at FDA
- Pharmacist Positions at FDA
- Pharmacologist Positions at FDA
- Statistician Positions at FDA

http://www.fda.gov/AboutFDA/WorkingatFDA/default.htm
Pharmacologist Positions at FDA
FDA Hiring Initiative

The Food and Drug Administration is recruiting for 1,300 medical and science positions to fill critical needs.
More on the FDA hiring initiative

Description of Position

Pharmacologists at FDA in non-laboratory settings perform duties that include:

- reviewing and evaluating the pharmacological and toxicological data contained in New Drug Applications (NDAs) and Investigational New Drug Applications (INDAs)
- reviewing and evaluating the results of preclinical pharmacological and toxicological studies submitted in support of NDAs, INDAs, and amendments to assess the safety of drugs based on toxicity experiments conducted by the investigator (including evaluation of animal testing to ensure that animal studies support the manufacturer’s claims for safety, and reviewing recommended dosage levels to determine the margin of safety for clinical use)
- preparing a comprehensive summary of data reviewed
- submitting recommendations and conclusions for approval.

In a laboratory setting, pharmacologists might:

- conduct research on the absorption and metabolism of chemicals in skin (such as colors, cosmetics, and other topically applied products)
- investigate the disposition of xenobiotics in normal and diseased animals
- investigate the effects of drugs and toxins from the molecular level to the total body response
- develop new methodology for the evaluation of chemicals, drugs, and toxins.

Career Opportunities at FDA for Engineer

Engineer Qualifications

- Completion of a full 4-year professional engineering curriculum leading to a bachelor or higher degree in engineering in an accredited college or university
- Knowledge of the physical and mathematical sciences underlying professional engineering
- Understanding the engineering sciences and techniques and their application to one of the branches of engineering.
Compensation and Benefits

- GS Pay Scale

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FDA Has Many Career Opportunities!

For information concerning all current FDA vacancies, please click on this link: http://www.usajobs.gov. Using this site, click on “Search,” select the Department of Health and Human Services/Food and Drug Administration, and search for the specific position by entering a General Service (GS) series, Occupation Type or Job Title.
CAREER OPPORTUNITIES AT THE FDA

Dionna Green, MD

My Path to the FDA

- Rationale Behind Dosing
- Variable Drug Response
- Clinical Pharmacology Intro

Value-Driven Career Choices ... Progressive Career Pathways
Career Opportunities at FDA for Physicians

**Medical Officer Qualifications**

- Doctor of Medicine or Doctor of Osteopathy from an accredited school in U.S. or Canada
- Foreign medical school graduates must be ECFMG certified
- Various medical specialties accepted
- Board certification and experience conducting clinical trials are a plus (but not required)

Compensation and Benefits

- **GS Pay Scale**

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www.opm.gov
**Compensation and Benefits**

- **Title 38 Physicians Pay**
  - Pay authority intended to recruit and retain highly qualified professionals
  - Mechanism to compensate at levels comparable to private sector physicians within same locality area
  - 2-component system (Title 5 GS base pay and Title 38 market pay)
  - Physician Comparability Allowance up to $24,000 (depending on years of federal service)

- **Annual leave**
- **Sick leave**
- **10 paid federal holidays/year**
- **Health Insurance**
- **Life Insurance**
- **Retirement**

**How can I be part of OCP?**

- **Short-term internships (trainees)**
- **Fellowships**
- **Collaboration on specific projects**
- **Presentations/seminars**
Work/Life Balance

- **Alternative Work Schedules**
  - Provides schedule options other than the 8 hrs./day, 40 hrs./wk.
- **Flexible Workplace Arrangement**
  - Allows employees to work at an alternative site (e.g., home) on a recurring basis
- **Transhare Programs**
  - Offers transit subsidies to employees commuting by public transportation or vanpool
- **Voluntary Leave Transfer Program**
  - Allows employees to request donated leave to cover medical or family emergencies
- **Child Care Center**
  - Accredited center located on FDA campus that provides care for children ages 6 weeks to 5 years

Professional Development at FDA

- Position-specific training
- Courses in regulations governing IND, NDA, BLA, and generic drugs
- Leadership courses
- Available for MDs, PharmDs, and RNs
- Scientific Rounds, Seminars, Workshops, Journal Club, Courses
- Available all year

- HHS University
  - Provides core, leadership and technical competency-based learning activities
- 1-1 mentoring
  - Intended to build leadership capacity, increase job satisfaction & employee retention
- 10-month program

Committed to Providing a Continuous Learning Environment
Professional Development -- External

- Travel funds for 1-2 meetings/year
- Regulatory workshops
- For MDs, PharmDs, RNs
- Excused absence for clinical work, teaching, or research
- Part of official duty hours (up to 4 hrs./wk.)

**FDA Partnerships with Centers for Excellence**
(Georgetown University and University of Maryland)

**Fellowship Opportunities at FDA**

- Commissioner’s Fellowship Program
  - 2-year fellowship
  - Combines rigorous regulatory science training and a scientific, policy, or regulatory science research project
  - Graduate-level coursework
  - Applicants must have Doctoral level degree (or a Bachelor’s or Master’s degree in an engineering discipline)
  - Competitive salaries and travel funds
  - FDA employee
  - Benefits package (including health insurance, retirement, paid vacation leave and sick leave)

- ORISE Fellowship
  - Temporary appointment (limited to a total of 5 years)
  - Provides practical research training
  - Engage in scientific studies and investigations
  - Applicants can be pre-doctoral, postdoctoral, faculty, foreign national trainees, or summer research participants
  - Contractors (non-FTEs)
  - Monthly stipend (amount determined based on past experience, years in position, and scientific contributions)
  - Travel funds
  - May not include benefits package (nor earned annual or sick leave)
Fellowship Opportunities at FDA

• Interagency Oncology Task Force (IOTF) Fellowship
  – 2-5 year fellowship (depending on training track)
  – NCI, NIH and FDA joint fellowship program
  – Combines training in cancer-related scientific research and research-related regulatory review
  – Offers 4 different training tracks (oncology, clinical oncology, clinical oncology for board certified oncologists and cancer prevention fellowships)
  – Applicants must have Doctoral level degree (Ph.D., Master’s degree, or equivalent)
  – Competitive salaries and travel funds
  – CRTA funding mechanism (non-FTEs)
  – Benefits package (including health insurance, paid vacation leave and sick leave)

• Regulatory Pharmaceutical Fellowship
  – 2 years fellowship
  – FDA-Academia-Industry joint fellowship program
  – Applicants must have PharmD degree
  – Competitive stipend and benefit package
  – Reimbursement for relocation and professional travel expenses

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

Student Rotation Opportunities at FDA

• Pharmacy Student Experiential Program
  – 4-6 week rotation
  – Provides an opportunity to become familiar with the mission, function and organizational structure of HHS, FDA, and other governmental agencies/institutions in the Washington area
  – Attend lecture series, FDA Advisory Committee hearings, and congressional hearings
  – Rotation must occur during 4th year of pharmacy school
  – Unpaid volunteer
  – Provides academic credit hours required for the PharmD degree

http://www.fda.gov/aboutfda/workingatfda/fellowshipinternshipgraduatefacultyprograms/pharmacystudentexperientialprogramdefault.htm
CDER Science and Research Programs

http://www.fda.gov/drugs/scienceresearch/default.htm

• Research Grant
  – Critical Path Grants
  – Regulatory Science Research and Review Enhancement Grant
  – Office of Women’s Health
  – Medical Countermeasure Initiative

• Scientific Interest Group
  – A group of volunteer members with a common interest in a particular scientific topic
  – Current SIGs in OCP include: PGx, PBPK, Geriatrics, Biologics, Transporters, Bioanalytical

• OCP Sabbatical/Scientific Visit Program
• Visiting Fellows Program
• OCP Science Day/Presentations/Publications
Thank You

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Food and Drug Administration

- Center for Biologics Evaluation and Research (CBER)
- Center for Devices and Radiological Health (CDRH)
- Center for Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Tobacco Products (CTP)
- Center for Veterinary Medicine (CVM)
- National Center for Toxicological Research (NCTR)
- Office of the Commissioner (OC)
- Office of Regulatory Affairs (ORA)
- Office of Chief Counsel
Office of Clinical Pharmacology

• Mission
  – To assure the safety and effectiveness of new drugs through the evaluation of clinical pharmacology and biopharmaceutics data in support of the CDER’s IND, NDA, and Biologics License Application (BLA) review programs.
  – Through research, we assure that regulatory policy and decision making are based on the best available science.

• How do we accomplish this?
  – Evaluate what the body does to the drug and what the drug does to the body
  – Understand inter-patient variabilities that relate to benefit and risk
  – Optimize dose and dose regimen to balance benefit and risk
  – Translate knowledge from NDA/BLA reviews into labeling language that is understandable and actionable
  – Conduct research to expand our knowledge of clinical pharmacology to better evaluate benefit and risk

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm106189.htm

OCP Strategic Plan 2010-2015

• Demonstrate the scientific value and clinical relevance of clinical pharmacology data analysis and interpretation
• Focus on continually improving the efficiency, consistency, timeliness and quality of our review process
• Recruit individuals with appropriate skill sets and reward them for their actions and behaviors related to the implementation of the strategic plan
• Enhance internal and external communication
Pre-IND to IND

**Industry**

- Disease Targeted

- Combinatorial Chemistry
- Highthroughput Screening
- Formulations development
- Preclinical Pharmacology/Toxicology
- Preclinical PK/Metabolism
- In Vitro Human Metabolic Screening
- Pharmacogenetics
- Screening IND

**FDA/OCP**

- Pre-IND meeting

- Phase 1: 1st time in humans.

- IND: NME

Phase 1 to Phase 2

**Industry**

- Phase 1: 1st time in humans

- Phase 2: Patients

- Pharmacokinetics
- Pharmacogenetics

**FDA/OCP**

- Phase 1 report

- IND: Phase 2 Protocol

- Pharmacokinetics
- [Pharmacogenetics]
- Exposure-response
- Drug interactions
- Bioequivalence
Phase 2 to NDA

**Industry**

- **Phase 2:** Patients
  - End Of Phase 2 meeting
  - • Optimal dose selection

- **Phase 3:** large trials
  - Pre-NDA Meeting
  - • Population Pharmacokinetics
  - • Specific Populations

- **NDA filed**
  - NDA Review Begins

**FDA/OCP**

NDA to Approval

**Industry**

- **NDA filed**
  - NDA Review

- **Industry Presentation**
  - Advisory Committee

**FDA/OCP**

- **Final Action**
- **OSE**

- Drug Marketed

**OSE**
Pharmacometrics is the science of quantifying disease, drug and trial characteristics with the goal to influence drug development, regulatory and therapeutic decisions.

Pediatric Clinical Pharmacology deals with the complex process of integrating the therapeutic considerations of pediatric disease, pediatric ontogeny, and pediatric drug development with the regulatory science behind the Pediatric Research Equity Act and Best Pharmaceuticals for Children Act.
Clinical Pharmacologists at the FDA: Genomics

- Optimize efficacy
- Minimize risk

- Experimental evidence for pharmacogenomic interaction
- Major polymorphic pathways
- Restricted first-in-human, drug interaction, and healthy volunteer trials
- Enriched and stratified trials
- Stratified dose-finding trials
- Stratified closing trials

Nonclinical

Phase 1
Phase 2
Phase 3
Phase 4

Knowledge

Metabolism, transport
Drug-target interactions
Nonclinical safety
ADME
Intrinsic and extrinsic factors
Safety
Efficacy
Dose response, concentration response

Updated by CS 07/24/12

Reference: Pharmacogenomics in the assessment of therapeutic risks versus benefits: inside the United States Food and Drug Administration; Zineh et al.; Pharmacotherapy; Aug 2011; 31(8); 729-35

Clinical Pharmacologists at the FDA: Safety

- Pharmacological mechanism guided personalized medicine
- Leveraging systems biology, genomics, and toxicology
  - Prospective prediction of drug safety signals (INDs and NDAs)
  - Differentiating between true and false positive safety signals
  - Identifying the subgroups of patients at risk
Career Opportunities at FDA for Physicians

Cross-Discipline Review Teams:

• **Pre-Market**
  – Medical Officer/Physician
  – Project Manager
  – Chemist
  – Pharmacologist (Toxicologist)
  – Clinical Pharmacologist
  – Statistician

• **Post-Market**
  – Epidemiologist
  – Risk Management
  – Safety Evaluator

Reviewer (Medical Officer) duties:

• Ensure all human drugs/biologics manufactured for interstate sale are effective with truthful and informative product labeling

• Evaluate data submitted by sponsors of Investigational New Drug Applications (IND), New Drug Applications (NDA), Biologic Licensing Applications (BLA), and generic drug applications to support the marketing of a drug/biologics

• Determine the scientific validity of manufacturers’ tests, drug safety and efficacy claims
Moving Up at FDA

Examples in OCP Leadership

Issam Zineh, Pharm.D., MPH, Director, OCP
Shiew-Mei Huang, Ph.D., Deputy Director, OCP
Darryl Abernathy, M.D., Assoc. Director, OCP
Select CDER Accomplishments (2013)

1. 27 NMEs Approved
2. 9 First-in-Class Drugs
3. 9 Orphan Drug Approvals
4. Innovative/Expedited Pathways to Market
5. ~400 Scientific Publications


How can I be part of OCP?

- Reviewers have a variety of different backgrounds (Pharm.D., Ph.D., MD) and skill sets
- Submit a CV approximately 3-4 months before completion of degree program (ocp@fda.hhs.gov)
- Phone and/or on-site interview
- Assistance with visa processing
Opportunities Outside OCP

- CDER/Office of New Drugs (OND)
  - Clinical reviewers
- CDER/Office of Compliance (OC)
  - Office of Scientific Investigation/Division of Good Laboratory Practice and Bioequivalence
  - Reviewers
- FDA/CDER/Office of Pharmaceutical Sciences
  - Office of Generic Drugs (OGD)
    - Reviewers