



Opportunities and Career Development in FDA and USPHS

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Outline

- Introduction
- Opportunities as a Chemist
- Career Development
- A case study



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FDA

- Center for Drug Evaluation and Research (CDER)
- Center for Devices and Radiological Health (CDRH)
- Center for Biologics Evaluation and Research (CBER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- National Center for Toxicology Research (NCTR)
- Center for Veterinary Medicine (CVM)
- Center for Tobacco products (CTP)
- Office of Regulatory Affairs (ORA)

All Centers need Chemists!

~15,000 Located Around the World



White Oak Campus, Silver Spring, MD

CDER

- Office of the Center Director
- Office of Regulatory Policy
- Office of Management
- Office of Communications
- Office of Compliance
- Office of Medical Policy
- Office of Translational Sciences
- Office of Executive Programs
- Office of Strategic Programs
- Office of Surveillance and Epidemiology
- Office of New Drugs
- Office of Pharmaceutical Quality
- Office of Generic Drugs

- Chemists
- Engineers
- Biologists
- Pharmacists
- Toxicologists
- Physicians
- Veterinarians
- Pharmacologists
- Lawyers
- Statisticians
- Project Managers

- Review of applications
- Inspections
- Testing
- Research
- Surveillance
- Project Management

Office of Pharmaceutical Quality (OPQ)



☐ 1,400 staff; ~ 10% of FDA

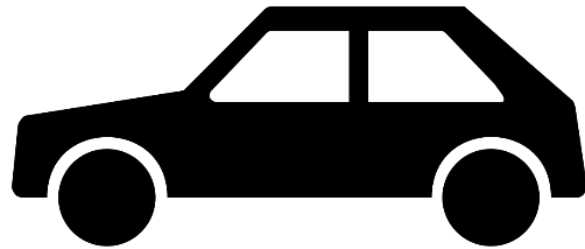
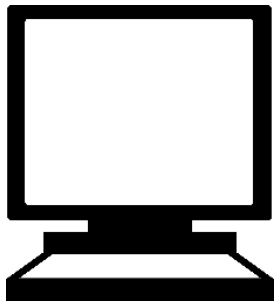


Most Offices need Chemists!

Pharmaceutical Quality




A quality product of any kind consistently meets the expectations of the user.



Drugs are no different.

A close-up photograph showing a hand holding an orange pill bottle, pouring white, oval-shaped pills into the palm of another hand. The background is softly blurred, focusing attention on the action of taking medication. The text is overlaid in a large, white, sans-serif font across the center of the image.

**Patients expect safe and effective
medicine with every dose they take.**

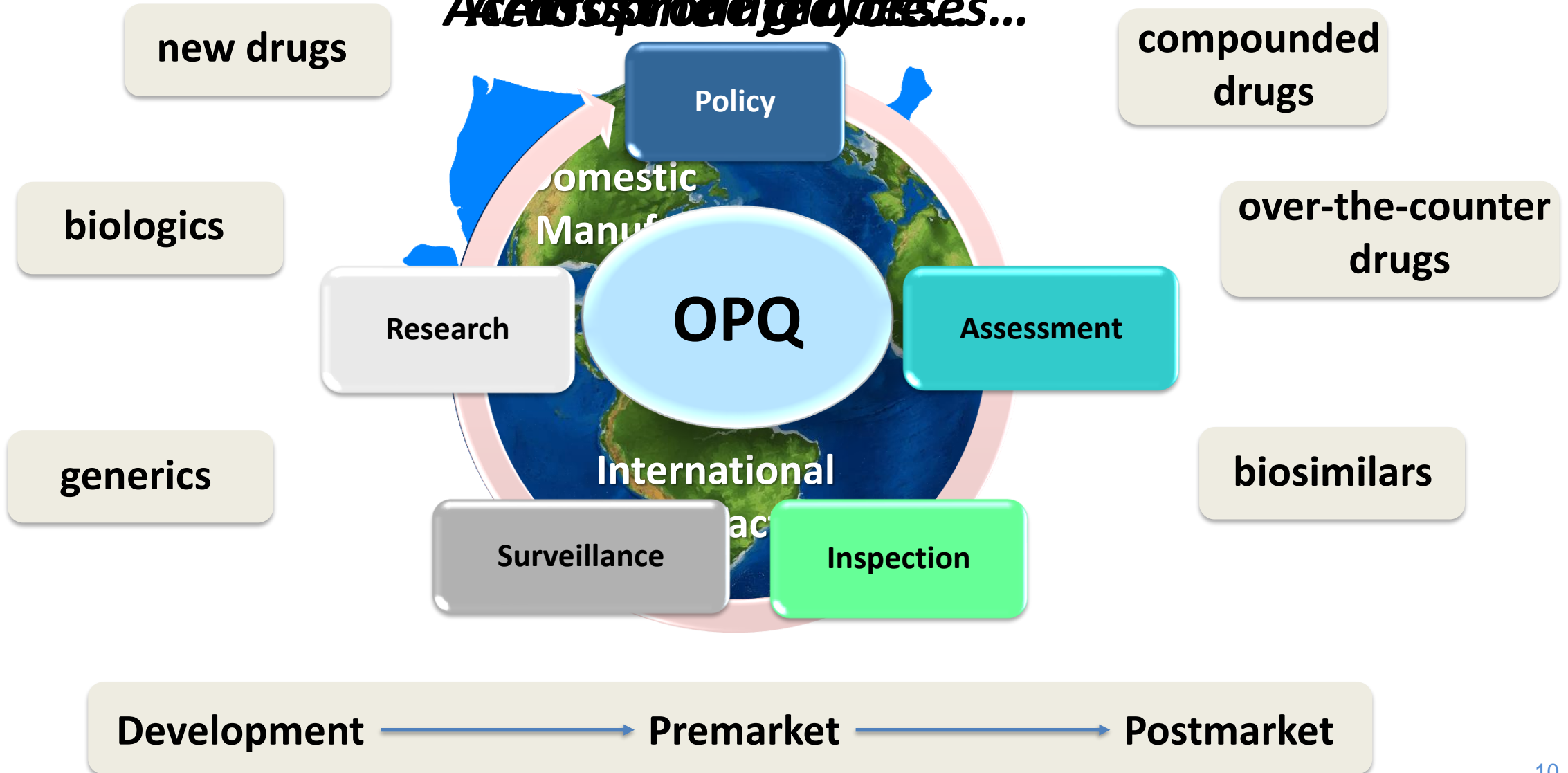


Pharmaceutical quality is consistently meeting standards that ensure every dose is safe and effective, free of contamination and defects.

Office of Pharmaceutical Quality



~~Access to high quality medicines...~~



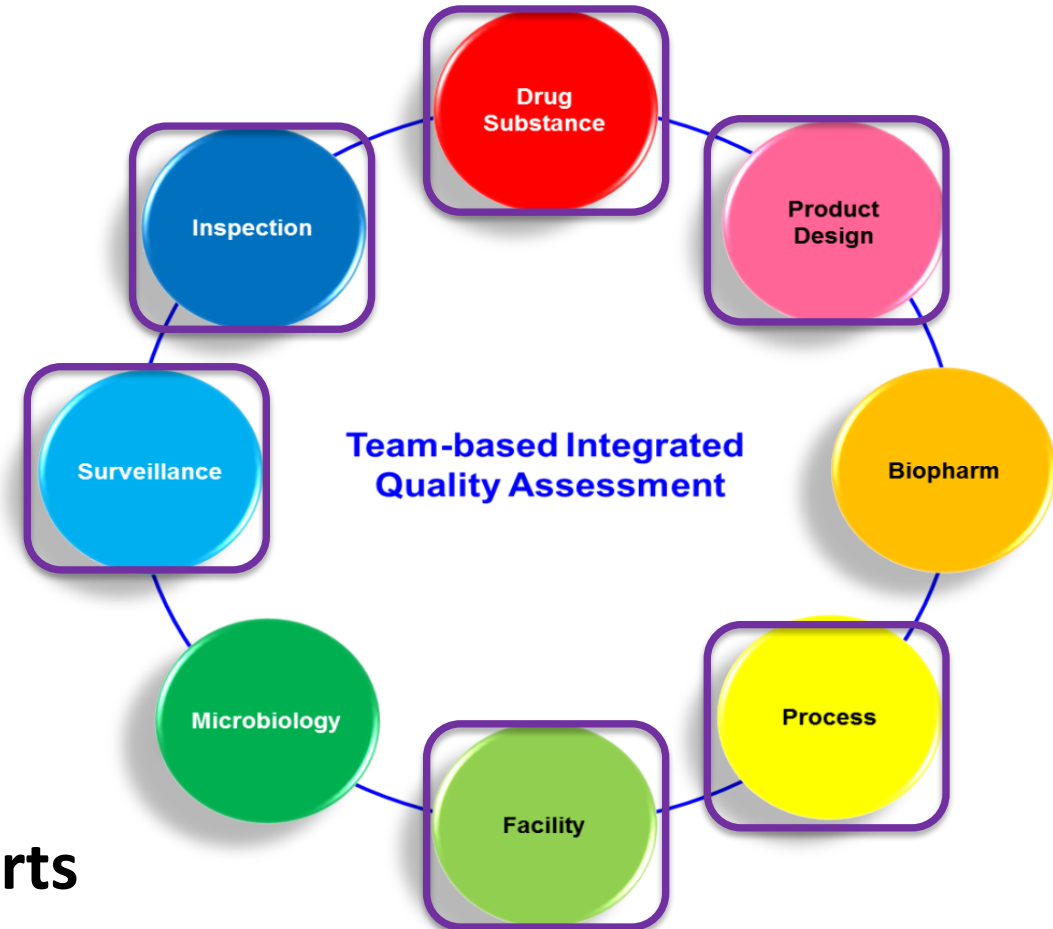
OPQ: By the Numbers

☐ Assessments of Chemistry, Manufacturing and Controls for submissions in a year:

- Around **20** biologics
- Around **200** new drugs
- Around **3,000** investigational new drugs
- Around **4,000** generics
- Around **7,000** supplements

☐ Surveillance of **6,000** facilities

☐ **>100** Publications and **>200** Technical Reports



FDA Opportunities

Where to look:

- www.usajobs.gov
- www.linkedin.com
- www.facebook.com
- Via professional network
- www.Zintellect.com (ORISE)

U.S. Citizenship? Permanent Residency? J-1?

- General Schedule (GS) position: Citizenship
- Staff Fellow position: Permanent Residency or Citizenship
- Visiting Associates: H visa
- ORISE Fellowship Program: OPT, J-1, ...

Tips:

- CV: ~ 5 pages; summary page → tailored to the position
- Potential concerns: large gap in CV, frequent job changes
- International Education Verification by a U.S. based company
- Prior to the interview, learn some basics about the Center/Office
- During the interview, give concise examples with specifics



U.S. Public Health Service (USPHS)



Mission: Protect, promote, and advance the health and safety of the nation.



In the service of health

The USPHS Commissioned Corps is one of the nation's uniformed services — a branch committed to the service of health. Officers advance our nation's public health, serving in agencies across the government, as physicians, nurses, dentists, veterinarians, scientists, engineers and other professionals.

11

professional
categories

6,100+

officers and
growing

800

locations across
the U.S. and
around the world



U.S. Public Health Service (USPHS)



Mission: Protect, promote, and advance the health and safety of the nation.



Scientist

Spearhead research for vulnerable communities.

USPHS Commissioned Corps scientists conduct biomedical, clinical, behavioral, and epidemiological research, enforce drug and medical device regulations, and manage national and international research programs.

Where we work



Agency for Healthcare Research and Quality

Agency for Toxic Substances and Disease Registry

Centers for Disease Control and Prevention

Food and Drug Administration

Centers for Medicare and Medicaid Services

Indian Health Service

National Institutes of Health

Health Resources and Services Administration

Office of the Assistant Secretary of Health

Office of the Secretary

Program Support Center

Substance Abuse and Mental Health Services Administration

Office of the Assistant Secretary for Preparedness and Response

Environmental Protection Agency

Federal Bureau of Prisons

National Oceanic and Atmospheric Administration

National Park Service

U.S. Department of Agriculture

U.S. Department of Defense

U.S. Department of Homeland Security

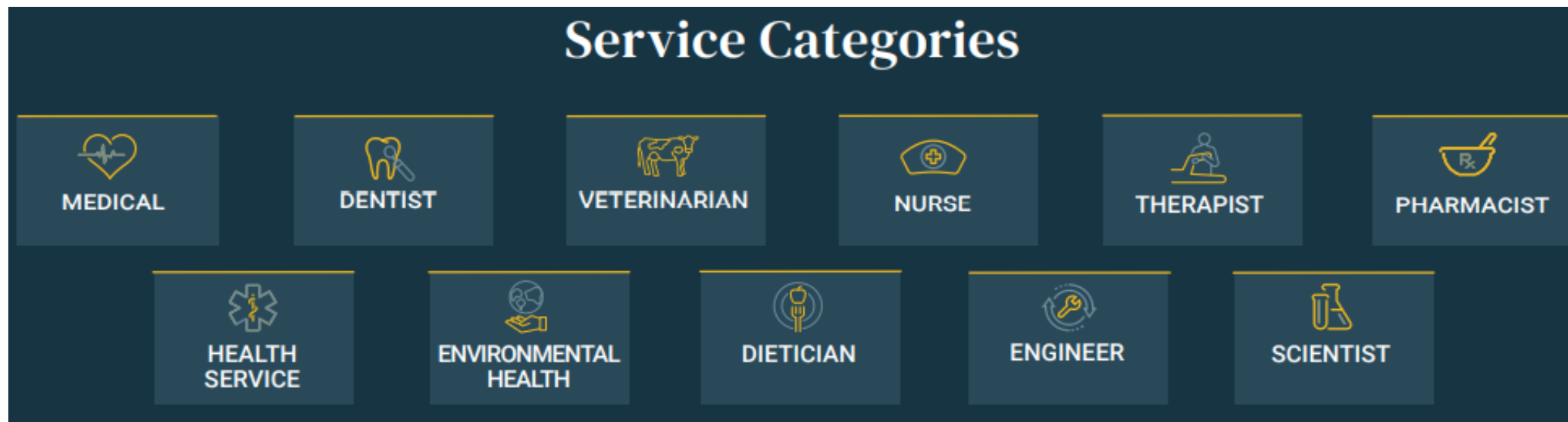
Division of Immigration Health Services

U.S. Coast Guard

U.S. Marshals Service



U.S. Public Health Service (USPHS)



Facts:

- All officers, no enlists
- Regular and Ready Reserve Corps
- Candidates: U.S. Citizens, ≤ 44 yrs, qualifying degrees, good health, security clearance
- Benefits similar to other uniform services
- Chemists: Scientist and Engineer categories, depending on the qualifying degrees

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Career Paths for Chemists

- ❑ Managerial: e.g., reviewers → team lead → supervisor (e.g., Chief or Staff Director) → manager (e.g., Division Director) → senior executives...
- ❑ Expert: specialties in certain scientific areas (e.g., nanomaterials or transdermal drug products); peer reviewed; renewed every 3-5 years; on-hold now)
- ❑ Master: broad knowledge and experience of related FDA regulated products (same as Expert)
- ❑ Cross-discipline: self-develop and take on
 - Data analytics
 - Project management
 - Policy Lead
 - Regulatory Counsel (e.g., obtained J.D. after Ph.D.)



USPHS Commissioned Corps

Career Development Strategies:

- ❑ Geographic move: move across locations and department/agency
 - Pro: Large network and amount of opportunities
 - Con: May lose expertise and focus, perceived as a jumper
- ❑ Program move: move up to take on increasing leadership roles and responsibilities within the same organization
 - Pro: Maintain expertise within the same/similar area
 - Con: Leadership positions are very limited
- ❑ Tips:
 - Serve the underserved populations and locations
 - Increasing leadership roles and responsibilities
 - Two jobs, promotion challenges



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Geoff as a Case Study

Research Scientist:
bench work focused



Review Chemist: post-marketing
CMC changes for generic drugs



Special Assistant to the Director:
science, comm, HR, budget, etc.



**Associate Director for Science and
Communication + Staff Supervisor:** science,
comm, HR, budget, review, direct supervision



Acting Deputy Office Director (+ Division Director):
science, comm, HR, budget, review, operations, etc.

Reflection: FDA

- Keep an open mind, be flexible
- Nothing is too trivial to take on (depending on career focus)
- Identify mentors & experts to learn from
- Constantly check & adjust career path
- If possible, find a niche area

Reflection: USPHS

- Allow me to build a large network
- Avoid certain conflict with civilians
- It is hard to serve as a good PHS officer due to committant assignments; but nothing comes free!



Thank you!

Question?



U.S. FOOD & DRUG
ADMINISTRATION