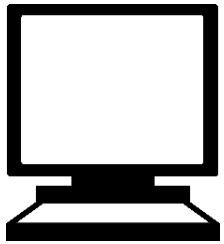
Pharmaceutical Quality

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



Pharmaceutical Quality

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

Drugs are no different.


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

Pharmaceutical quality is

assuring *every* dose is safe and effective, free of contamination and defects.


It is what gives patients confidence
in their *next* dose of medicine.

Research in a regulatory agency: the advantages of the researcher/assessor model at OPQ/CDER

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Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA's views or policies.

Outline

- Background
- What does FDA do?
- What are the different types of jobs in OBP?
- PI at US FDA: what do I do, how did I get there and some thoughts 4 years later

My Background

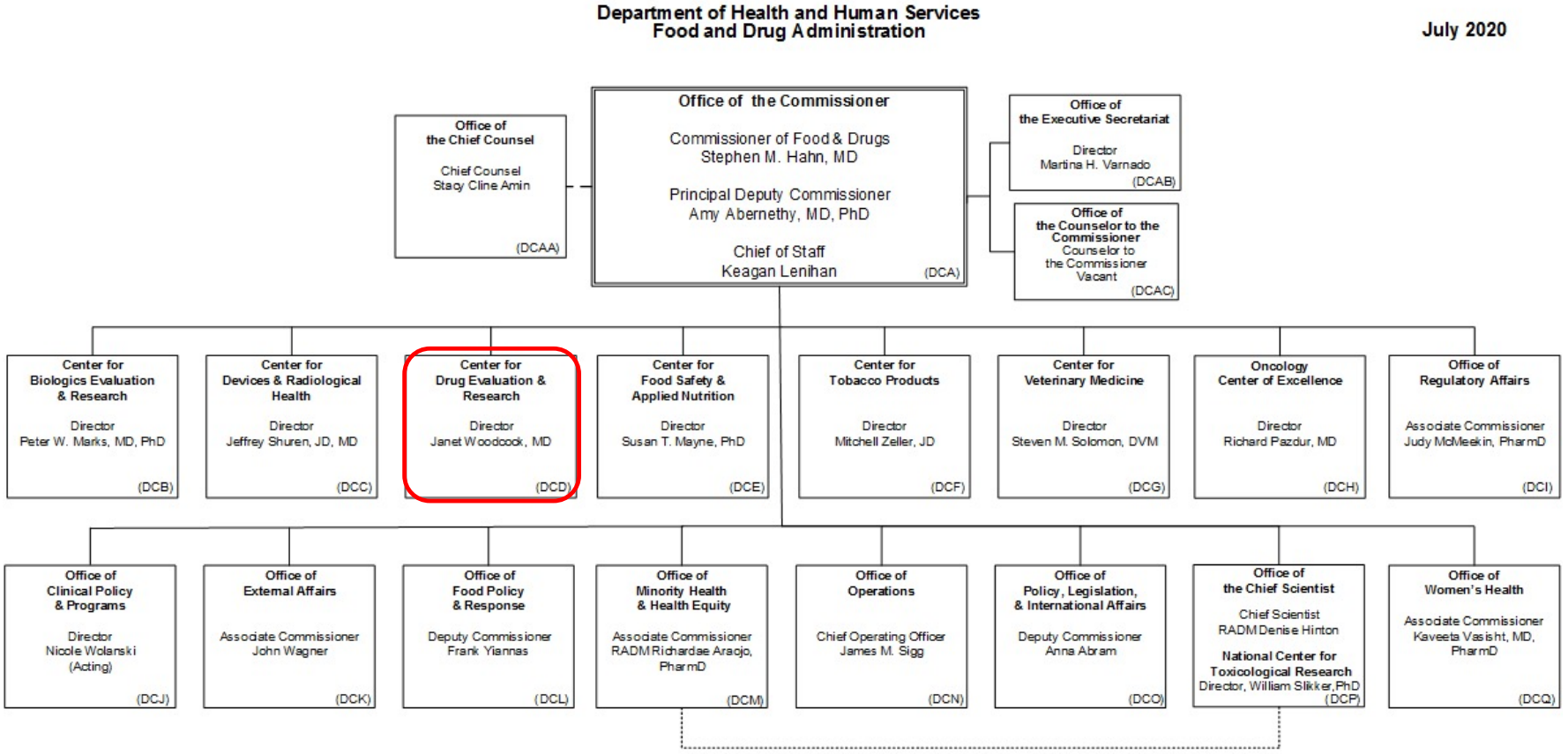
- PhD in pharmacology in Strasbourg (France)
- Postdoc/Staff Scientist at NCI (UOB) – 10 years
- PI at US FDA – 4 years

FDA

FDA is responsible for

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from harmful, counterfeit, adulterated drugs
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health

FDA/CDER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Food and Drug Administration
July 2020
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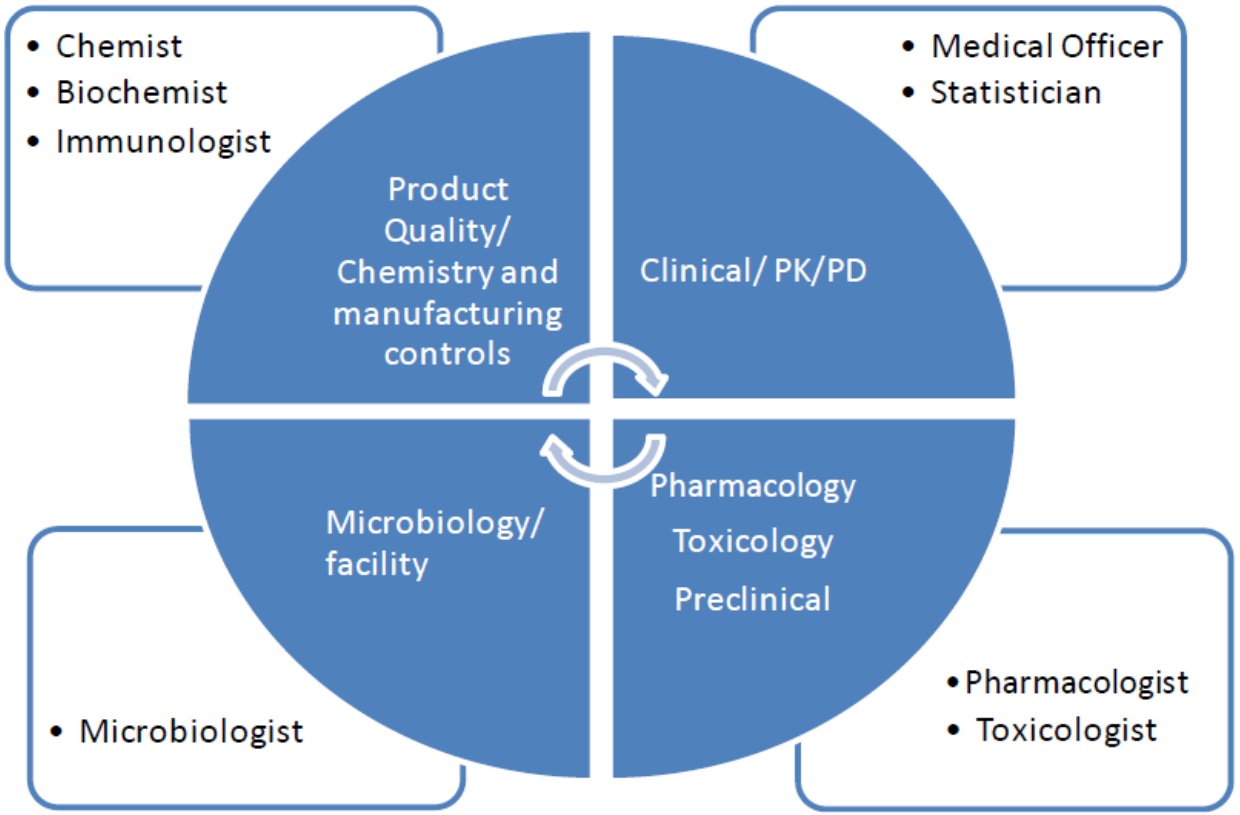
A multidisciplinary review process



Dependent on the phase of development and Center. An FDA project manager is usually the primary liaison.

FDA/CDER/OPQ

June 2020

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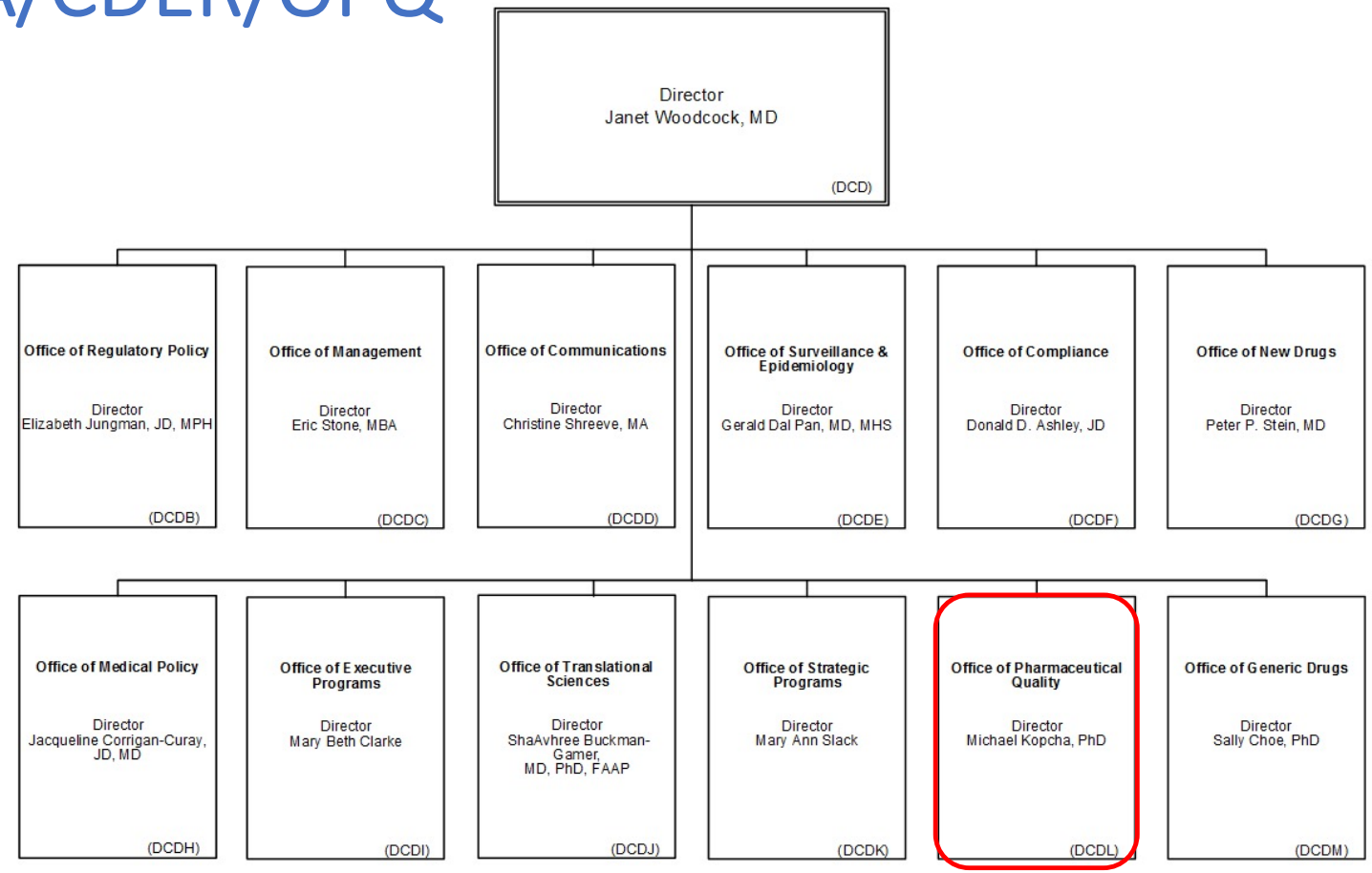
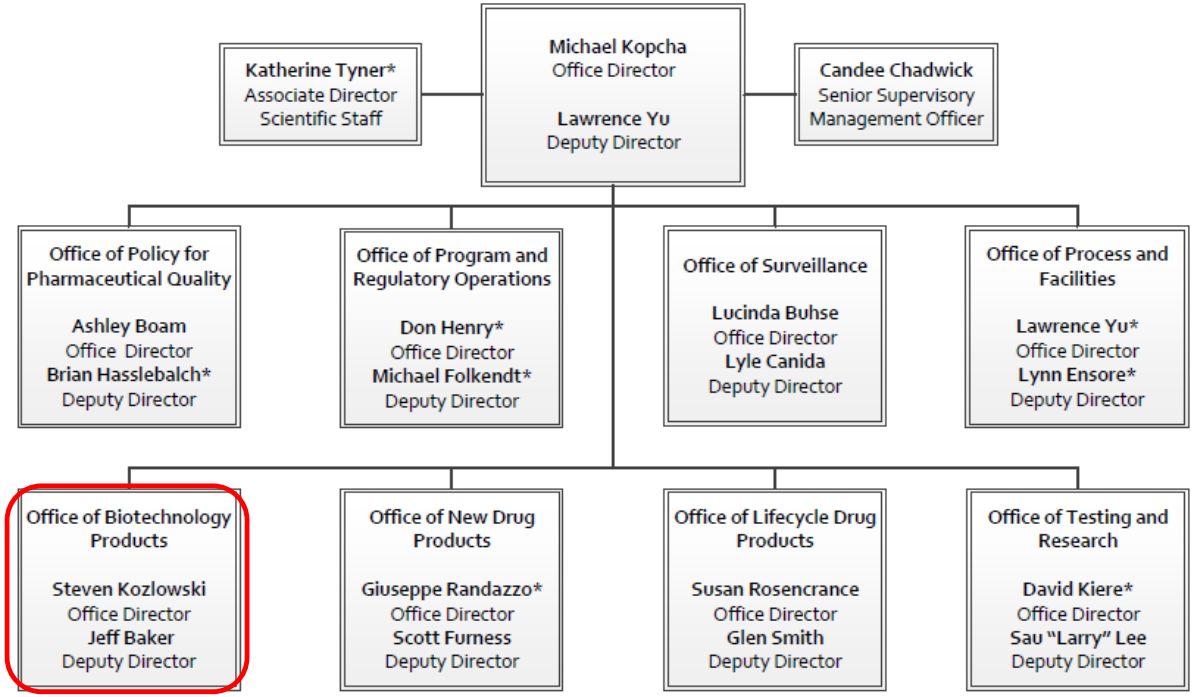


FDA/CDER/OPQ/OBP



OBP personnel

- Full time Assessor
  - Performs review of regulatory submissions: PreIND, IND, BLA, PMA, IDE, NDA
  - Evaluates biotechnology protein product quality issues and perform risk assessments for quality, safety, and efficacy
  - Review includes the manufacturing of the drug substance and product, characterization (analytical methods), mechanism of action, and immunogenicity
  - Inspections
- Full time Researcher
  - Primary research on novel topics related to regulatory research (including manufacturing processes, infectious diseases, cancer, biochemistry, immunology, protein characterization,…)
  - FTE, contractors (e.g. ORISE fellows)
- Researcher/Assessor
  - Splits time between review work and research
  - FTE, IOTF fellows

What do I do? The PI job in OBP/CDER

Regulatory – 30%	Research – 70%
Primary assessor Train/oversee lab members Participation to SC, WGs Communication (conferences, outreach etc..)	Run a research program Team/Lab management Writing: Grants, reports and consults Communication (conferences, outreach etc..) Participation to SC, WGs, COEs

- Research : mission relevance
- Regulatory work (public health impact)

What is mission-relevant research?

Developing bioassays that can support manufacturing quality, advanced manufacturing technologies, compliance investigations and biosimilar development.

Insulin products bioassays

Advanced manufacturing and control strategies; **Defining mechanism of action** and critical quality attributes to enable sensor-based quality control and real time release strategies.

Ir-endocrinopathies

ICIs on RCC metabolism

Electrochemical microsensors for continuous manufacturing (Bill Bentley- UMD)

How did I get to FDA?

- Traditional PI application process – Science Job ad

Phone interview, followed by on-site interview with research presentation and chalk talk

- Skills

  - ✓ Research expertise that could be translated to regulatory issues (immunology, virology, metabolism, oncology, etc…)
  - ✓ Leadership experience (participation to WG, committees such as the SSSC)
  - ✓ Communication skills, scientific writing, and ability to work with others

Some final thoughts…

Where to look for PI positions at FDA?

- Centers: mostly CBER

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https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/principal-investigator-viral-vaccines

Any Questions?