

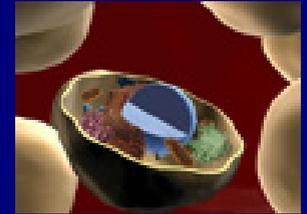
Center for Biologics Evaluation and Research

**Applying Regulatory Science to
Advance Development of Innovative,
Safe and Effective Biologic Products**

Carolyn A. Wilson, Ph.D.

Associate Director for Research

CBER Strategic Plan for Regulatory Science Follows CBER's Strategic Goals



- Increase national preparedness to address threats from bioterrorism, pandemic and EIDs
- Improve global public health through international collaboration
- Enhance ability of science and technology to facilitate development of safe and effective biological products
- Ensure safety of biological products
- Advance regulatory science and research
- Manage for organizational excellence

CBER Strategic Plan FY2012-2016:

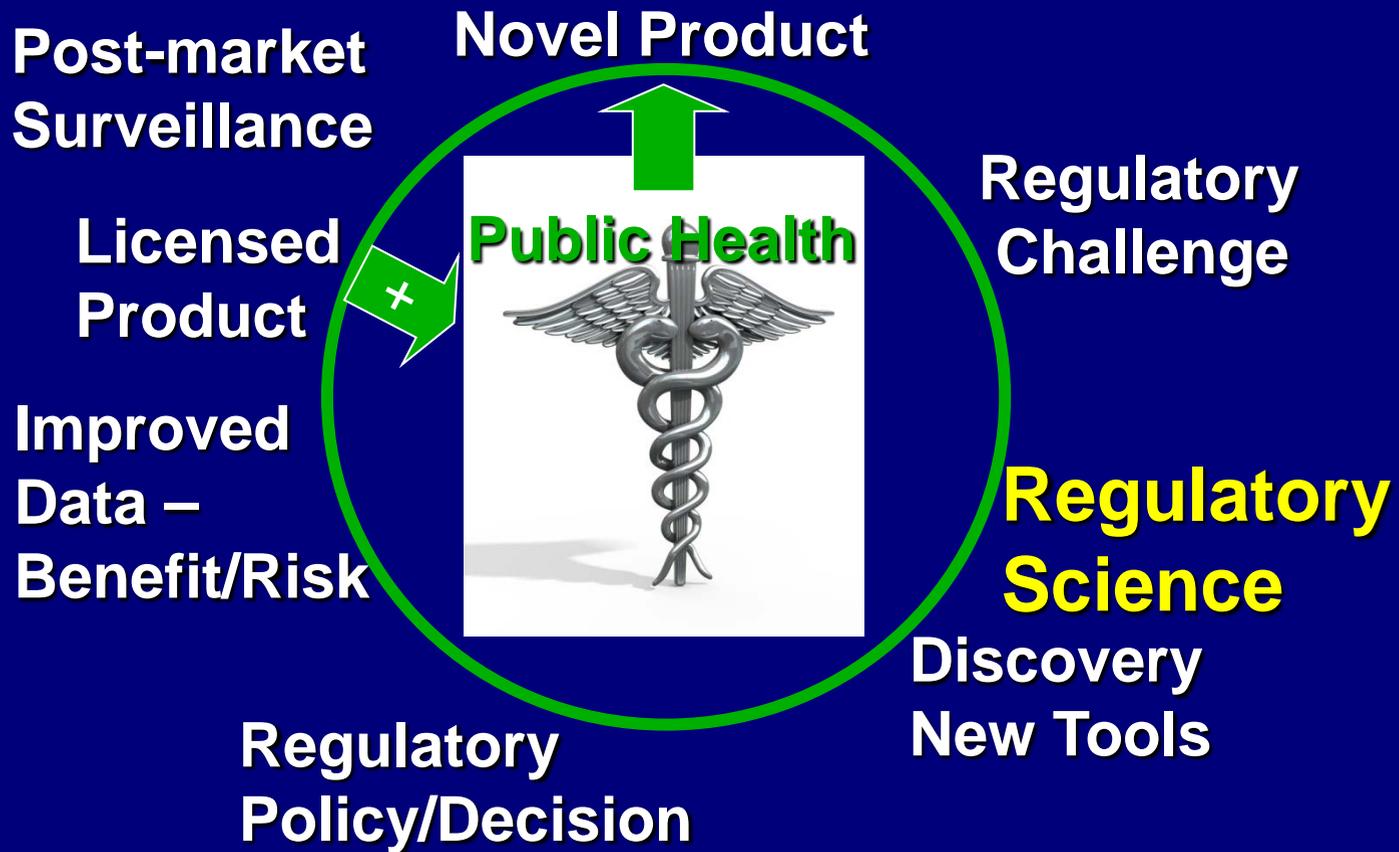
<http://www.fda.gov/downloads/aboutfda/centersoffices/cber/ucm266867.pdf>

CBER's Strategic Plan for Regulatory Science and Research:

<http://www.fda.gov/downloads/BiologicsBloodVaccines/ScienceResearch/UCM303542.pdf>



Using Science and Regulation to Advance Product Development



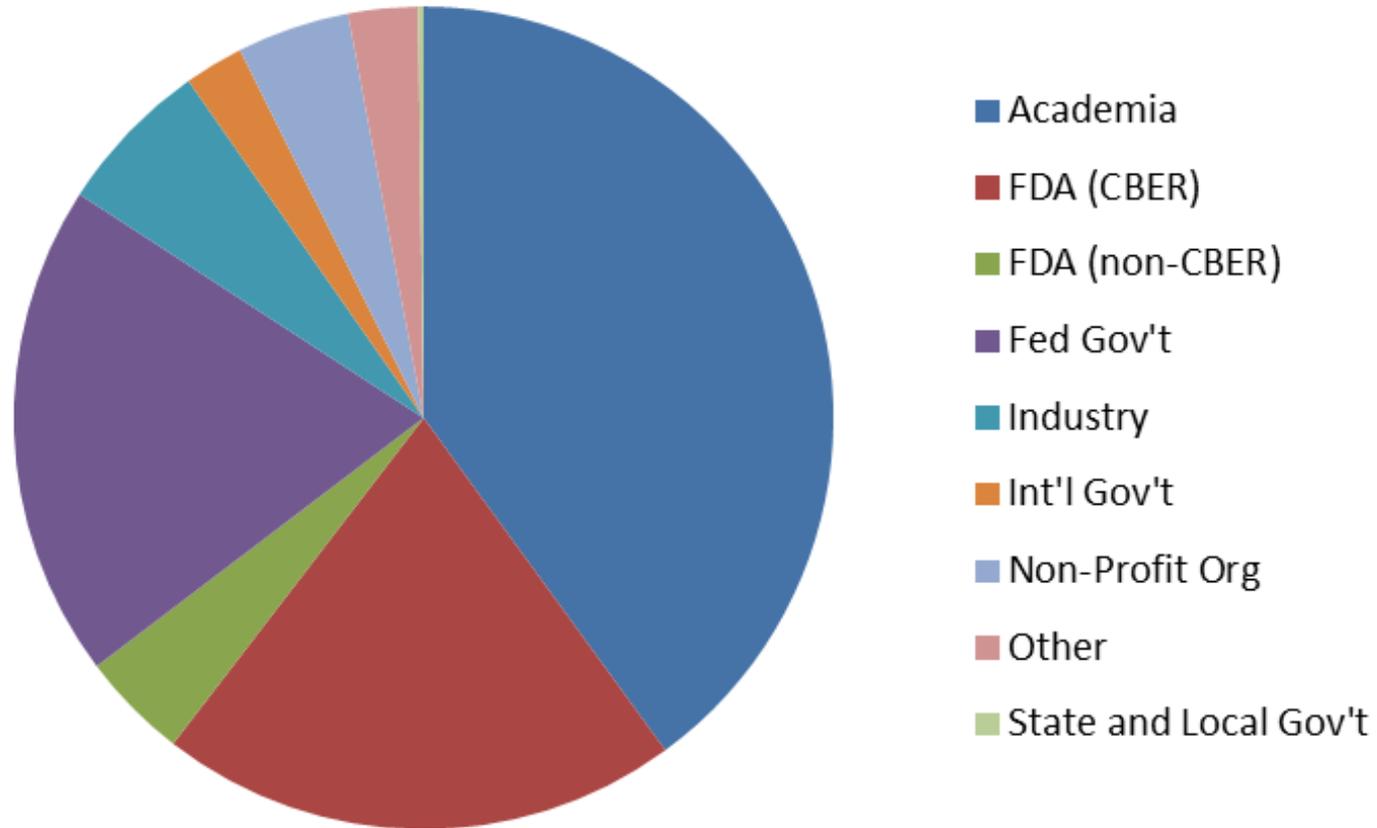
CBER researcher =
“Researcher-Regulator”
~20% CBER Staff

Integration of research and
review ensures

*Relevance, Expertise,
Timeliness, and Usability*



CBER Advances Regulatory Science through External Collaborations



*Data from FY15 CBER
Research Reporting
Database*

Annual Review of Research

PI provides

For each project

Progress report

Future plans

Budget Request

Presentations, Pubs

Other output

Information reviewed

Lab chief, DD, ADR, OD

Relevance

Productivity

Quality

Research Reporting
Database

Funding Allocated

Relevance to priority

Scientific/Reg Output

Feasibility



Cyclic Peer Review of Every PI Every 4 Years

External – Site Visits
peer review by scientific experts



Internal – Promotion, Conversion, Evaluation
Committee



Site-Visit Report

- Draft report is distributed to full Advisory Committee
- Final report is approved by full Advisory Committee
- Final report used in many ways:
 - Internal peer review of research/PI by Promotion, Conversion, Evaluation Committee (PCE) for personnel actions
 - By PIs for improving research program
 - By management, resource allocation decisions may be impacted by report (pending resource availability)



What's New?

- CBER Peer Mentoring Group
 - Monthly meeting, open to all PI's
 - Discuss general issues, how to manage different responsibilities, eg, recruitment, budget, personnel issues, etc
 - Informally mentored by senior PI volunteers
- Move to White Oak Campus

Life Sciences Biodefense Laboratory* “SE Quad”, White Oak Campus Occupied Since Summer, 2014



*Laboratory Programs of CBER and CDER/OBP

White Oak Lab Facility

- State-of-the-Art Vivarium
 - Imaging facility with MRI, digital X-ray, IVIS, ultrasound
 - Transgenic derivation facility
- Expanded Space for Core Technologies:
 - Flow cytometry
 - Confocal microscopy
 - High throughput sequencing and bioinformatic support
- 10 BSL-3 suites
 - Designed to support work of at least 12 infectious agents and work of 36 PI's
 - Many suites with capacity for animal holding rooms
 - 1 suite to support sterile sorts and live cell confocal microscopy on BSL-3 agents
 - Insectariums (BSL-2 and BSL-3)
- Suites designed to support Microarray and PCR
- Expanded NMR facility and Mass Spec Suites

DNA Sequencer, Illumina HiSeq 2500, Capable of Sequencing 200 Human Genome Equivalents in ~11.5 days



Flow Cytometry Core Facility

BSL-2 and BSL-3 Live Cell
Sorting Capability



Traditional Analytical Flow Cytometry and
12-parameter cytometric measurement capabilities

High resolution mass spec for analysis of glycan moieties on glycoproteins and polysaccharide conjugate vaccines

**NMR, up to 850 MHz:
preparing for biosimilars**



High resolution
Confocal microscopy
Fixed and Live cell
BSL-3 capacity



Thank you!

To the Site Visit reviewers and
Advisory Committee

Your input improves CBER's research programs

External review is critical to fulfilling our
regulatory mission!

