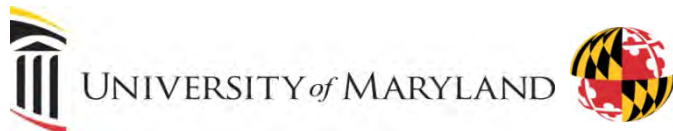


# **A Food and Drug Administration Initiative: Center of Excellence In Regulatory Science at University of Maryland**

Lex Schultheis, MD, Ph.D.  
Research Professor, Department of Bioengineering  
Director, Regulatory Science Initiative

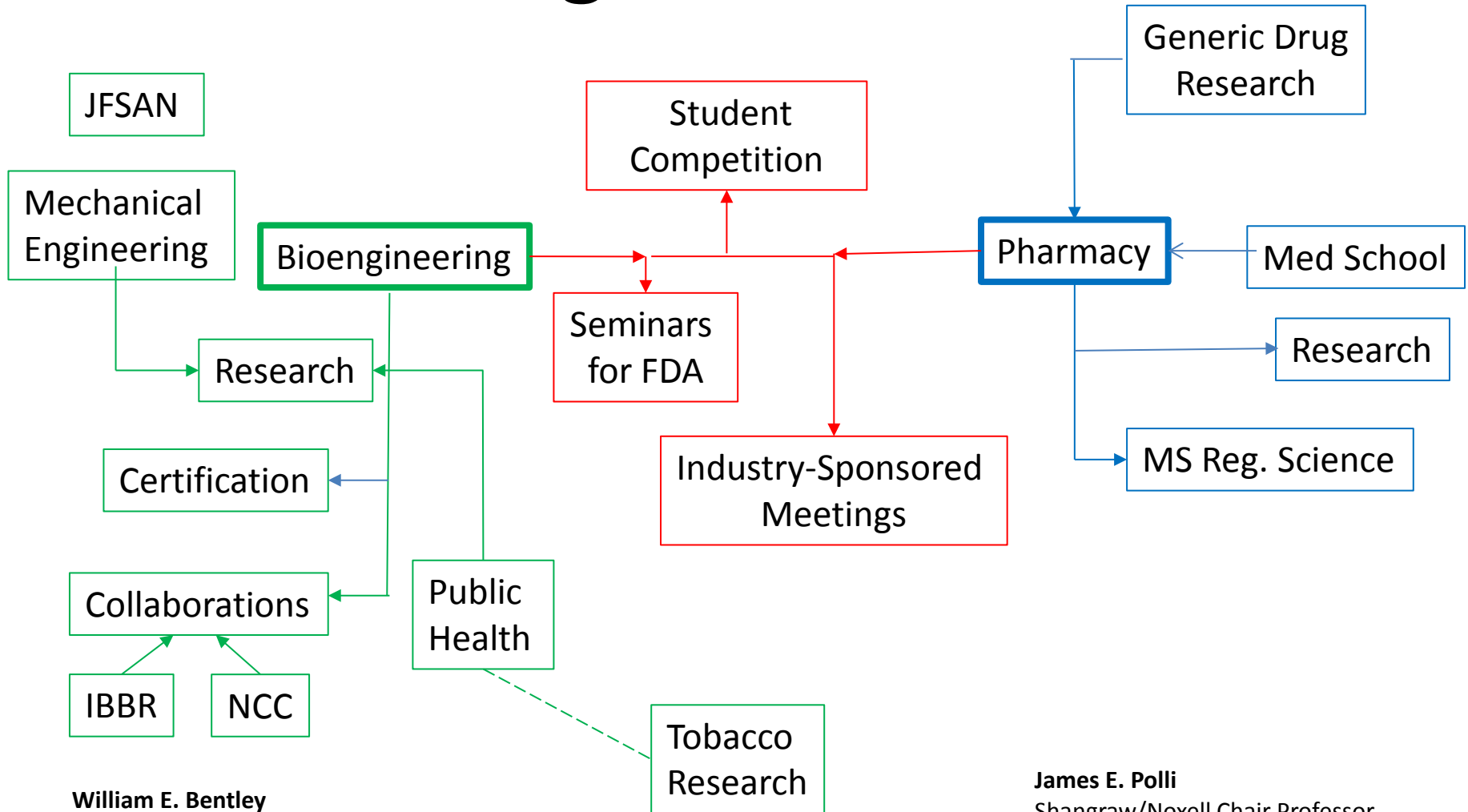
Ann Anonsen  
Coordinator,  
Center of Excellence, Regulatory Science



# FDA/UMD Center of Excellence

- **Develop new review tools for FDA**
- **Present advances in science and technology to FDA scientists**
- **Conduct research in critical areas of FDA interest**

# Original CERSI



**William E. Bentley**

Robert E. Fischell Distinguished Professor &  
Chair, Fischell Dept. Bioengineering  
University of Maryland, College Park

**James E. Polli**

Shangraw/Noxell Chair Professor  
Dept. Pharmaceutical Sciences  
University of Maryland, Baltimore

# UMD Baltimore Campus

## School of Dentistry

- Immersion Experience
- Educational Programs

## Medical School- University Hospital

- Conduct Clinical Studies (549 in progress)
- Innovation in Clinical Study Design

## School of Pharmacy

## University of Maryland Medical System

- University Hospital (816 beds)
- Midtown Campus (208 beds)
- Mt Washington Pediatric (102 beds)
- Baltimore-Washington Medical Center (319 beds)
- Charles Regional (121 beds)
- Rehabilitation and Orthopedic Institute (144 beds)
- St Joseph Medical Center (232 beds)
- Shore Regional Health
  - Chestertown (41 beds)
  - Easton (132 beds)
- Upper Chesapeake Health
  - Bel Air Medical Center
  - Harford Memorial Hospital, Havre de Grace

## Law School

- Guidance Commentary
- Ethics of New Paradigms for Clinical Studies
- ACA (Obamacare)

# School of Engineering

## Mechanical Engineering

- Human Factors
- Feedback Control Systems
- Robotics

## Chemical and Biomolecular Engineering

- CMC
- In situ Drug Manufacturing
- GMP

## Aerospace Engineering

- Supersonic Fluid Flow
- Remote Sensing
- Artificial Environments

## Bioengineering

## Reliability Engineering

- Quality Systems by Design
- Manufacturing and Design Controls
- Safety Assurance Case Studies
- Barcoding of Medical Devices

## Electrical and Computer Engineering

- Microprocessor controllers
- Interoperability (interfacing)
- Frequency Domain Signal Processing

# College of Agriculture and Natural Sciences

## Nutrition and Food Science

- Elemental Diets
- Enteral Diets for Metabolic Diseases
- Dietary Inhibition of Drug Metabolites

## Physics

- Femtosecond lasers

## Computer Science

- Software static testing
- Traceability analysis
- Safety Assurance Case (Fraunhofer Center)

## Chemistry, Cell Biology

- Molecular Design
- Biomarkers for Clinical Outcomes

## Animal Science

- Pharmacology/Toxicology
- GLP

## Information Technology in Health Sciences, Smith School Of Business

- Patient Assessment Risk/Benefit
- AERS/MDRs Search Tools
- Case Reports Medical Device Reviews

## Bioengineering

## School of Public Health

- Nanotechnology Environmental impact
- Addiction Management
  - Opiates
  - Alcohol
  - Nicotine
  - Electronic Cigarettes

# New Extramural Relationships with UMD CERSI/FDA

## University of Pennsylvania Children's Hospital of Philadelphia

- Next Generation Sequencing
- Single-nucleotide polymorphism arrays

## Walter Reed National Military Medical Center

- Rehabilitation and Physical Medicine
- Anesthesiology

## MedStar National Rehabilitation Network



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## University of Maryland Center Assisted Reproductive Technology-Shady Grove

## Washington Adventist Hospital

- Radiology
- Nephrology and Dialysis

# Capital Resource Commitment to Regulatory Science Initiative by University of Maryland



Current Architectural Rendition, Jan. 2014



The University of Maryland, with commitments from the State of Maryland, have completed planning for this \$150M 160,000 sq ft building, propelling bioengineering, regulatory science and health innovation. This building will house an Institute dedicated to regulatory development of medical products.

Groundbreaking 2015      Completion 2017



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Thank you!