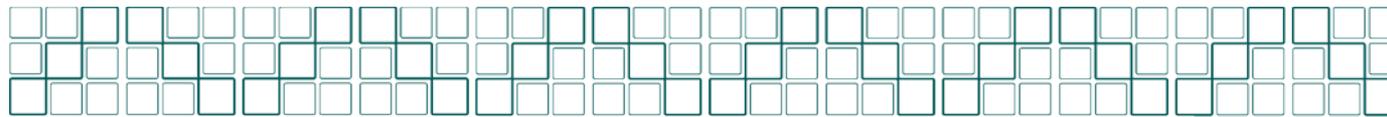

How to:

Regulatory Affairs

11-23-2010

Lori M. Conlan, PhD
conlanlo@mail.nih.gov

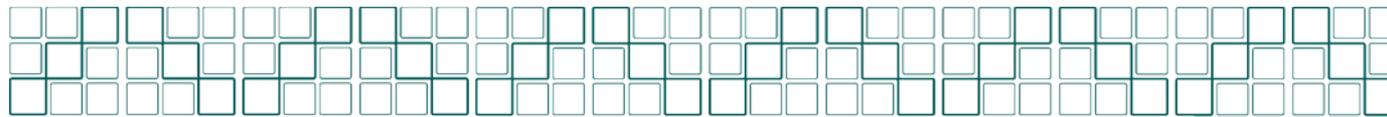




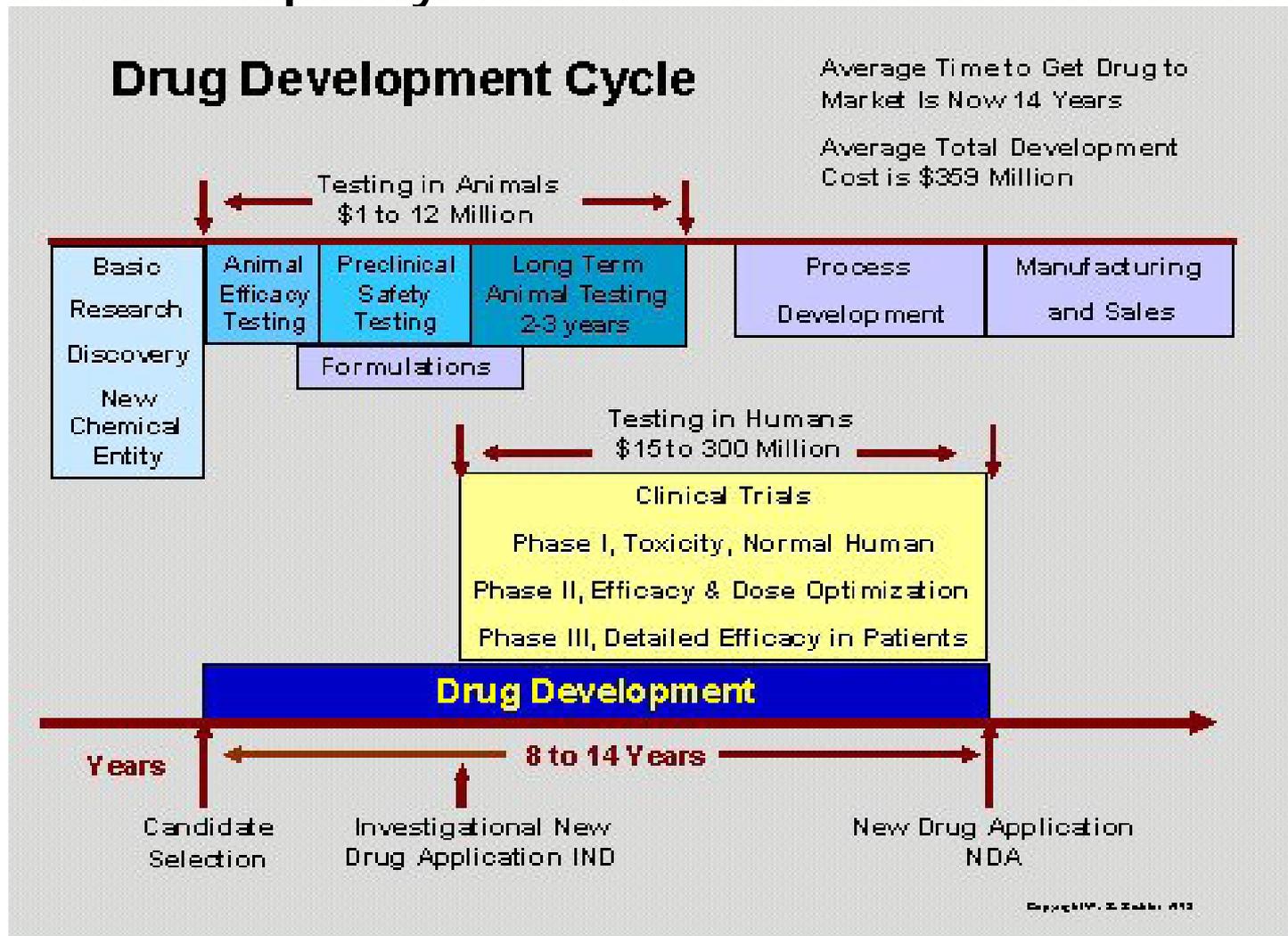
Regulatory Affairs

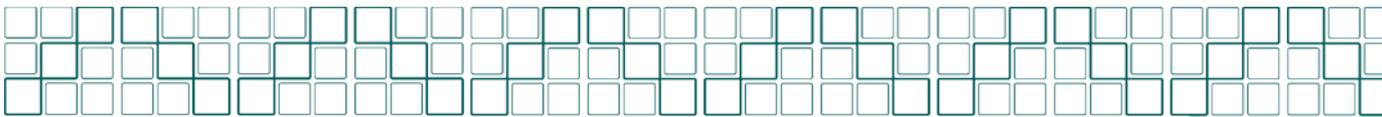
A profession that functions to apply laws, regulations, and policies to the development, production, and sale of products within regulated industries.

- Food
- Pharmaceuticals
- Medical devices
 - Energy
 - Biotech
 - Clinical
- Health care products

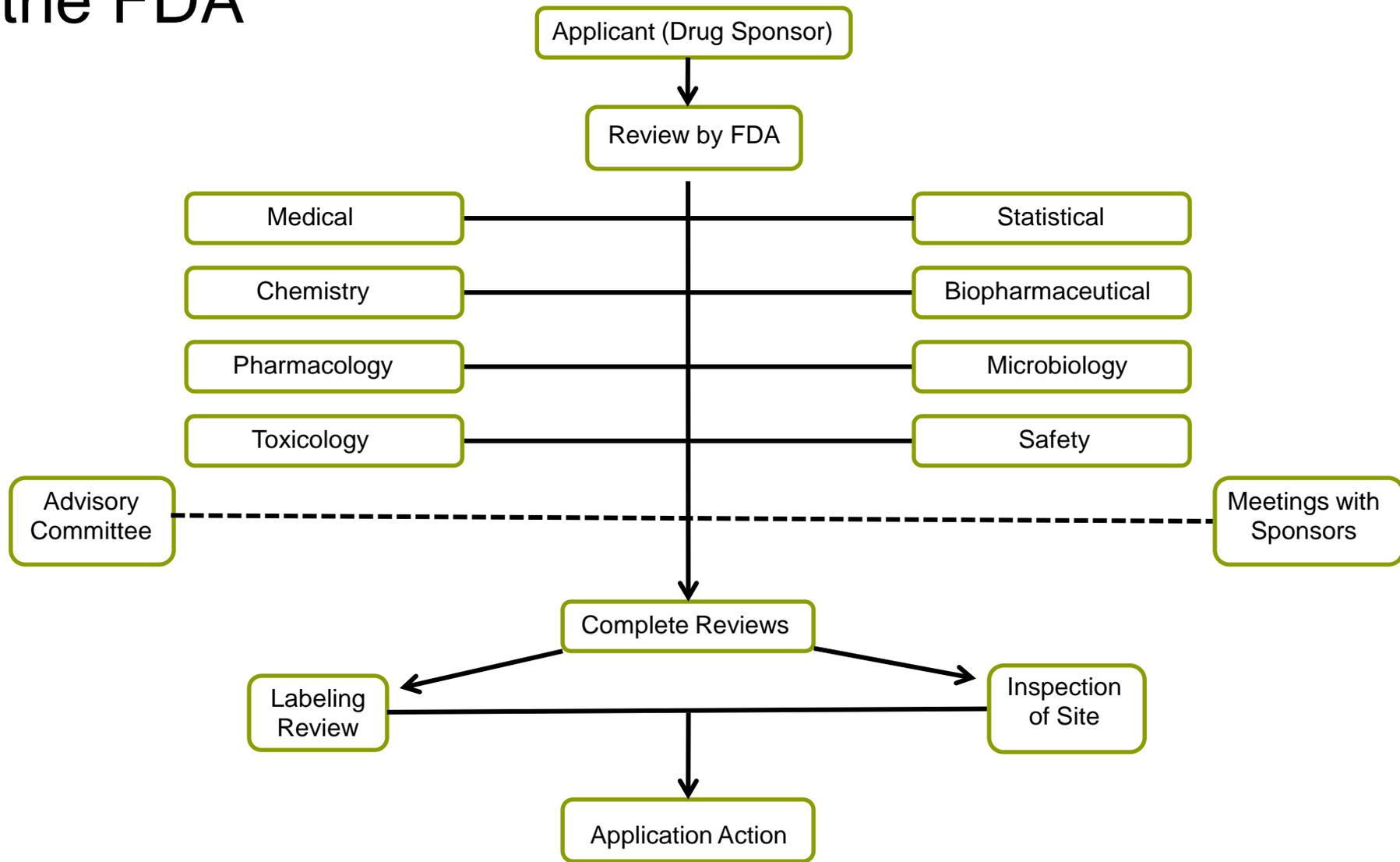


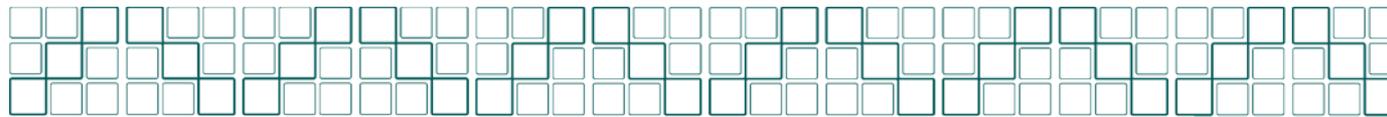
Multiple people and scientific disciplines at the company





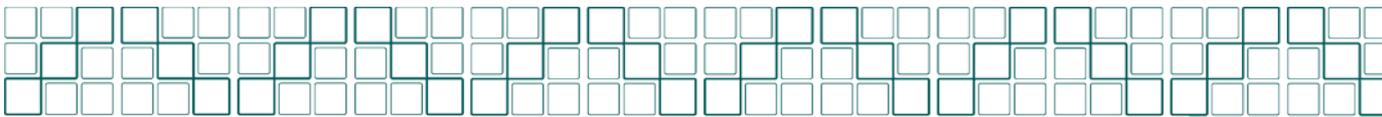
Multiple people and scientific disciplines at the FDA





Food Regulation at FDA

- Food Labeling and Nutrition: e.g. Ingredient Lists; Serving Size; Nutrient Content (**Trans Fat**).
- Dietary Supplements: e.g. Health Claims; Structure/Function Claims.
 - Produce and Plant Products: e.g. Field Sanitation; Packing Facility Sanitation.
- Seafood: e.g. Methyl Mercury; Environmental Chemical Contaminants and Pesticides (**Gulf of Mexico Oil Spill**).
- Food Ingredient and Packaging: e.g. Food and Color Additives; Food Contact Substances (**BPA**).



Safety Alerts



**FDA requests manufacturers to provide information
of the safety of their products**

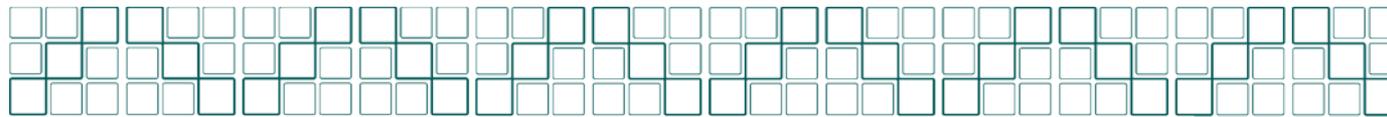


Scientific Review

- Information by product manufacturers
- Published peer-reviewed literature
- Experts in toxicology, neuropharmacology, emergency medicine & epidemiology
- Independent lab analysis by FDA

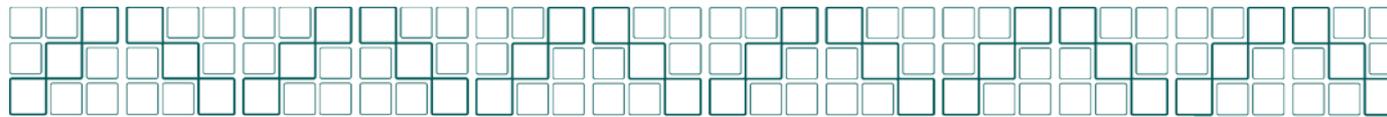


**Decision
Safe/Unsafe**



Regulatory Affairs in the Fed

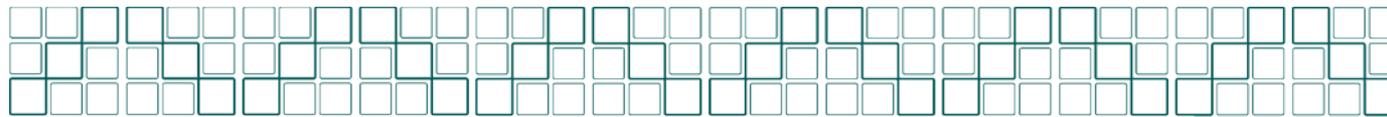
- (1) FDA: FDA scientists review test results submitted by sponsors, so that FDA can decide whether the drug is safe enough for clinical trials, whether the drug can be sold to the public, and what should go on the drug's professional labeling (cf. What happens at the FDA)
- (2) USDA: Inspect food safety, and collect and analyze surveillance data of foodborne outbreak; Conduct studies and evaluations, such as Child Nutrition Studies, Food Security Studies, etc. in response to the needs of policy makers and managers.
- (3) EPA: Assess exposure, hazard, and risk of chemical substances and/or toxic substances; assess risks of environmental pollutants, and develop biological indicators.



Regulatory Affairs: Private Sector

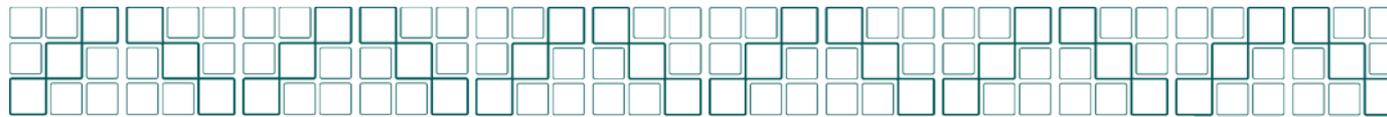
- Industry
 - Gather data necessary for submission to government. Manage process of regulatory approval.
 - Regulatory Affairs Associate

- Regulatory affairs services (Consulting)
 - Provide evaluation of the best regulatory path. May provide outsources submission and follow-up services.



Skill Sets

- Knowledge of science, regulations, and policy
- People skills
- Verbal communication skills
- Written communication skills
- Analytical and organizational skills
- Project and time management skills
- Computer skills

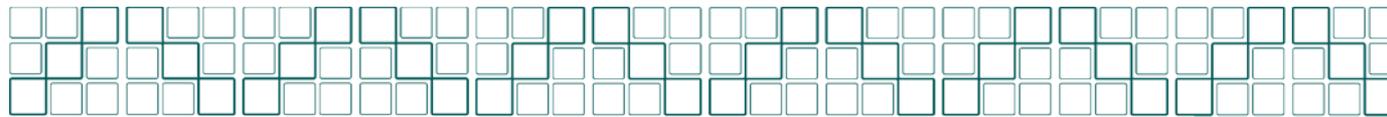


Knowledge of science

Strong science background: An overall understanding/
broad overview of the regulated fields

How to prepare yourself:

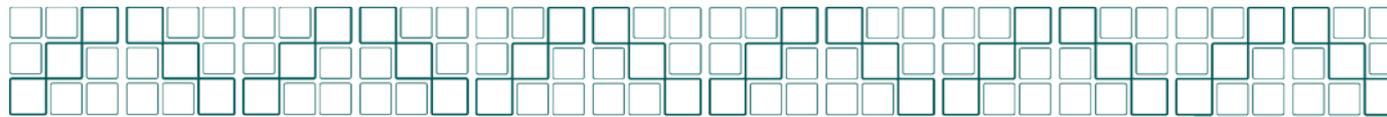
- Read widely
- Keep abreast of the latest scientific and technological developments
- Attend seminars, journal clubs, conferences, etc.
- Know and talk to the experts in the fields
- Learn from the expertise and experience from others



Knowledge of regulations/policy

- What is the regulatory process?
 - How does the system work?
 - What protocol to follow?

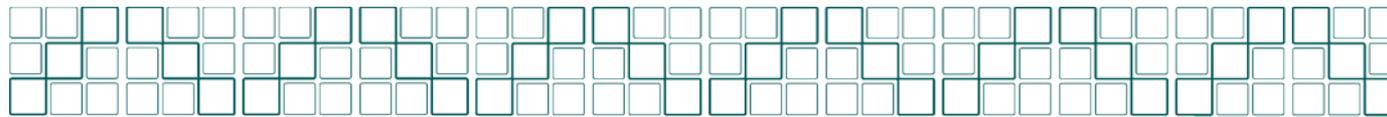
 - **How to prepare yourself:**
 - Be familiar with GMP/IND and other regulatory acronyms
 - Keep track of regulations in related fields
 - Gain real-world experiences:
 - Trainings: FAES, RAPS
 - Fellowships/Internships
- NOTE: May be on-the-job training



People Skills

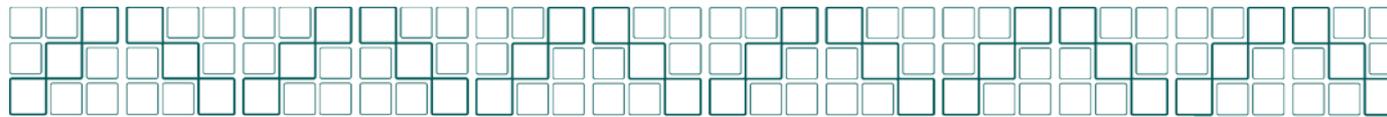
- Accommodate different personalities
- Coordinate different parties
- Understand mutual goals and constraints
- Work as a team
- Mediation, compromise and consensus skills

- **How to prepare yourself:**
 - Participate in community services; Felcom, SIG (Special Interest Groups), etc.
 - Join, organize and lead meetings, journal clubs, and speaker visits
 - Collaborate with people in own and other labs
 - Take Leadership courses in OITE



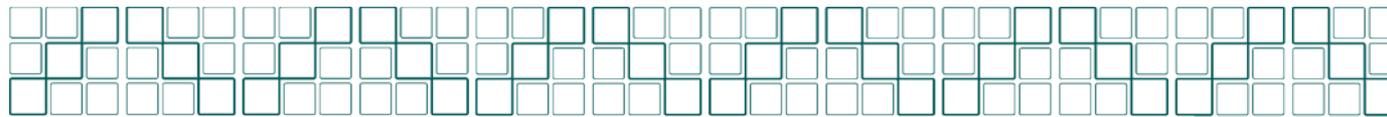
Verbal Communication Skills

- Talk and negotiate with people from various sectors
 - science, companies, policy, law, etc.
- Interact with various groups
 - research, production, sales and marketing, etc.
- **How to prepare yourself:**
 - Practice public speaking, join Toastmasters
 - Speak with folks outside of your discipline
 - Active listening
 - Effective questioning



Written Communication skills

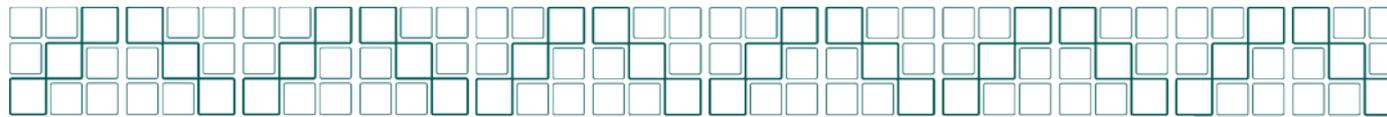
- Able to write Regulations
 - Good Manufacturing Practices (GMP)
 - IND/NDA reviews
- Applications
 - Investigational New Drug Application (IND)
- Business correspondence
 - Memos and emails
 - Clear and concise language
- **How to prepare yourself:**
 - Write papers, reviews, grants, Catalyst or other newsletter articles
 - Join NIH Fellows Editorial Board
 - Take Science Writing classes



Analytical/organizational skills

- Able to decipher, analyze and organize info
 - What's important?
 - What actions to take?
 - What protocol to follow?
- Show attention to detail

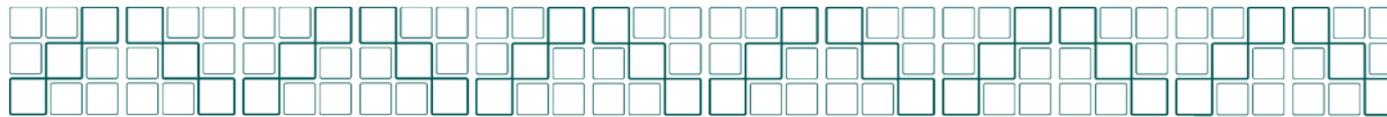
- **How to prepare yourself:**
- Transferable skills from bench science –
 - Gather, analyze and organize information
 - Find and test solutions to problems
 - Formulate plans



Project and Time Management

- Plan the tasks and allocation of resources
- Manage different projects at the same time
- Complete tasks on deadline

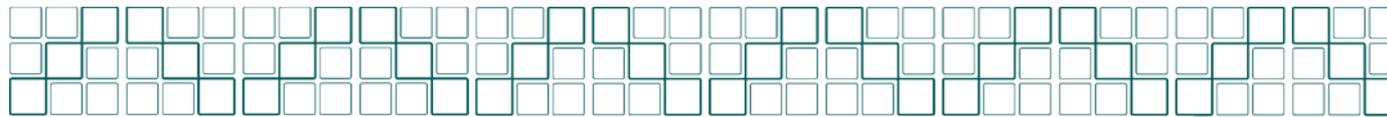
- **How to prepare yourself:**
 - Goal Setting
 - Planning, scheduling, and prioritizing
 - Organizing
 - To-do list
 - Detail oriented



Computer Skills

- Able to use software and database
- Microsoft Office
- Email
- Internet

- **How to prepare yourself:**
 - Take NIH Library courses



Professional Societies

- The Regulatory Affairs Professionals Society (RAPS)

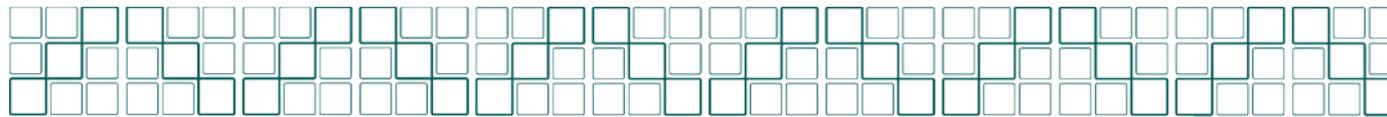
<http://www.raps.org>

- The Organization for Professionals in Regulatory Affairs (TOPRA)

<http://www.topra.org>

- The Canadian Association of Professional Regulatory Affairs (CAPRA)

<http://www.capra.ca>



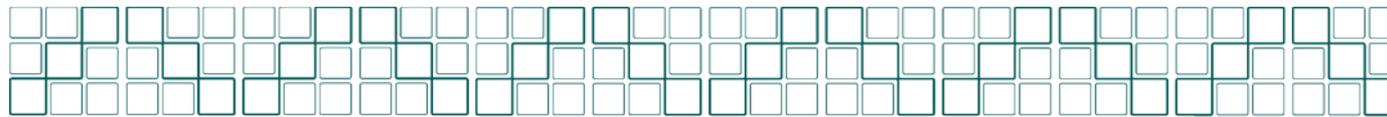
Sources of Trainings

- NIH FAES Graduate School
- The Regulatory Affairs Professional Society (RAPS) Online University
- Commissioner's Fellowship Program (FDA)
- CDER Academic Collaboration Program (FDA)
 - University of Florida College of Pharmacy
 - ASU Phoenix College of Nursing and Health Innovation
- Johns Hopkins Master of Science in Bioscience Regulatory Affairs
- CATO Fellowship
 - <http://www.cato.com/fp.shtml>



Resources/References

- Regulatory Affairs Branch (RAB), NIH, NCI
 - (<http://ctep.info.nih.gov/branches/rab>)
- Regulatory Affairs Professionals Society (RAPS) Online University
 - (<http://www.raps.org/personifyebusiness/ConferencesTraining/OnlineUniversity>)
- FAES Graduate School (<http://www.faes.org>)
 - TECH 501, Inside and Outside the FDA
 - TECH 504 FDA Regulation, Industry, and Hidden Intellectual Property
- Johns Hopkins University
 - Master of Science in Bioscience Regulatory Affairs
 - (<http://advanced.jhu.edu/academic/biotechnology/bioscience/>)
- U.S. Food and Drug Administration (FDA) (<http://www.fda.gov>)

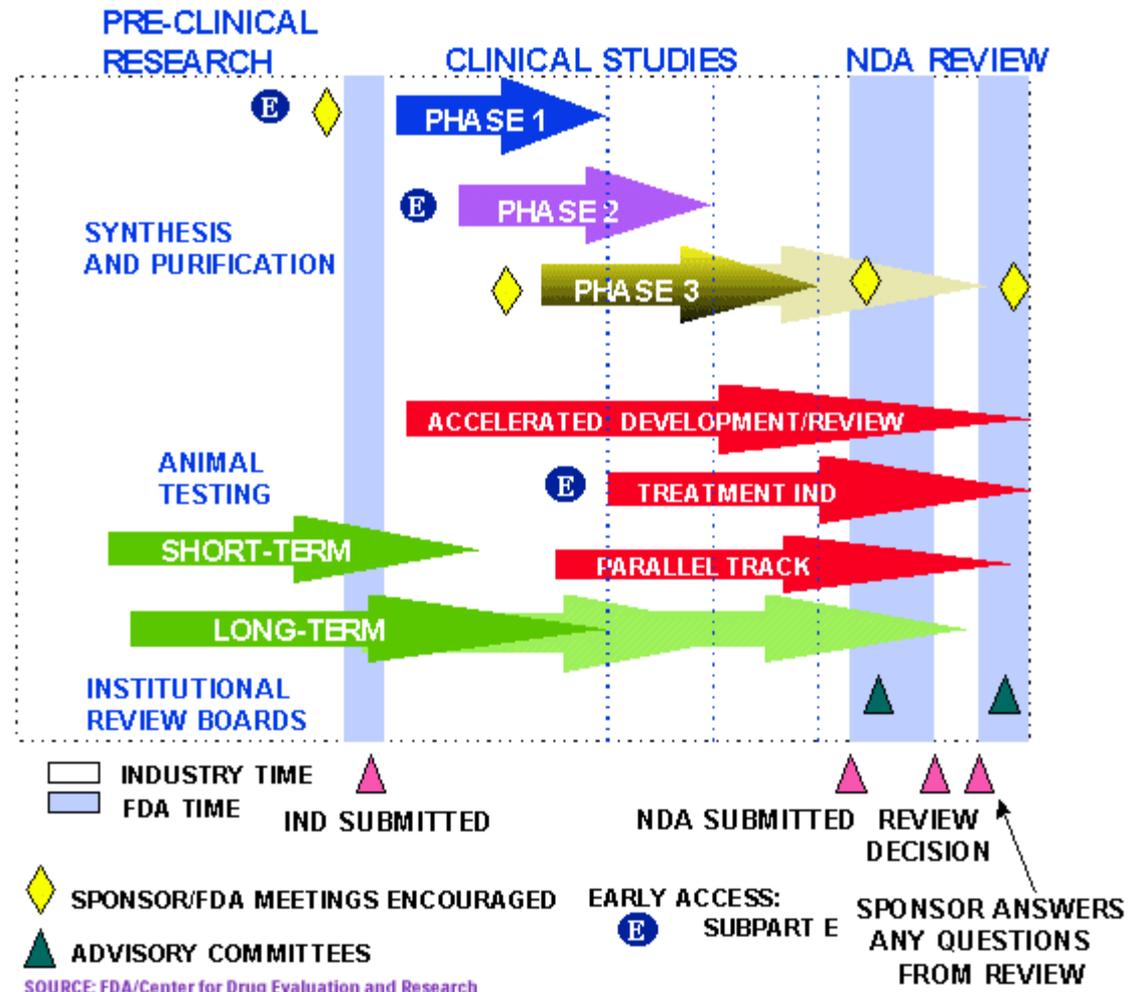
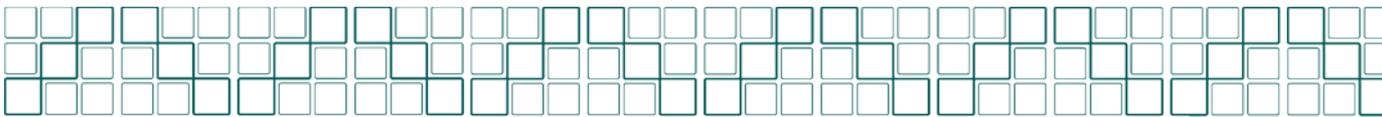


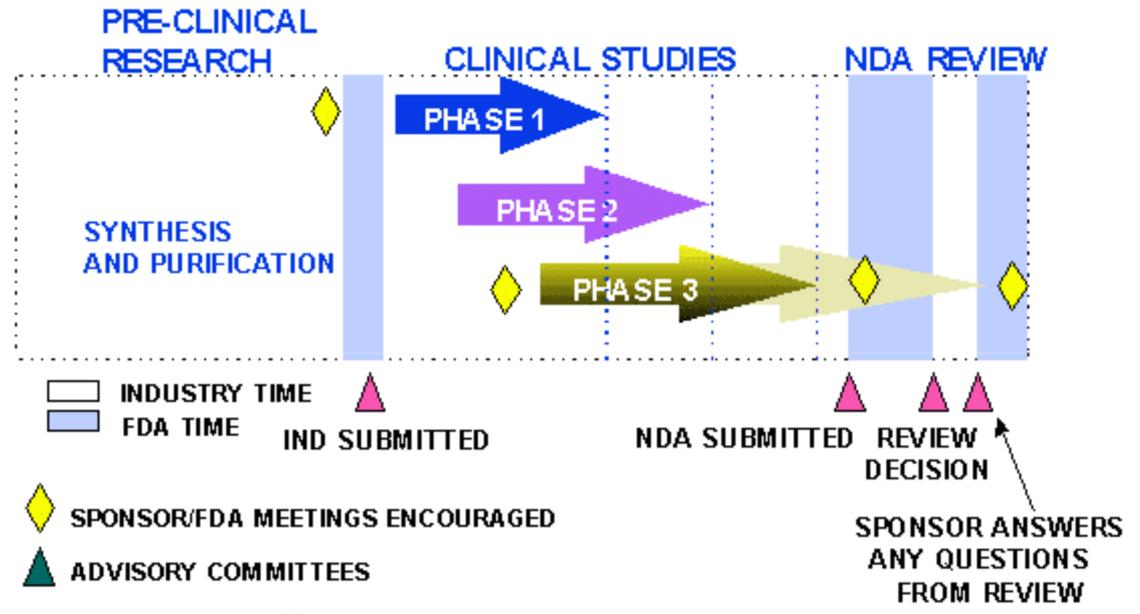
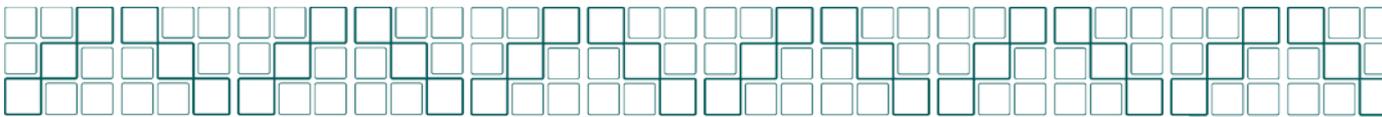
Questions??



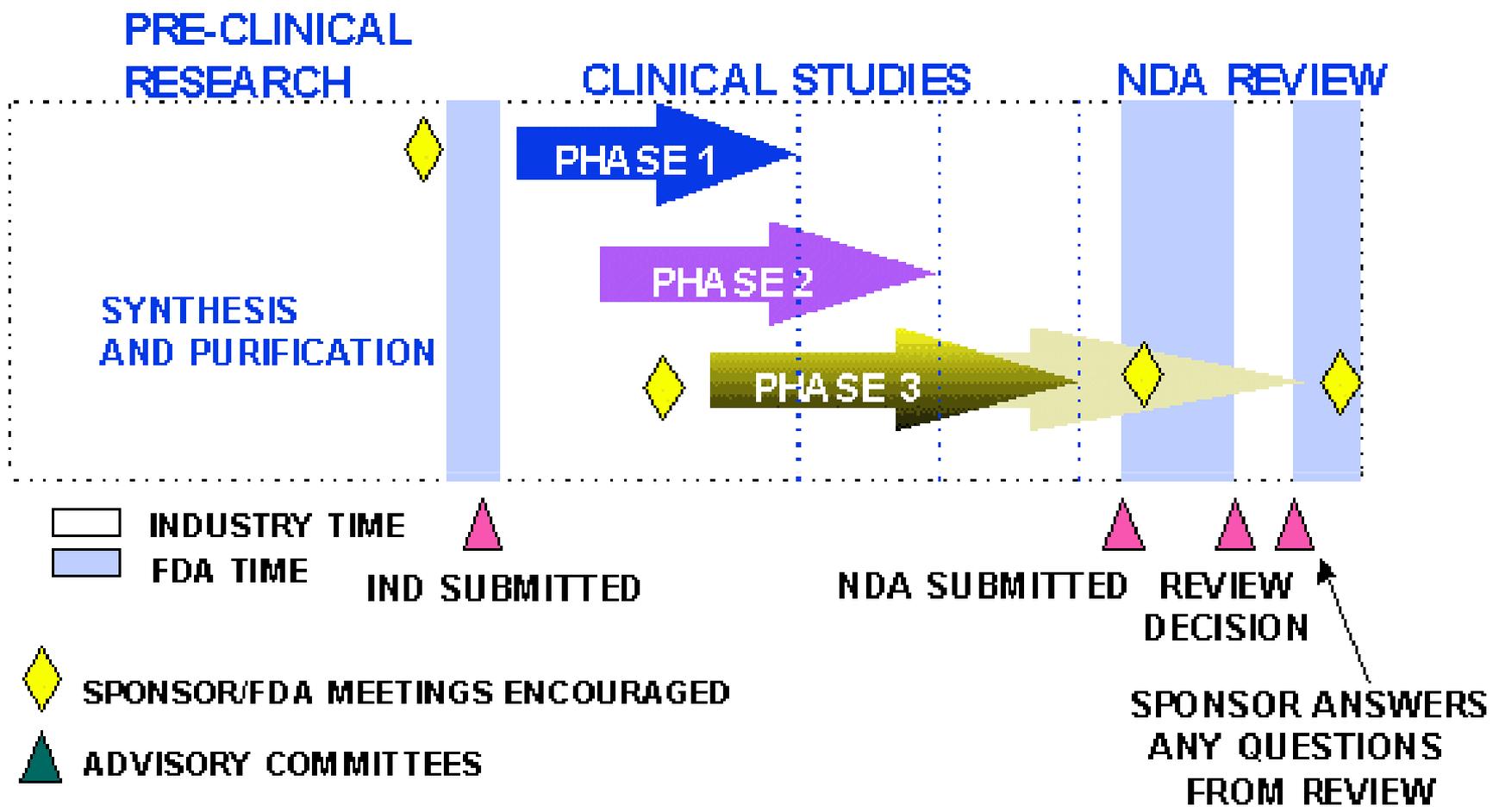
What do scientists do in regulatory affairs?

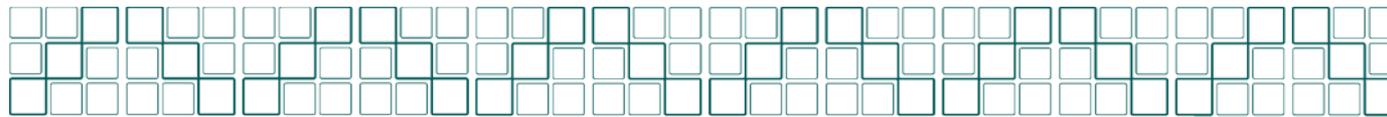
- Evaluate potential product candidates and trials
 - Mediate among interested parties
e.g. research, production, sales and marketing,
regulatory agencies, etc.
- Find common ground and compromise
 - Gain consensus





Multiple people and scientific disciplines at the company





Regulatory science “is the art and science of taking new medical and food products to market and keeping them on the market, under the constraints of a variety of laws and requirements. You’re doing science, but you’re doing it in a legal framework.”

Frances Richmond
Director, Regulatory Science Program, USC



Why we need regulatory affairs

Make sure company businesses/products abide by applicable regulations, laws, and guidelines, in every country where a product will be marketed.

Every step in product development is regulated

eg. Biomedical products

- Research and development
 - Preclinical studies
 - Clinical studies
- Manufacturing process
 - Marketing
- Postmarketing surveillance

*Regulatory scientists participate in
each and every one of the steps.*



Regulatory affairs requires expertise from multiple disciplines

- Research science
e.g. physicists, life scientists, chemists, engineers
 - Pharmacy
 - Statistics
- Veterinary medicine
 - Nursing
 - Clinical medicine
 - Etc.