NCSU Intro Regulatory Science/Affairs in Agriculture

Day 1- AUGUST 21

Intro

Course introduction **(Keith Edmisten)**

Introduction

1. Course introduction **(Keith Edmisten)**
   a. Introduction to agriculture
   b. Developed countries versus undeveloped countries
   c. Importance of crop protection

2. Summary of Discovery to Market (**Chris Hofelt**)
   a. Screening (bioefficacy)
   b. Safety studies
   c. Formulation and Manufacturing
   d. Commercialization
   e. Benefits document (part of registration)

Day 2 (Scott Shore) – AUGUST 28

Intro

Overview of laws, regulations and agencies (deep dive in future lecture)

a) EPA, FDA, USDA
b) FIFRA
c) 7 CFR Part 340
d) FFDCA
e) OSHA, HazCom, WPS, etc.

3. Deeper dive into laws that govern regulation, what are they and how they came about.

Local (top 4 are very relevant to biotech regulation, bottom 5 more relevant to crop protection products)

a) Plant Protection Act
b) Federal Food, Drug, and Cosmetic Act
c) Federal Insecticide, Fungicide and Rodenticide Act
d) National Environmental Policy Act

e) Endangered Species Act
f) Clean Water Act
g) Toxic Substances Control Act
h) HazCom and WPS
i) State laws (how state laws may differ)

Day 3 – SEPTEMBER 11 (lecturer 1) 3pm to 3:50

Intro

Traits 101 **(Ralph Dewey) (Ali Scott from Bayer has offered to help)**

a) What is a GMO?
b) How does a transformation happen
c) Where does a gene come from (donor organisms)?
d) Terminology
e) Stacks (and regulatory issues)
f) Comparison with conventional breeding/mutational/gene editing

Day 3 September 11 (lecturer 2) 3:55 to 4:45

4. Conventional pesticides 101 **(Travis Gannon) (Mark Parrish from Bayer has offered to help)**
    a. What is a pesticide
    b. Discovery
    c. Screening
    d. Mode of actions
    e. Targets (pest)

Day 3 September 11 (lecturer 3) 4:55 to 5:45

5. Biological-based pesticides 101 **(George Fountas)**
    a. Biologicals sources
    b. How is a biological manipulated in the lab?
    c. Formulating/fermentation
    d. Biostimulants, biofertilizers, biopesticides
    e. Differences from conventional pesticides
    f. Positioning of biologicals in organic ag and IPM

Advanced

Traits 102 (Keith Edmisten)

a) grower acceptance
b) traits

c) new technologies

Days 4 and 5 SEPTEMBER 18 & 25 (Volker Bornemann & Jessica Fernandez)

Conventional pesticide regulatory affairs (and biological pesticide regulatory affairs)

a. Development (phase 2)
    i. Formulation
    ii. Product chemistry (and biology for biological pesticides)
    iii. Toxicology (just high-level overview, mostly covered in a separate section)
    iv. Ecotoxicology
    v. Non-target plants/animals, phytotoxicity
    vi. Environmental Fate, persistence /stability
    vii. Metabolism, Residues, Residue Definitions
    viii. Risk assessment
b. Development/Registration (phase 3)
    i. Regulatory studies compilation
    ii. Submission of dossier
    iii. Benefits discussion and (draft) EPA document
    iv. Life-cycle management (patent lifespan, strategy, etc.)
    v. IR4 and minor crops
    vi. Label uses and efficacy claims
c. Commercial, Post-Registration (phase 4)
    i. Label amendments
    ii. Adverse effect reporting
    iii. Marketing/ Post-market conditional registrations
    iv. Resistance monitoring & best management practices
    v. State registration
    vi. Food chain/ international trade, MRLs, trade barriers, secondary standards
    vii. Stewardship (product, distribution channel, grower, food value chain)

Selected examples of contemporary issues and topics (as time permits), e.g., pollinator safety, drift, synergy, and additional MRL relevant topics in EU, Asia Pacific, and US.

Days 6 and 7 – October 2 & 9 (Laura Privalle & Friends) (Dean Bushey, Ali Scott, Michael Weeks from Bayer have offered to help)

Lecture 6 - Traits Regulatory Affairs

a) What the Farmer Needs
b) Cost of Product Development
c) Regulatory Roles

d) Phases in the Development of a Biotech Product
    a. Discovery
    b. Technical Concept Testing
    c. Commercial Concept Testing
e) What is GLP?

Lecture 7 - Traits Regulatory Affairs

a) Phases in the Development of a Biotech Product
    a. Safety Assessment
    b. Commercial Launch
b) Stewardship
c) Labeling Requirements
d) Insect Resistance Management

Day 9 OCTOBER 23 (Damian Shea)

a. Toxicology 101 for compliance personnel
    a. Acute vs Chronic
    b. Hazard vs risk
    c. Toxicological endpoints
    d. LD50 / LC50
    e. GLP

Day 8 OCTOBER 16 (Katie Davis)

Risk assessment - Understanding and translating environmental and human safety studies, product characterization, etc.

Day 10 & 11 OCTOBER 30 & NOVEMBER 6 (Scott Kohne)

Intro
Global and 'big picture' topics (lecture would be cross-technology)
a. Trade flow of agricultural products, key import/export markets
b. Global Stakeholder Trade Strategies
    1. Innovation (chemistry and biotech) Producer Commercial Launch Commitments
    2. Value Chain
    3. Government

c. Overview of key (US-centric) national and regional non-US regulatory systems and issues (relate to trade flow)
    1. EU (trait and crop protection)
    2. China
    3. Other key countries/regions

Do we keep this in intro? Move to advanced?

Local issues discussion and debate (cross-technology)
    a. Secondary non-regulatory standards lecture
    b. Agricultural coexistence (discussion or debate)
    c. Food labeling laws and voluntary systems (discussion or debate)

Day 12 NOVEMBER 13 (Michael Weeks)

Intro

Field research compliance

a. This should come after the overview of the laws and regulations
b. Could demonstrate how a biotechnology permit is put together and the process for submitting and subsequent reporting requirements
c. Isolation,
d. in-season and post-harvest monitoring
e. Movement and import of biotechnology products
f. Quality management and identity preservation tactic
g. Audits and field inspection process

Advanced

Hands on exercise - develop a containment protocol for a permit for a novel GE plant
a. brief presentation on the biology of the plant,
b. small groups to develop various portions of what we would think the USDA would require for containment (e.g., volunteer management, reproductive isolation, etc.).

Day 13 NOVEMBER 20 (Iian Kelly)

Intro

The future and regulatory for new (or undiscovered) technologies

a. Innovations and technology
b. Challenges
c. Opportunities
d. Outlook

Careers in regulatory science review: **(Bob Graney)**

Day 14 NOVEMBER 27

Careers in regulatory science review: **(Bob Graney)**

Careers in regulatory affairs panel. (**ALL)**