

REGULATORY AFFAIRS AG VS. BIOTECH

What's the Difference ?

Lauren Seabrook

ABOUT ME

Senior Regulatory Manager at Enzyvant Therapeutics. Experience with IND, BLA, and promotional submissions. Started my regulatory career at Bayer in 2009 and have experience in the regulation of Biotech (FDA) and Agricultural products (USDA and EPA). Held full time positions at Wyeth, Bayer, Syngenta, and BASF. Co-VP of Programs for the North Carolina Regulatory Affairs Forum.



AGENDA

AGRICULTURE

- PESTICIDES & GM CROPS
- REGISTRATION PROCESS

BIOTECH

- REGISTRATION DIFFERENCES
- REGISTRATION SIMILARITIES

CONCLUSIONS

- TRANSITION
- OPPORTUNITY
- Q&A



AGRICULTURE

CONVENTIONAL PESTICIDES

- HERBICIDES
- FUNGICIDES
- INSECTICIDES
- RODENTICIDES

GENETICALLY MODIFIED (GM) CROPS

- IMPROVED YIELDS
- ENHANCED NUTRITIONAL
VALUE
- RESISTANCE TO WEATHER
VARIATIONS AND PESTS

AGRICULTURE REGISTRATION PROCESS



FIELD TRIALS

- Efficacy of the product or crop
- Expected residues in crop at harvest, used to determine MRL's.



DATA

- Product Performance
- Product Chemistry
- Hazards to Humans, Domestic Animals, and NTO's
- Exposure
- Risk Assessments
- Environmental Fate



SUBMISSION

- Product Label
- Data Package
- PRIA fee



REVIEW & APPROVAL

- Agency meetings
- ~2-year approval timeline
- Information Requests
- Post Marketing Commitments



BIOTECH

DIFFERENCES

- Agency oversight and regulation
- Submission types (IND, NDA, BLA, etc.)
- Recurring inspections
- Regulatory disciplines (CMC, Ad-Promo, and Strategy)

SIMILARITIES

- Agency interactions and negotiation
- Extensive data package
- Product labelling requirements
- Electronic submission process
- Agency review process
- Post approval submission process

CONCLUSIONS

TRANSITION

- Changing industries from Ag to Biotech will require a knowledge and understanding of the regulations for biologics, drugs, and medical devices
- NCRAF membership
- RAC certification
 - Prep course sponsored by NCRAF

OPPORTUNITY

- Ag regulatory professionals have product registration experience and can be considered as viable candidates for Biotech roles
- Staffing shortages could be reduced by considering candidates outside of the industry



Q&A

- Thanks for attending !

