What does regulatory toxicology mean to industry?

- Just 1 part of the overall safety assessment

Regulatory Toxicology requirements/guidance should be considered **MINIMUM** requirements

- For some ingredients, company may be more conservative in their internal risk assessments
- Company may have specific ingredients they choose to avoid even though regulations allow (e.g. BPA)
- Company may have consumer habits and practices data that weigh in to the safety assessment
What does regulatory toxicology mean to industry?

- Regulatory path and requirements based on product claim (drug versus dietary supplement versus food) – any inherent toxicity will still be the same regardless the regulatory path.
What does regulatory toxicology mean to industry?

• In addition to major government agencies (e.g. EPA, FDA, Health Canada, EMA, etc), may include requirements from:
  – Country-specific Boards of Health, state-specific requirements (California Proposition 65), pharmacopeias (e.g. USP)

• Requires close partnership with internal regulatory manager and others as needed (e.g. QA, analytical, process and formulation, legal, etc.)

• One of the most interesting and sometimes challenging aspects occur when we differ in interpretation of regulations across industry, government, and legal (NOTE: to illustrate this point, I’ll briefly talk through the example of pesticide levels in botanical raw materials for use in dietary supplements versus drug product or food, DSHEA vs drug regulations)
“Hot Topics” in regulatory toxicology (personal healthcare industry perspective)

• FDA Monograph Reform
  – New opportunities for product innovations
  – May require additional work for some drug actives

• ICH Elemental Impurities
  – Ever-increasing analytical detection limits often translate into new regulations and challenges for ingredients that have a long history of safe use
  – May require reformulation which can completely change aspects of product (e.g. degradant profile, stability issues)

• New Dietary Ingredient Regulations
A “typical” day in industry

• Based on experiences in both Pharma (Rx) and Over-the-Counter/Supplement space
  – Pharma timelines are considerably longer; planning regulatory strategies across years (10-12) which makes day-to-day somewhat more predictable
  – OTC and supplement product timelines are much shorter (months to 2-3 years) coupled with hundreds of SKUs in the global marketplace
• New regulatory requirements can impact a large number of products
  – Changes to a formulation may completely change product profile (e.g. stability, degradants, etc.)
A “typical” day in industry

- Unpredictable issues can arise that may result in products considered mislabeled, misbranded, or adulterated
  - Product may get shipped or warehoused incorrectly which can alter formulation (e.g. precipitation of drug actives)
  - We’re human – mistakes may get incorporated into product labels (dosing instructions, cautionary statements, etc). Principle-led companies find and correct these mistakes immediately
  - Manufacturing mistakes (Quality Incidents/Serious Quality Incidents)
- Consumer complaints (safety surveillance) need to be addressed
- New studies/findings reported in the literature may have implications for product or product ingredients (sometimes these studies are picked up by media and intensify scrutiny)
- Social media – must respond to overt misuses of products
Entry-level responsibilities and growth opportunities

- Internal and external training available, often specific to assigned product category
  - Assigned a daily coach (business-specific) and a mentor (company-wide)
- Important to partner closely with regulatory counterpart and others (QA, analytical, legal, etc.); especially when issues arise
- Initially, interfaces with regulatory agencies may be limited, or you will shadow a more experienced toxicologist
- Growth opportunities may include serving on trade association task forces (e.g. Consumer Health Products Association), other organizations like USP Expert Committees, more advanced positions may include government advisory panels
Graduate student/Post-doc preparation advice

- Solid technical foundation is #1! (we are all scientists first and foremost)
- Begin to think about where your research fits within the appropriate regulatory agency (EPA, FDA, etc.)
- What other regulations or authorities might apply to your work? (e.g. CA Prop 65, USP)
- When preparing for an interview with a certain agency or company – know something about the history and authority of the regulatory agencies most applicable to the job, have some general knowledge of the most important guidances that govern that business
Regulators and Industry have the same ultimate goal

To protect consumers by ensuring safe products are in the marketplace

Thank You!