Laboratory Testing: Considerations for Regulators

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Purpose of Testing

- Confirm Regulatory Compliance
- Product Safety and Consistency
- Process Improvement

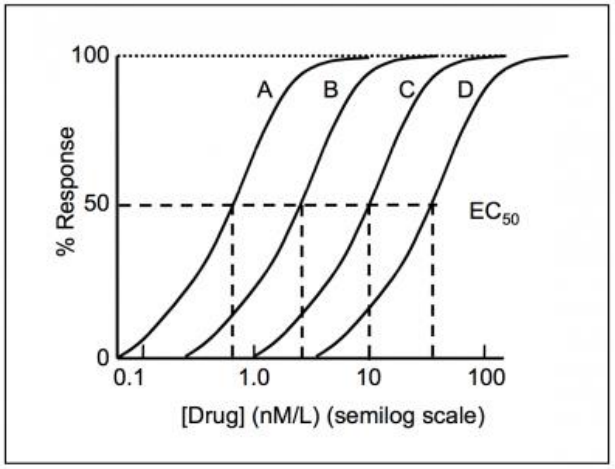
Product Lifecycle

Analytical Categories

- Potency
- Biological Contaminants
- Pesticides
- Heavy Metals
- Trace Solvents

Potency Analysis

- Sample Collection
- Acidic vs NonAcidic Cannabinoids
- GC vs LC
- Overdose/Underdose



Case Study 1

- A infused product manufacturer made multiple batches of a chocolate product using a concentrate which had been tested prior to infusion. With product distribution, consumer feedback was that the product was ineffective. No post production quality testing had been performed. What happened?

Case Study 1

- The extract was analyzed using GC and identified as being roughly 87% w/w THC.
- Reanalysis using HPLC showed the extract was 49% w/w THC.
- The manufacturer had added roughly half of the amount of extract needed to achieve the quantity listed on the package label resulting in a misbranded product and dissatisfied consumers.

Microbiology

- Sample Collection
- Smaller flowers decreased likelihood for failure
- Microwave
- UV-C <280 nm
- Appropriate analysis and threshold for product category

Case Study 2

- A concentrate intended for distribution was analyzed for potency and adulterants.
- Analysis showed mold and enterobacteria contaminantion
- The product was quarantined pending an investigation.

Case Study 2

- Internal Investigation Showed
  - Compliance with internal production controls
  - Inability of product to support biological growth
  - Indicated potential secondary contamination during analysis
- Lab Investigation
  - Contaminated commercially sourced reagent
  - Over 50% of samples failed were false positives

Pesticides

- Sample Collection
- Action Levels
  - May Vary by Route of Administration/Exposure
- Remediation
  - Oxidizing Agents
    - Accelerate Degradation
- Intermediate Ingredient
  - Dilution

Thought Exercise

- Does plant material or concentrate adulterated with unsafe levels of pesticide residues, heavy metals, residual solvent or bio-burden need to be destroyed?
- 10 lbs of flower material with a retail value of $15,000 is found to contain 1ppm Myclobutanil which has an action level of 0.2 ppm in the state of Oregon. The cultivator insists they did not apply the compound to their crop and that its presence is due to application at nearby non-cannabis farms. Should the harvest be destroyed resulting in a total loss for the cultivator?

Thought Exercise

- 1 ppm Myclobutanil Detected in Flower
- 0.2 ppm Action Level
- 10 ppm Concentrate Containing 75% w/w THC
- Make 100 8oz Chocolate Bars Each Containing 100 mg THC
- Use ≈ 13g of Concentrate into 22,667g of Chocolate
- 0.13 mg of Myclobutanil into ≈ 22,680 g of Chocolate and Concentrate
- Final ppm = 0.0057 or 5.7 ppb

Summary

- Testing is not quality control it is quality assurance
- When used in conjunction with a quality control program data is useful for more than just regulatory enforcement
- In developing regulations analysis should reflect where sample is in terms of product lifecycle

Questions

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Regulatory Ecosystem

- State Regulations
  - ISO 17025
  - Industry Standards and Best Practices
  - cGMP
- Industry Based
  - ASA/AHPA
  - FOCUS
- Voluntary Consensus Standards
  - ASTM
- Emerging
  - Self-Regulatory Organizations (SRO)