USP/GMP High Purity Alcohol Regulatory Considerations

FELC 2021

Parts

- State of the Game
- A Tale of Two Regulators
- The Pre-Nuptial Agreement: equipment, data, and documents
- Specification Management

A note on scope:

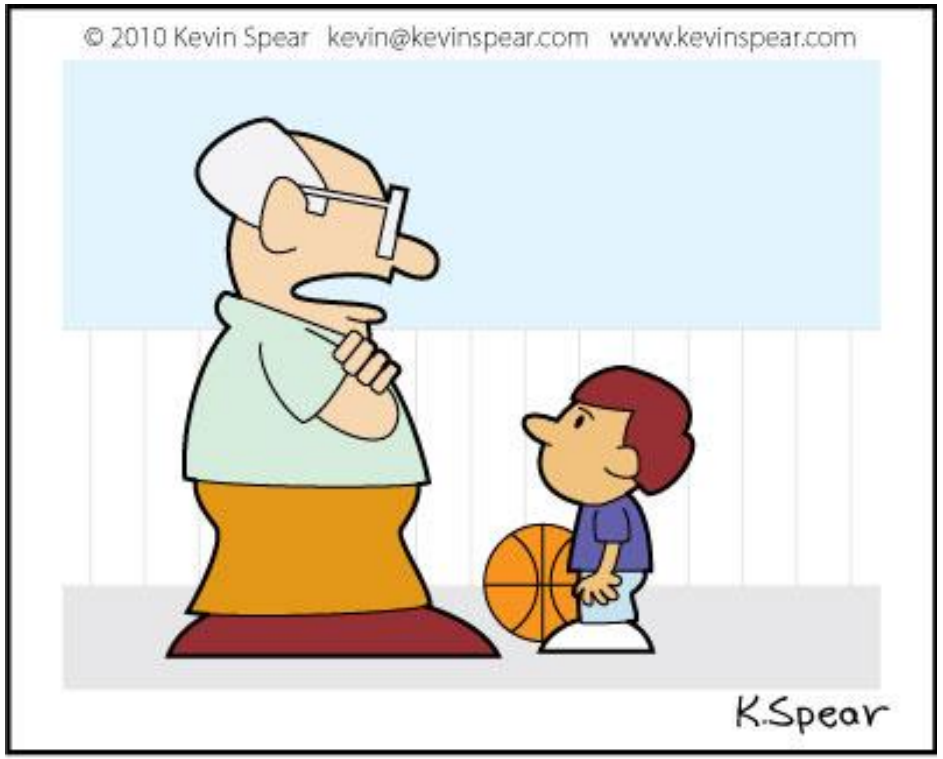
High purity ethanol is the core of this discussion but the principles can be expanded to other highly regulated markets (high protein animal food markets, etc.)

Part 1: State of the Game

	USP (US Pharmacopeia)	Industrial Grades	Grain Neutral Spirits
Regulating Body?	FDA	It depends…	TTB
Specifications?	Monograph(s)	Customer Requirements	It depends…
Markets?	Pharmaceuticals, Consumer goods, Cleaning agents, Cosmetics…	Paint, Chemical manufacturing, Solvents…	Beverage, Food production, Mouthwash…
Customer Sophistication	*Almost universally higher than our fuel and feed markets!*		

And so much more!

Part 2a: A Tale of Two Regulators



"Just wait until you're my age
and you forget what it's like to be your age!"

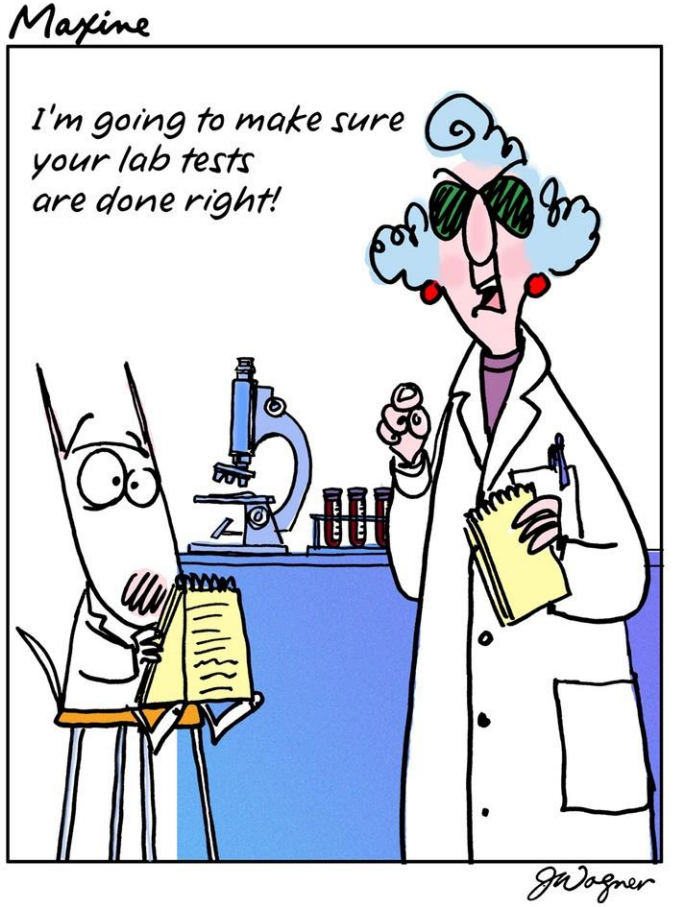
- Food Safety Modernization Act – Signed into law in January 2011, Compliance dates 2016-2018 dependent on business size
- Federal Food, Drug, and Cosmetic Act – Signed into law in June 1938

Part 2b: Perspective

- The majority of the (fuel) ethanol industry has focused on FDA requirements for our co-products around animal food per FSMA.
  - We're (relatively) new to this environment. So is the FDA.
- USP and high purity markets are filled with human-contact/consumption applications
  - Active Pharmaceutical Ingredients (APIs) have been around for a long time and the FDA is very mature with its oversight of such items.

Part 3: The Pre-Nuptial Agreement: Equipment, Data, and Documents

- The “dating” phase of emergency authorization is over.
- Equipment needs to be qualified.
  - Are we in control of our process?
  - Do we have the capability to measure what we’re being asked to measure?
- Methods need to be validated and verified.
  - How much do we trust our procedures?
- Suppliers need to be approved.
  - Are we getting what we expect and need?
- Document traceability and management must be robust.
  - Can we find what we need efficiently?
  - Can we follow a paper trail for each batch?
- Physical scope of program.
  - Zoning of location?
  - Raw material definition?



* Intermission on Water *
Potable vs. Process vs. USP

- When is process water acceptable?
- Is your product drinkable? Is the water potable?
  - Water source?
  - Water treatment?
- When does it need to be USP?
  - 190 proof → 200 proof → 190 proof
- How do we categorize the water in the azeotrope?

Part 4: Specification Management

- Compliance structures and certifications…
  - SQF… FSSC… ISO…
- Customer-specific specifications…
- Denaturant formulas…
- Flavor and aroma profiles…
- Batch management…
- Logistics…
  - Transportation vessel…
  - Loadout isolation…
- Supply agreements and purchasing timelines…

Now What?

- These new markets are attractive due to the value proposition and market diversification.
- Focus on the scope of these new markets. What do you want to tackle first?
- Guidance documents – fantastic for describing ***what*** you need. Make sure you can address ***how*** you meet the requirement.
- Understand your systems, particularly data and document management.
  - Can you trace your product streams for each batch?
  - Can you attribute your test results to a qualified piece of equipment performed by a trained operator?