FDA Compliance with '*New and Improved*' Products

obviumQ

Regulatory Compliance & Quality Management Consulting Firm

PRODUCT DEVELOPMENT

FROM INNOVATION TO VALIDATION

THURSDAY, APRIL 18TH, 2019

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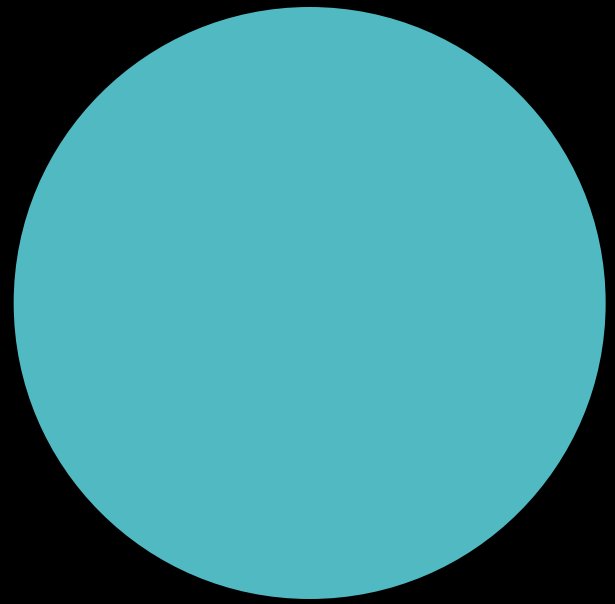
Agenda

- Changes in Regulatory environment
  - ”New and Improved” FDA
  - NSF’s “Hybrid Child”
- Learn from past data
  - Top Chart 2018
  - Examples
- Quality starts with development
  - Domino effect



“New and Improved” FDA

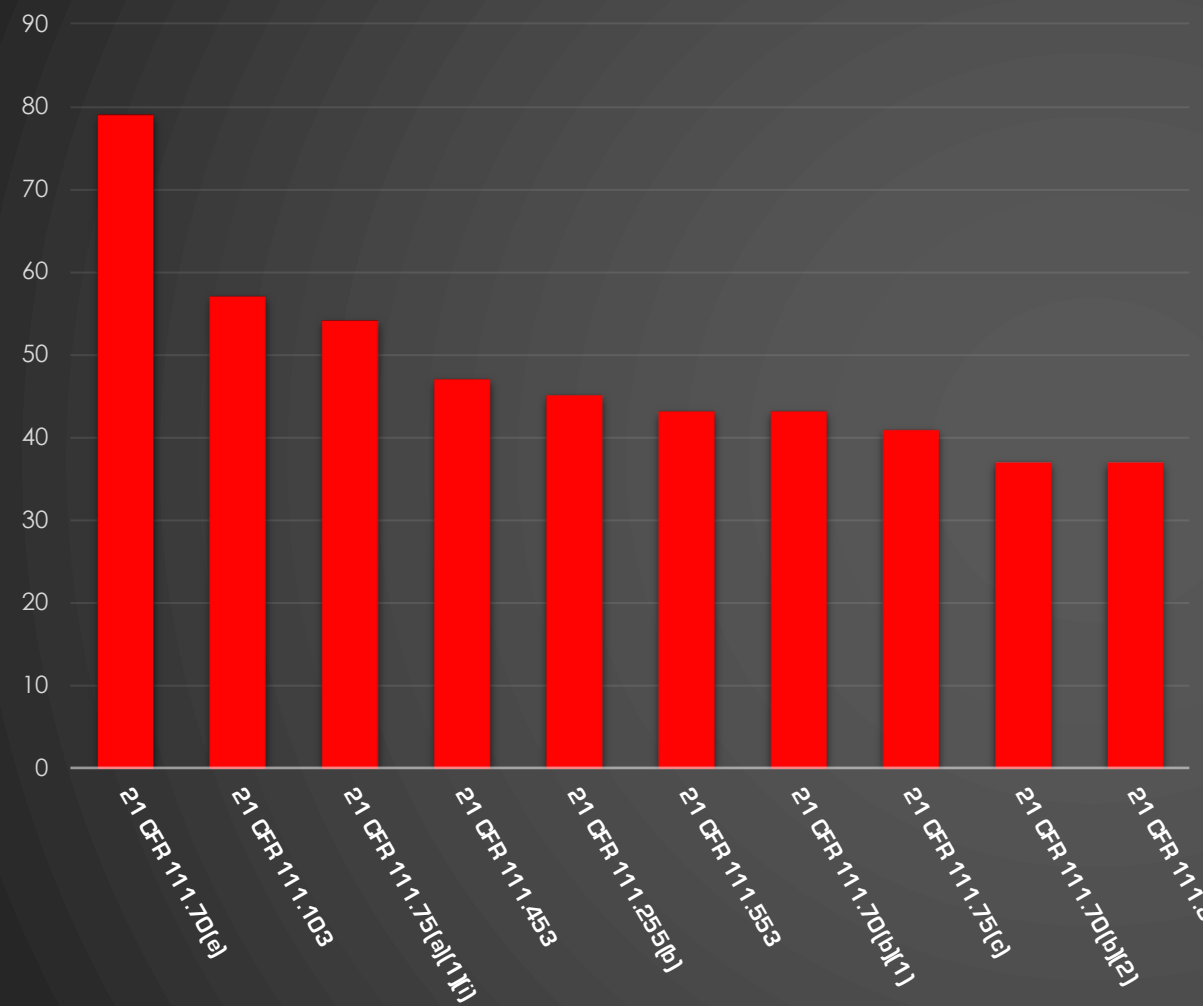
- In February 2019 the Food and Drug Administration it planned to beef up oversight of the sprawling, $50-billion-a-year dietary supplements industry, warning that the sector’s explosive growth has resulted in risks to consumers — more supplements “spiked” with unlisted drug ingredients, and false and misleading claims about health benefits
- FDA Commissioner Scott Gottlieb said the agency is planning policy changes that could lead to the most important regulatory modernization since enactment of the 1994 Dietary Supplement Health and Education Act, which set up the regulatory regime.

NSF's new "Hybrid Child"

- NSF/ANS 173-2018 effective 10/22/2018 is a radical change where focus is shifted to 21 CFR 117 including Preventive Control, Management Review, etc.

- Expectations are to investigate, analyze, trend, etc. which is the normal practice for 'mature quality systems", but is the Dietary Supplements industry there yet?

Top Chart 2018



21 CFR 111.70(e) - FP Specifications
21 CFR 111.103 - Written Procedures for Quality Control Operations Including Responsibilities
21 CFR 111.75(a)(1)(i) - Identity Testing
21 CFR 111.453 - Written Procedures for Holding & Distributing Operations
21 CFR 111.255(b) - Batch Production Record Requirements
21 CFR 111.553 - Written Procedures for Complaints
21 CFR 111.70(b)(1) - Identity Specification for each Component
21 CFR 111.75(c) - Documentation for Qualifying Suppliers
21 CFR 111.70(b)(2) - Component Specifications
21 CFR 111.83(a) - Hold Reserve Samples of Each Lot

2018... year of the Brands

"...As the own label distributor of dietary supplements that contracts with other manufacturers to manufacture dietary supplements that your firm releases for distribution under your firms name, the FDA considers you to be the manufacturer of such dietary supplements. As such, you have ultimate responsibility for the dietary supplements that you introduce or deliver into interstate commerce."

Food and Drug Administration, Warning Letter W/L 57-11

You did not verify that your finished batch of dietary supplement meets product specifications for identity, purity, strength and composition.

Specifically, your firm did not verify that your finished batches of dietary supplements received from your contract manufacturers meet product specifications for identity, purity, strength, and composition for products that you formulated. Furthermore, your firm does not perform any analytical tests or examinations to ensure your finished dietary supplement specifications have been met. For example,

- Your firm was unable to provide documentation that your [redacted] Dietary Supplement met your finished product specifications for identity, purity, strength and composition for GABA and Gluten. Furthermore, your firm receives and reviews COA from your contract manufacturer for your [redacted] 30 Servings [redacted] Net Weight 8.0 OZ. (228 Grams) Dietary Supplement. Your firm provided documentation of organoleptic testing for color, flavor, texture, and solubility. However, your firm was unable to provide documentation of analytical testing for limits on contaminants, identity, purity, strength, and composition for Niacin, Calcium, Caffeine, [redacted] as specified in the COA.

You did not verify that your finished batch of dietary supplement meets product specifications for identity, purity, strength and composition.

Specifically, you did not verify that your finished batch of dietary supplement meets product specifications for identity, purity, strength, and composition for products that you formulated. For example:

- You stated your firm received and reviewed a COA from your contract manufacturer and relied on their finished product specifications for [redacted], prior to establishing your own specifications and conducting periodic testing. Your firm failed to verify the finished product specifications were met for the aforementioned product. Your contract manufacturer's specifications state the following: (totals are rounded to nearest tenth).

Active Ingredient	Actual Amount (g/serving)
Beta-Alanine	2.55
Creatine Nitrate	1.00
Choline Bitartrate	0.51
Citrulline Aspartate	0.50

Your quality control personnel did not reject a dietary supplement for which a specification was not met.

Specifically, your quality control personnel did not reject the dietary supplement, [redacted] for which a specification was not met. You stated your firm relied on the contract manufacturer's finished product specifications and COA prior to establishing your own specifications and conducting periodic testing. For example:

02/06/18	Niacin: 25.00 mg	26.019 mg	12,576 units released on 02/27/18
02/06/18	Calcium: 28.00 mg	28.82 mg	

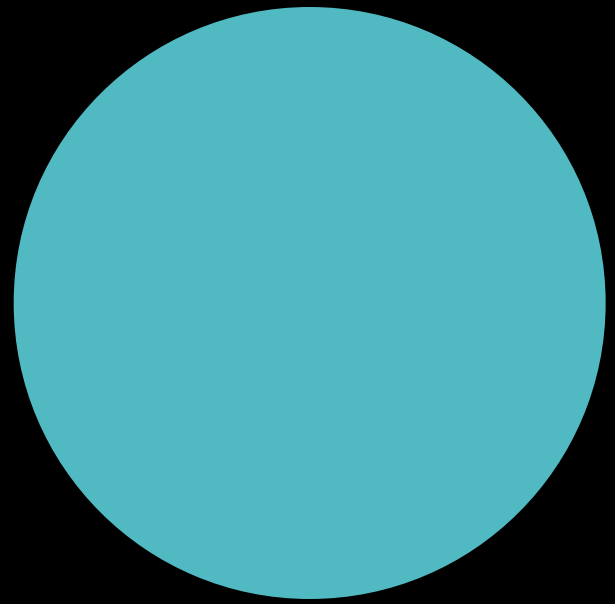
NO RANGE

Domino effect

- Myth No.1
  - R&D is not the part of cGMP and the Quality department will do it

TRUTH

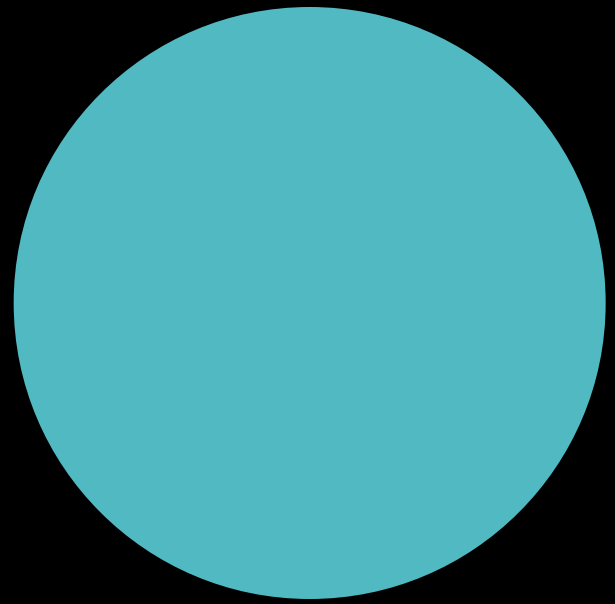
- Product Development sets product intended use
- Product Development sets target consumer group
- Product Development selects components and from which supplier
- Product Development sets formula and “how it is made”, etc.



What is “Mature QMS”

- At the point of transition form Product Development to Commercial Product, full product dossier is done and handed over to QC/QA
  - Specifications for components, In-Process Control, Finished Product
  - Manufacturing steps and their controls
  - CCP from perspective “point when things could go wrong” and how to detect before system fails
  - Testing methodology, frequency, control, ….

Q&A



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