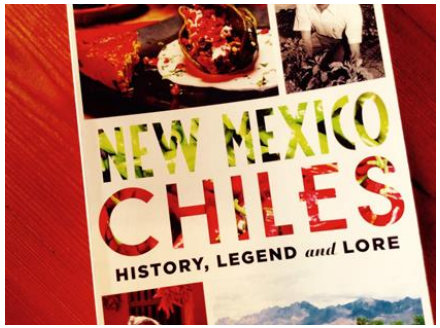

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UNITED NATURAL PRODUCTS ALLIANCE®

Regulatory Update

Larisa Pavlick

V.P., Global Regulatory and Compliance

9th Annual UNPA Member Retreat

United Natural Products Alliance
1075 E. Hollywood Ave.
Salt Lake City, UT 84105

p: 801.738.2975
larisa@unpa.com
unpa.com

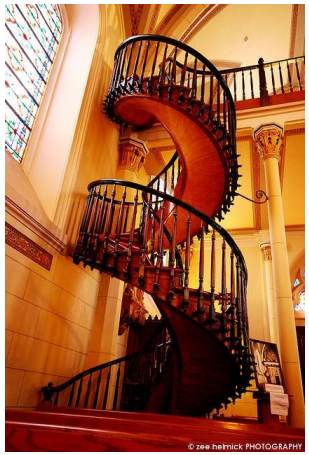
Welcome!

Did you know, at a business presentation

- 91% of listeners admit to day dreaming and
- 39% admit to sleeping?

Forbes 2017

At any one time, there is a chance….no one will be listening.



Loretto Chapel and the “miraculous staircase”
The Loretto Chapel
207 Old Santa Fe Trail
Santa Fe, NM 87501

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Who am I?

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What am I doing for you at UNPA?

- Member Support
- FDA Liaison
- Quality Initiatives
- Training and Education Program
  - ✓ FSMA, PCQI, FSVP
  - ✓ Dietary Supplement GMP Training

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UNPA's 2017 Quality-Initiative Activity

DSQC

Dietary Supplement Quality Collaborative

CHPA OTC ACADEMY SEMINARS

USP U.S. Pharmacopeial Convention™

IADSA

NIST National Institute of Standards and Technology U.S. Department of Commerce

SIDI WORKGROUP

GRMA

Global Retailer and Manufacturer Alliance

AOAC® INTERNATIONAL

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Quality Initiatives

Agricultural

- Good Agricultural Practice (AHPA)
- National Organic Program (NOP) by USDA

Raw Material

- Herbs of Commerce
- SIDI Protocol (Standardized Information for Dietary Ingredient)
- Identity

SIDI WORKGROUP

Testing and Monitoring

- AOAC: Methods
- USP: Standards for Botanicals
- Dietary Supplement Quality Assurance Program (DSQAP) by NIST/NIH

USP U.S. Pharmacopeial Convention

AOAC INTERNATIONAL

NIST National Institute of Standards and Technology U.S. Department of Commerce

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Quality Initiatives

GMPs and Quality Standards

- FDA 21 CFR Part 111
- DSQC:
  - Quality Matrix,
  - Tainted and Adulterated Products Working Group
  - Outreach
- Global Retailer and Manufacturers Alliance (GRMA)
- International Alliance of Dietary/Food Supplements Associations (IADSA)

Quality?

Registrations

- Online Wellness Library (OWL)
- Industry ODI list

What do you think?

Nutrition Facts

Serving Size 125g

Amount Per Serving

Calories 65	Calories from Fat 2
	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat	
Cholesterol 0mg	0%
Sodium 1mg	0%
Total Carbohydrate 17g	6%
Dietary Fiber 3g	12%
Sugars 13g	
Protein 0g	

Vitamin A	1%	• Vitamin C	10%
Calcium	1%	• Iron	1%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

NutritionData.com

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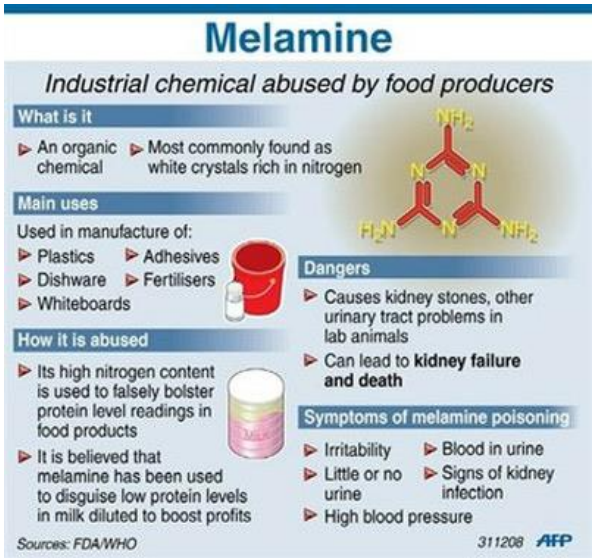
Evolution of Food Regulations

Centers for Disease Control and Prevention
National Center for Health Statistics

2009-2010 Foodborne Disease Outbreaks

- 9.4 million foodborne illnesses annually
- 1,527 outbreaks
  - 2009: 675
  - 2010: 852
- 29,494 illnesses
- 1,184 hospitalizations
- 23 deaths



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Outbreak Score Card

Centers for Disease Control and Prevention
National Center for Health Statistics

	Outbreaks	Hospitalizations	Deaths
Norovirus	X (42%)	X (9%)	1
Salmonella	X (30%)	X (49%)	
E. Coli/E. Coli 0517	X	X (16%)	0517 = 4
Listeria		x	9
Clostridium botulinum		x	5
Clostridium perfringens			3
Shigella			1

Shown in descending order

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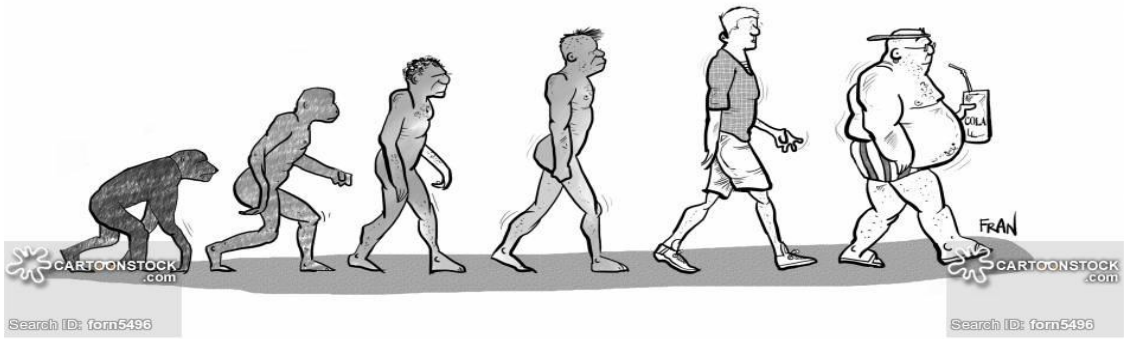
Food Safety Modernization Act (FSMA)

Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food (21 CFR Part 117)

- Referred to as the Preventive Controls for Human Food regulation



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FSMA

…is intended to ensure safe manufacturing/processing, packaging, and holding of food products for human consumption in the US.

Compliance Dates:

- September 2016 with progressive roll out
- Small (AKA medium) September 2017
- Very small in 2018

Survey 43%

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cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

- Includes:
  - Subpart B: GMP
  - Subpart C: Hazard analysis and risk-based Preventive Controls
  - Subpart G: Supply Chain Program
- The regulation requires that certain activities must be completed by a “preventive controls qualified individual (PCQI).”

cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

Subpart B – Current Good Manufacturing Practice

117.10 Personnel
117.20 Plant and Grounds
117.35 Sanitary Operations
117.37 Sanitary Facilities and Controls
117.40 Equipment and Utensils
117.80 Processes and Controls
117.93 Warehousing and Distribution
117.110 Defect Action Levels

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cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

Some of the changes from 110:

- Training as a requirement
- Cross contact
- Allergens
- Supervision of sanitation by Qualified Individual

cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

Subpart C--Hazard Analysis and Risk-Based Preventive Controls

§ 117.126 - Food safety plan.
§ 117.130 - Hazard analysis.
§ 117.135 - Preventive controls.
§ 117.136 - Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.
§ 117.137 - Provision of assurances required under 117.136(a)(2), (3), and (4).
§ 117.139 - Recall plan.
§ 117.140 - Preventive control management components.
§ 117.145 - Monitoring.
§ 117.150 - Corrective actions and corrections.
§ 117.155 - Verification.
§ 117.160 - Validation.
§ 117.165 - Verification of implementation and effectiveness.
§ 117.170 - Reanalysis.
§ 117.180 - Requirements applicable to a preventive controls qualified individual and a qualified auditor.
§ 117.190 - Implementation records required for this subpart.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=117

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½ way

-> PCQI

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Preventive Controls Qualified Individual (PCQI)

*"A qualified **individual who has successfully completed training** in the development and application of risk-based preventive controls at least equivalent to that received under a **standardized curriculum recognized as adequate by FDA** or is otherwise qualified through job experience to develop and apply a food safety system."*

21 CFR Part 117.3

cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Larisa Pavlick

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Lead Instructor Training for FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Kathy Gombas

completed on

03/30/2017

Robert Brackett, VP and Director
Institute for Food Safety and Health

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

Gerald Wojtala, Executive Director
International Food Protection Training Institute

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

Joseph Corby, Executive Director
Association of Food and Drug Officials

AFDO

Certificate # ea44e4a7

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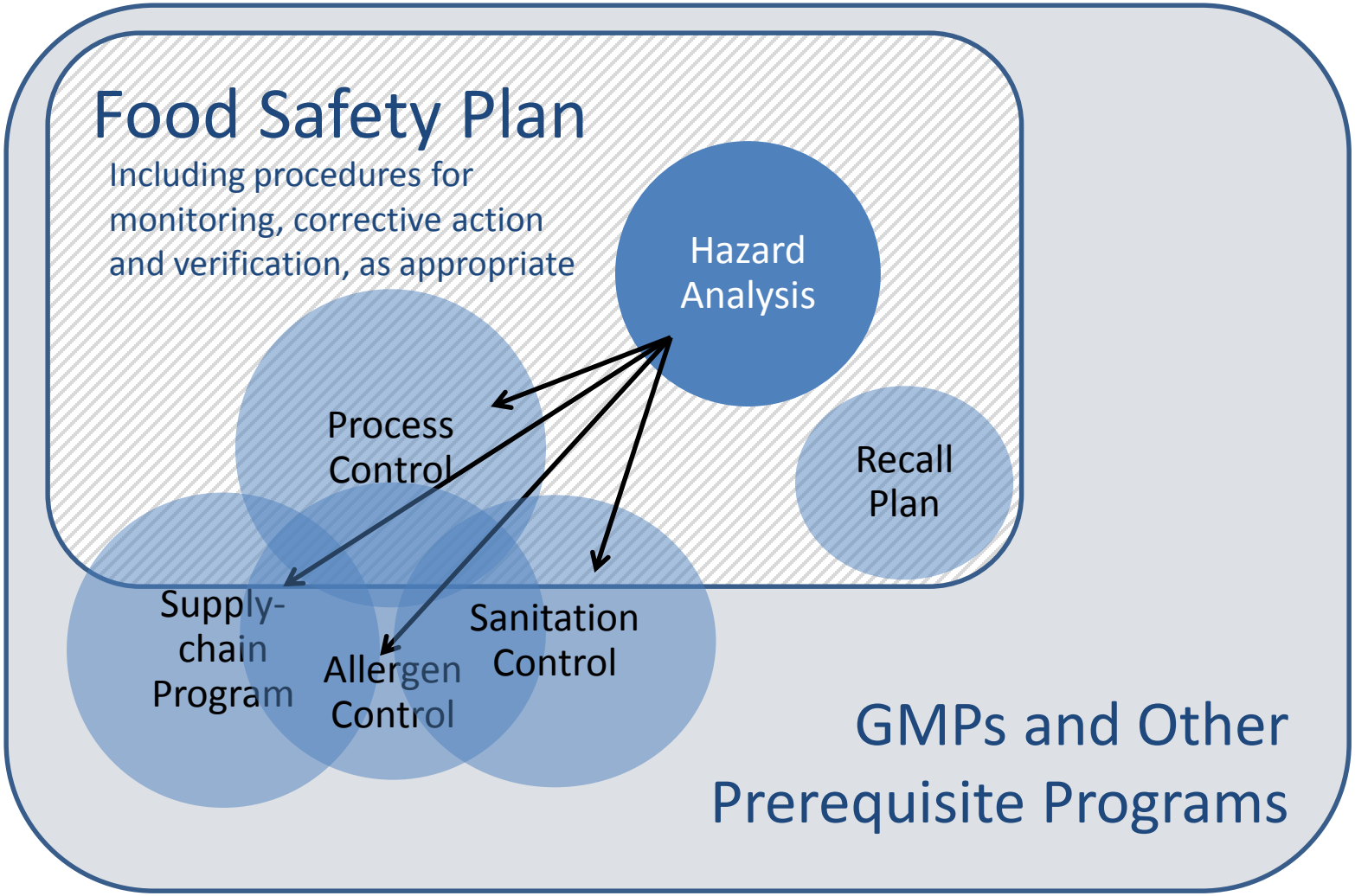
cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food (CFR Part 117)

Responsibilities of the PCQI include to oversee or perform:

1. Preparation of the Food Safety Plan
2. Validation of the preventive controls
3. Records review
4. Reanalysis of the Food Safety Plan, and other activities as appropriate for the food

21 CFR Part 117.180

Preventive Food Safety Systems



From PCQI instructor slides

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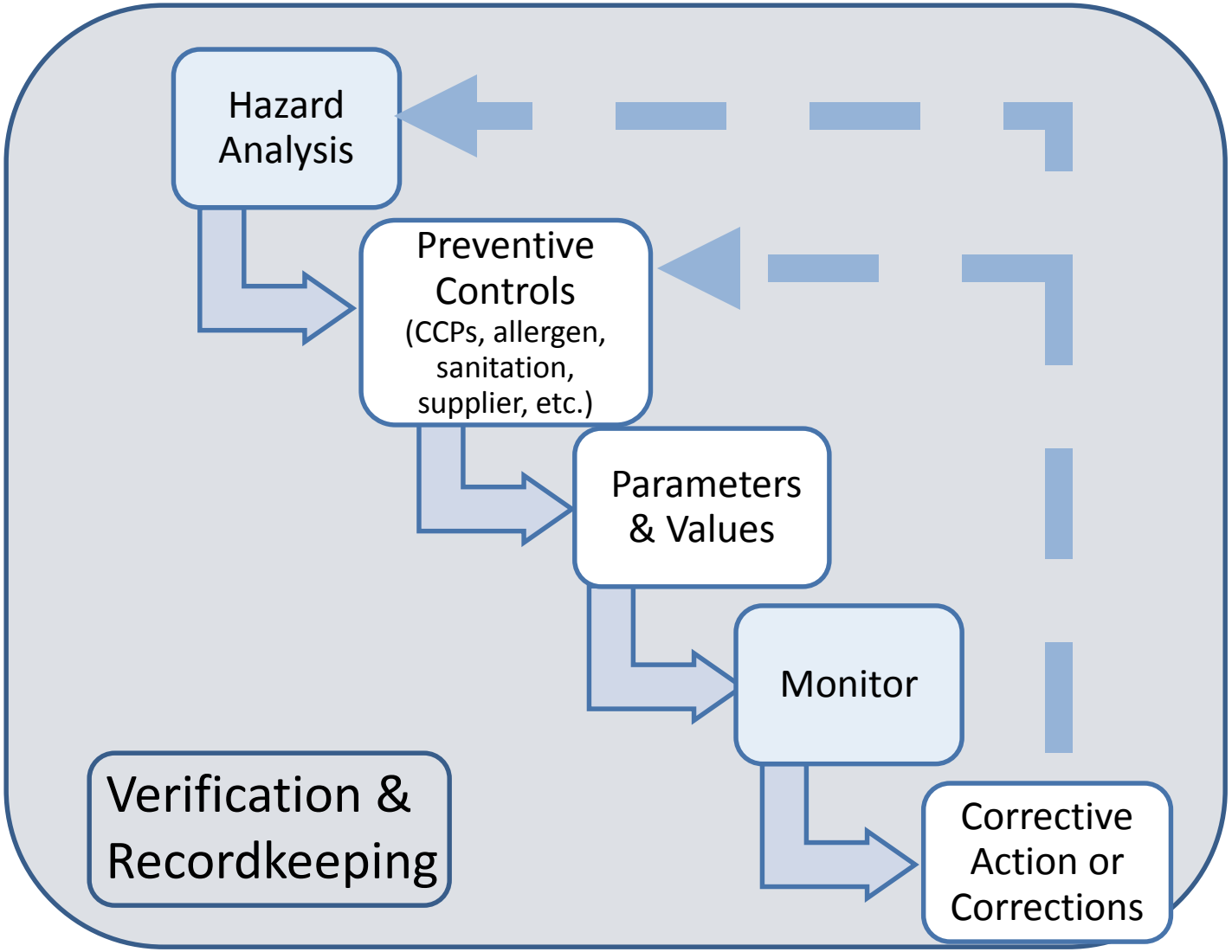
Preventive Controls Include More Than HACCP



From PCQI instructor slides

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What's New in a Food Safety Plan

Element	HACCP Plan	Added in Food Safety Plan
Hazard analysis	Biological, chemical, physical	Chemical hazards to include radiological; consider economically motivated hazards
Preventive controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs
Parameters and values	Critical limits	Parameters and minimum/maximum values (= critical limits for process controls)
Monitoring	Required for CCPs	Required as appropriate for other preventive controls
Corrective actions or corrections	Corrective actions	Corrective actions or corrections, as appropriate
Verification	For process controls	As appropriate for all preventive controls; supplier verification required when supplier controls a hazard
Records	For process controls	As appropriate for all preventive controls
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified

From PCQI instructor slides

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PREVENTIVE CONTROLS WORKSHOP FOR DIETARY SUPPLEMENTS

Preventive Controls Qualified Individual (PCQI) for Dietary Supplements

Preventive Controls (PCQI) for Dietary Supplements

This course meets FDA's PCQI training requirements. Participants will receive official FSPCA Preventive Controls Qualified Individual certificates.

Led by UNPA's Larisa Pavlick • Register at unpa.com/events

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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July 17-19 | Hilton Salt Lake City Center | Salt Lake City

Inspectional Observations Form FDA 483

Number of 483s Issued from the System*

Inspections ending between 10/1/2015 and 9/30/2016

Center Name	483s Issued
Biologics	84
Bioresearch Monitoring	215
Devices	934
Drugs	691
Foods	2196
Human Tissue for Transplantation	92
Parts 1240 and 1250	97
Radiological Health	32
Veterinary Medicine	281
Sum Product Area 483s from System*	**4622**
Actual Total in System 483s**	**4528**

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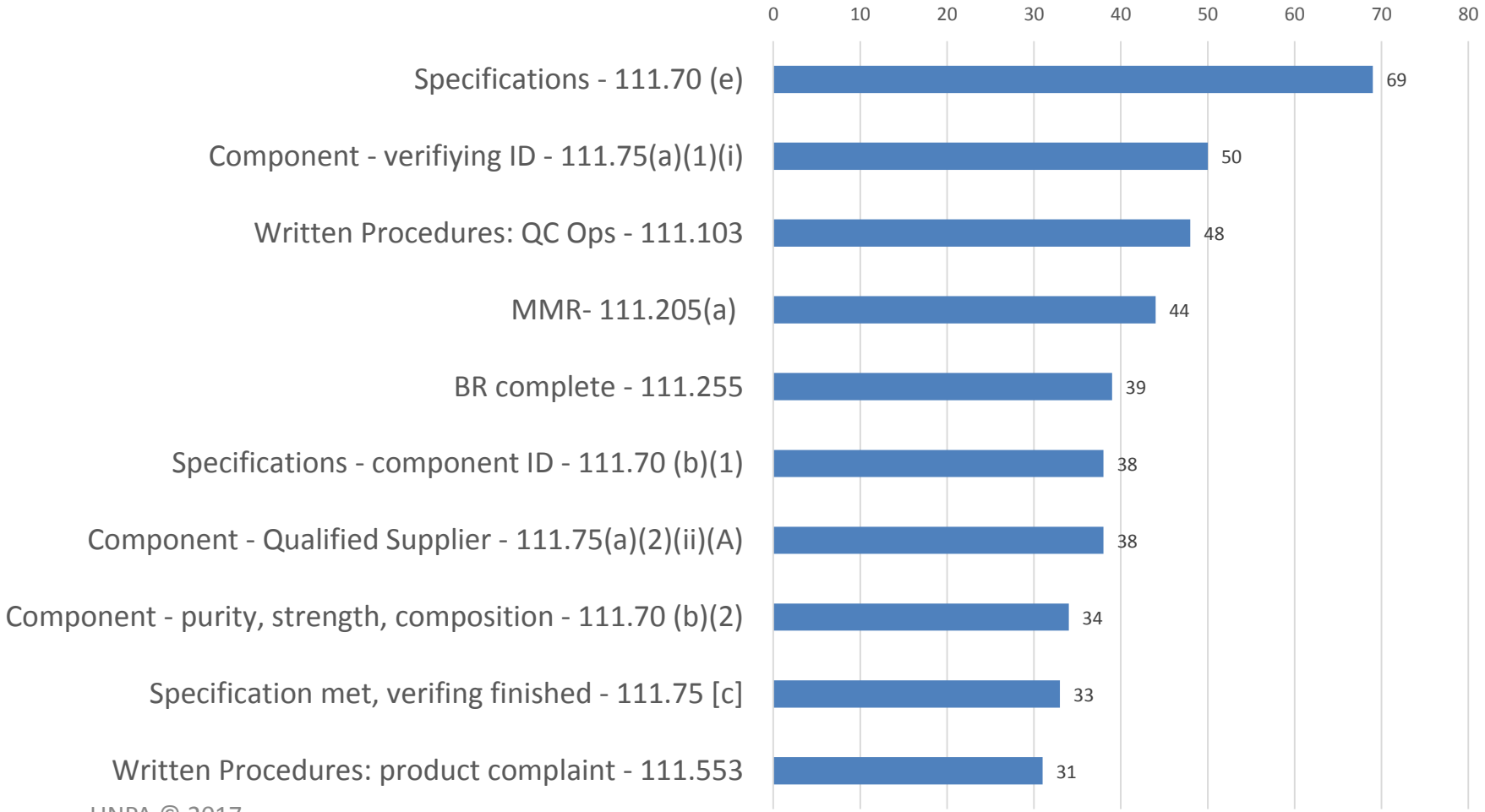
Summary of Dietary Supplement Citations From FDA FY16



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FDA Dietary Supplement Compliance Program Guide

https://www.fda.gov/food/complianceenforcement/foodcomplianceprograms/ucm071547.htm

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FDA Dietary Supplement Compliance Program Guide

A. GMP Violations

Under section 402(g)(1) of the Federal Food, Drug and Cosmetic Act (the Act), a dietary supplement is adulterated if it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.

Major deviations from cGMPs include:

- Lack of master manufacturing records or significant requirements not included;
- Lack of finished product release criteria or failure to test (all or subset of finished batches) or meet finished product release criteria critical to product safety and quality;
- For significant dietary ingredients, e.g. those that make up the bulk of the product, failure to establish specifications for incoming material or failure to conduct identity testing;
- No quality control review procedures or significant quality control procedures not implemented;
- No batch records;
- Significant physical plant deficiencies.

"Districts should prepare and submit to CFSAN/Division of Enforcement (DE)/Labeling Compliance Team (LCT) a **Warning Letter** recommendation for any firm with any of the above deviations."

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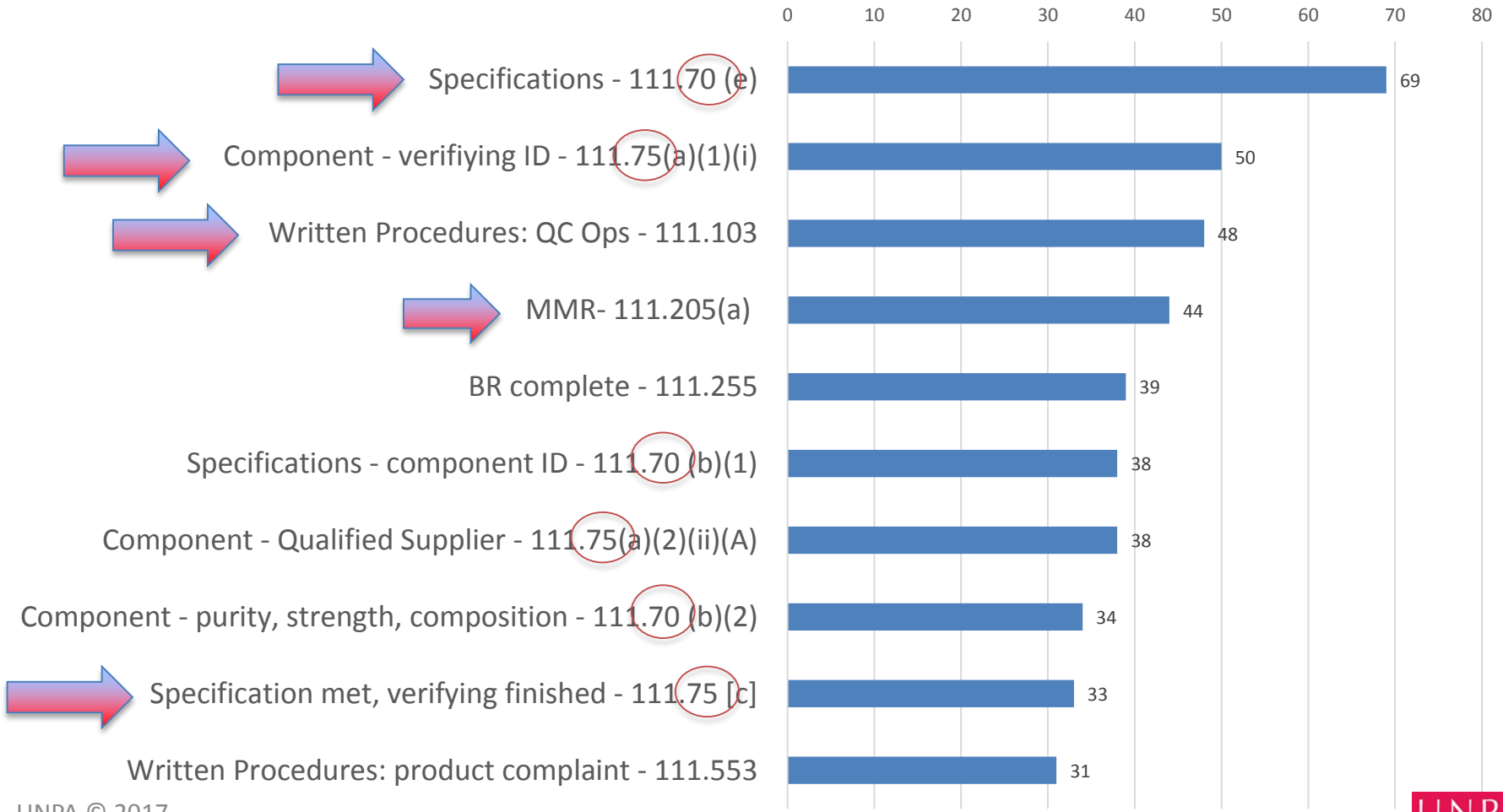
21 CFR Part 111

- 111.70 - Specifications
- 111.75 – Specifications Met
- 111.55 – Sub Part-E: Production and Process Control System

Summary of Dietary Supplement Citations From FDA FY16



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Sec. 111.70
What Specifications Must You Establish?

For what?

- Raw material
- In-process
- Labels
- Finished product

Including:

- Identity
- Purity
- Strength
- Composition
- Limits of contaminants or adulterants
- Any point, step, or stage in MFG
- Packaging

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Sec. 111.75
Responsibility for determining if specification is met

Certificate of Analysis

111.75a(2)(ii)(B)

- Description of the test or method used
- Limits of the test
- Actual results
- Units of Measure
- Reference

-> Q

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UNPA presents:

GMP INSPECTION TRAINING

How to avoid citations and prepare for your next FDA inspection

Taught by former FDA Investigator Larisa Pavlick

June 27-28 | Provo, Utah

Summary

- Quality Initiatives
- Training and Education Program
  - ✓ FSMA, PCQI, FSVP
  - ✓ Dietary Supplement GMP Training
- Questions?

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Thank you!

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