



# **2018 WORLD CONGRESS OF COMPOUNDING**

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# **ADDRESSING NUTRACEUTICAL QUALITY CONCERNS WITH INNOVATIONS IN COMPOUNDING**

David Mastropietro, R.Ph., PhD.

# HOUSEKEEPING



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# DAVID MASTROPIETRO, R.PH., PHD.



- Assistant Professor of Pharmaceutical Sciences at Nova Southeastern University
- Eighteen (18) years as a practicing pharmacist
- Six (6) years in the development, testing, and manufacturing of medications and dietary supplements
  - Senior Advisor for Formulation Development & Product Commercialization
  - Quality Control Specialist for Private Label Contract Manufacturer
- Four (4) years in academic teaching and research
  - Pharmacy compounding, calculations, and formulation development
  - Twenty four (24) journal publications and sixty (60) presentations
  - Three (3) book chapters
  - Seven (7) US & World patent applications

# OUTLINE

1

## **NUTRACEUTICALS**

- Overview
- Health benefits
- The revolution
- Consumer trends

2

## **CURRENT CONCERNS**

- Regulatory standards
- Labeling
- Undeclared / Illicit ingredients
- Varying ingredient amounts
- Heavy metals

3

## **QUALITY THROUGH COMPOUNDING**

- Raw material selection
- Documentation
- Preparatory steps
- Quality control
- Advanced innovations

# LET'S GET STARTED



## NUTRACEUTICALS

- Overview
- Health benefits
- The revolution
- Consumer trends

## CURRENT CONCERNS

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## QUALITY THROUGH COMPOUNDING

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# NUTRACEUTICALS

## OVERVIEW

- In the U.S., the Dietary Supplement Health and Education Act (**DSHEA**) of 1994 provided for the first time a definition of dietary supplements.
- Defined as a product intended to supplement the diet.
  - Intended for oral ingestion
  - Labelled as a dietary supplement
  - Contains one or more dietary ingredients

# NUTRACEUTICALS

## OVERVIEW

➤ Intended for **oral ingestion**

- Only products intended for ingestion may be lawfully marketed as dietary supplements



Sublingual



Transdermal

# NUTRACEUTICALS

## OVERVIEW

- Labelled as a dietary supplement
  - Statement of Identity
  - Supplement Facts Panel (SFP)



“Herbal Supplement”  
“Calcium Supplement”

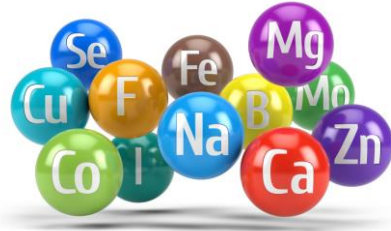
# NUTRACEUTICALS

## OVERVIEW

- Contains one or more dietary ingredients
  - According to DSHEA, dietary ingredients include:



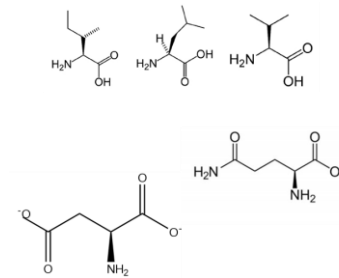
**Vitamins**



**Minerals**



**Herbs & Botanicals**



**Amino Acids**



**Other Substances**

- Enzymes
- Tissues from organs or glands
- Metabolites
- Extracts or concentrations

# NUTRACEUTICALS

## OVERVIEW

- Not a “Drug”
  - A special category of foods
  - Can not diagnose, treat, cure, or prevent any disease



“IMPROVE MEMORY”



“REDUCE BODY FAT”



“ENHANCE SEXUAL  
DRIVE & DESIRE”



“COMBAT DEPRESSION”



“BOOST IMMUNE  
FUNCTION”

# NUTRACEUTICALS

## OVERVIEW

➤ Acceptable claims:



### Health Claims

Describe the reduced risk of a disease or condition.



### Nutrient Content Claims

Describe the amount of dietary supplement in a product.



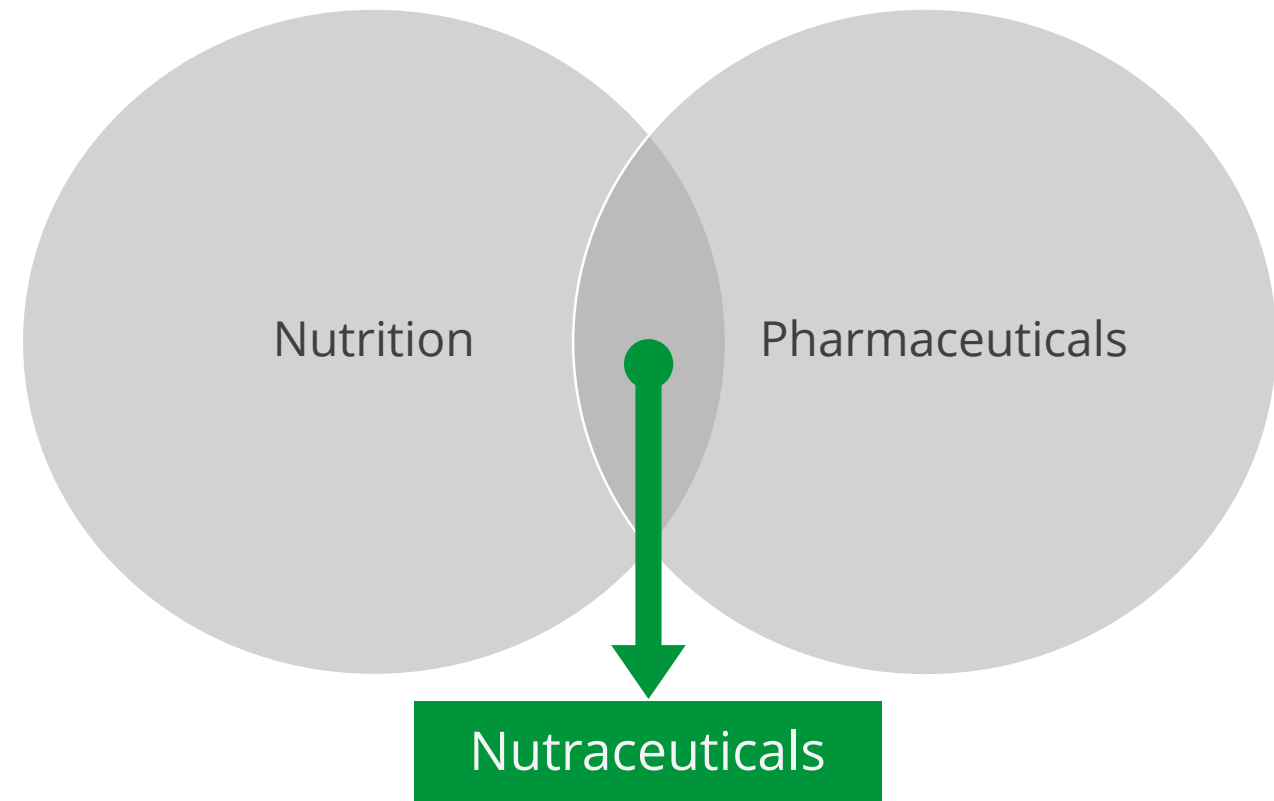
### Structure/Function Claims

Describe how the product may affect the body.

# NUTRACEUTICALS

## OVERVIEW

- The term “nutraceutical” was first coined by Dr. Stephen DeFelice\* in 1989.
- Describes a food or part of a food that claims to have health benefits, including the treatment and prevention of disease.



# NUTRACEUTICALS

“LET FOOD BE THY MEDICINE AND  
MEDICINE BE THY FOOD”

HIPPOCRATES



# NUTRACEUTICALS

## HEALTH BENEFITS

- Maintain nutritional sufficiency
- Support healthy body functions
- Compliment pharmaceuticals and help with nutrient depletions



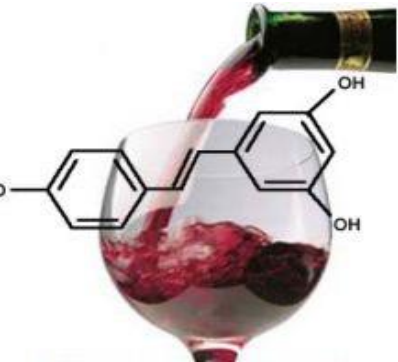
# NUTRACEUTICALS

## HEALTH BENEFITS – CARDIOVASCULAR HEALTH



### $\alpha$ -Linoleic Acid

- Dietary intake of  $\alpha$ -linoleic acid reduces the risk of developing coronary heart disease in a dose-response manner.<sup>2</sup>

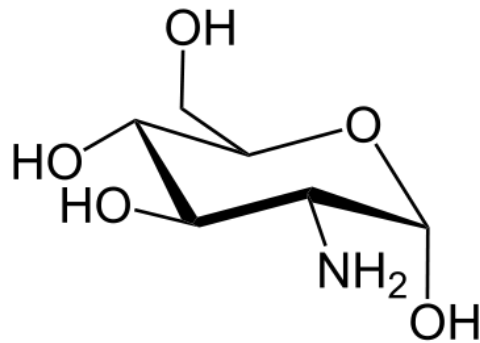


### Resveratrol

- Subjects with Type-2-Diabetes treated with hypoglycemic drugs + 250 mg resveratrol for 3 months had significant improvements in:<sup>1</sup>
  - ✓ Blood pressure
  - ✓ Glycated hemoglobin
  - ✓ Total cholesterol and LDL cholesterol

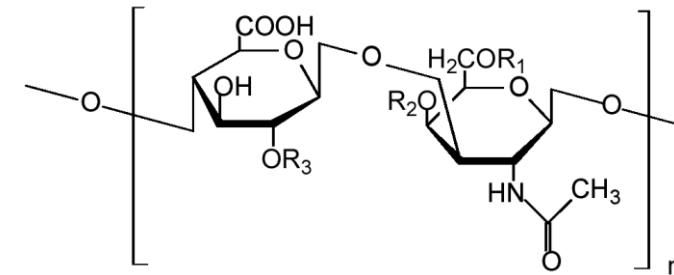
# NUTRACEUTICALS

## HEALTH BENEFITS – JOINT SUPPORT



Glucosamine

- Stimulates production of hyaluronic acid in joint fluid to repair damaged cartilage.
- Relieves pain and improves mobility.



Chondroitin

- The most abundant glycosaminoglycan in cartilage.
- Responsible for the resiliency of cartilage.

# NUTRACEUTICALS

## HEALTH BENEFITS – NEURODEGENERATION

### Antioxidant Vitamins (E + C)

- Patients who took vitamins E+C had a 2.5-3 year delay in receiving L-Dopa<sup>1</sup>

### Vitamin D

- Deficiency plays a significant role in the development and progression of Parkinson's disease<sup>2</sup>

### Coenzyme Q10

- Prevents DAergic loss induced by the neurotoxin MPTP<sup>3</sup>

### Creatine

- Improves mood and reduces dopamine replacement doses<sup>4</sup>

### Omega-3 Fatty Acids

- Prevents DAergic loss induced by MPTP<sup>5</sup>



1. Fahn, S. (1991). An open trial of high-dosage antioxidants in early Parkinson's disease. *Am J Clin Nutr*, 53, S380-S382
2. Knekt, P., et al. (2010). Serum vitamin D and the risk of Parkinson disease. *Arch Neurol*, 67, 808-811
3. Cleren, C., et al. (2008). Therapeutic effects of coenzyme Q10 (CoQ10) and reduced CoQ10 in the MPTP model of Parkinsonism. *J Neurochem*, 104, 1613-1621
4. Bender, A., et al. (2006). Creatine supplementation in Parkinson's disease: A placebo-controlled randomized pilot trial. *Neurology*, 67, 1262-1264
5. Bousquet, M., et al. (2008). Beneficial effects of dietary omega-3 polyunsaturated fatty acid on toxin-induced neuronal degeneration in an animal model of Parkinson's disease. *FASEB J.*, 22, 1213-1225

# NUTRACEUTICALS

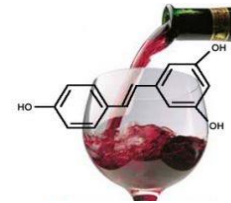
## HEALTH BENEFITS – ANTIOXIDANTS



Curcumin



EGCG



Resveratrol



I3C + DIM

- All possess antioxidant, anti-inflammatory, and anti-carcinogenic properties.
- Can up-regulate the expression of several tumor suppressor genes.
- **NOTE:** Antioxidants might prevent DNA damage to prevent tumor initiation. However, antioxidants can facilitate malignant behaviors once a tumor growth is established.

# NUTRACEUTICALS

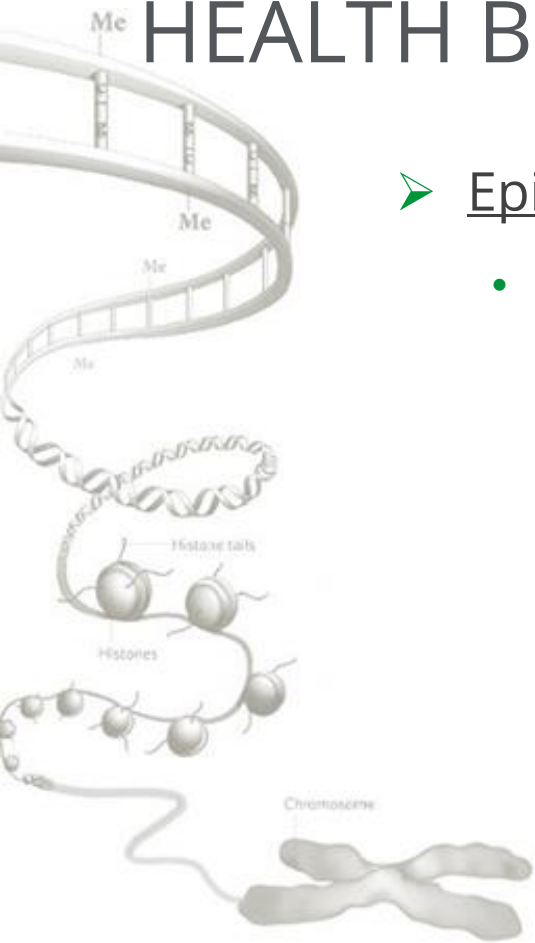
## HEALTH BENEFITS – EPIGENETICS

### ➤ Epigenetics

- Changes in gene expression and chromatin organization not due to alterations in DNA sequence.

### ➤ Role of Nutraceuticals

- Studies suggest certain nutritional compounds can **alter normal epigenetic states** and/or **reverse or silence abnormal gene activation**.
- E.g., Sulforaphane (an isothiocyanate) from cruciferous vegetables have been shown to have anticancer properties.



# NUTRACEUTICALS

# THE REVOLUTION

- The nutraceutical revolution began in the early 1980s when clinical benefits began to surface.
- Contributing factors include:
  - Increasing recognition and acceptance by physicians
  - Growing number of health conscious consumers



# NUTRACEUTICALS

## AUDIENCE QUESTION

**How many of you take products such as:**

- ☐ Vitamins
- ☐ Minerals
- ☐ Botanicals or Herbal Product
- ☐ Enzymes
- ☐ Probiotics
- ☐ Protein Powders
- ☐ Etc.



**76% OF U.S. ADULTS REPORT CONSUMING THESE TYPES OF SUPPLEMENTS<sup>1</sup>**

# NUTRACEUTICALS

## CONSUMER TRENDS

### Modern Lifestyle and Diet<sup>1</sup>

- Deficiencies in a number of nutrients
- Supplements are an appealing complementary therapy

### Public Education<sup>2</sup>

- Today, people are more nutrition-savvy than ever before
- Relation between nutrition and health is everywhere

### Alternatives to Pharmaceuticals<sup>3</sup>

- Seek treatments with less adverse effects that can often be associated with synthetic pharmaceuticals

# NUTRACEUTICALS

## CONSUMER TRENDS – 'CLEAN LABEL' MOVEMENT

### CLEAN

Natural / organic ingredients

No artificial ingredients

Minimal use of manufacturing excipients

### FREE FROM:

GMO

Gluten

Allergens

Preservatives

Artificial / synthetic components

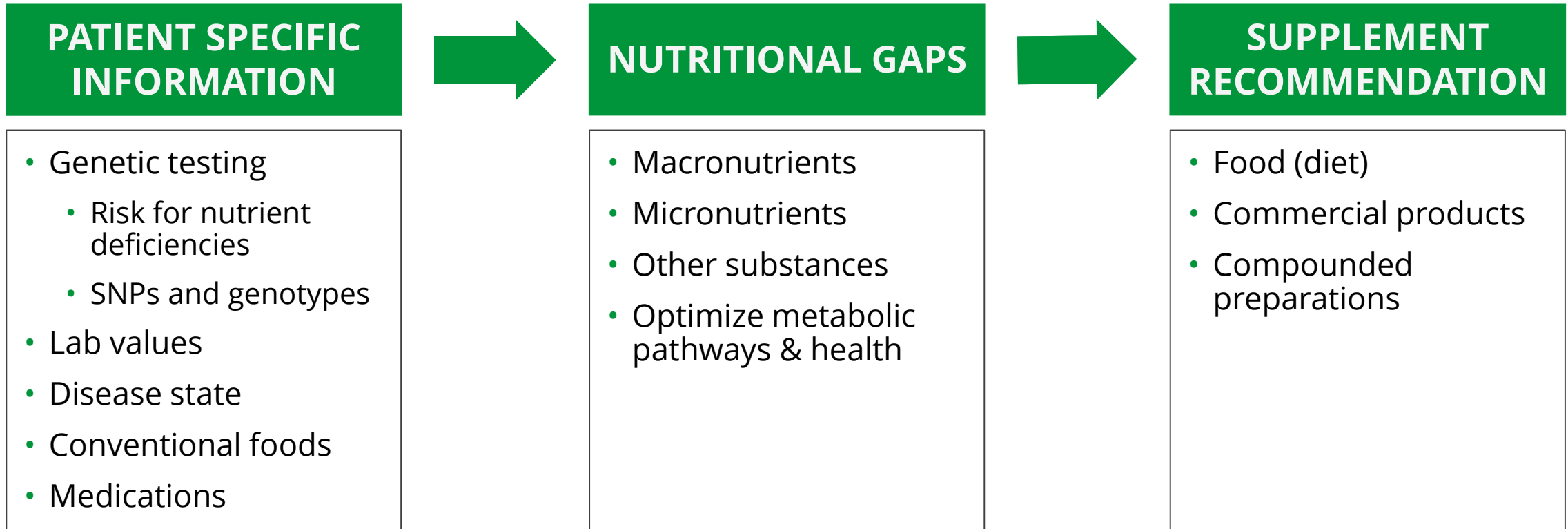
### SIMPLE

Recognizable ingredients

Simple ingredient names

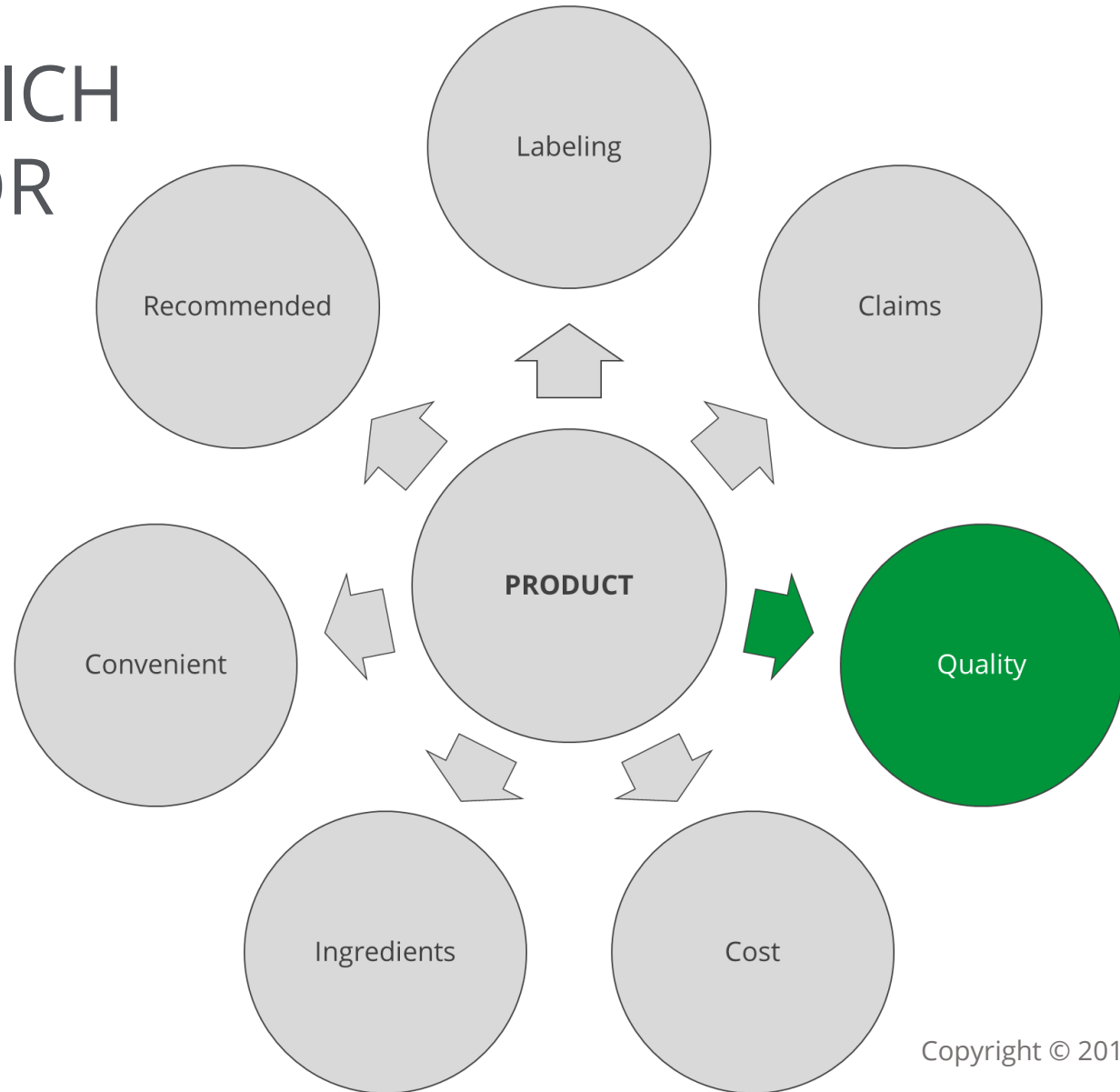
# NUTRACEUTICALS

## CONSUMER TRENDS – PERSONALIZED NUTRITION



# NUTRACEUTICALS

HOW TO DECIDE WHICH  
PRODUCT TO TAKE OR  
RECOMMEND?



# NUTRACEUTICALS

WHAT MAKES A GOOD



PRODUCT?

# CONCERNS



## NUTRACEUTICALS

- Overview
- Health benefits
- The revolution
- Consumer trends

## CURRENT CONCERNS

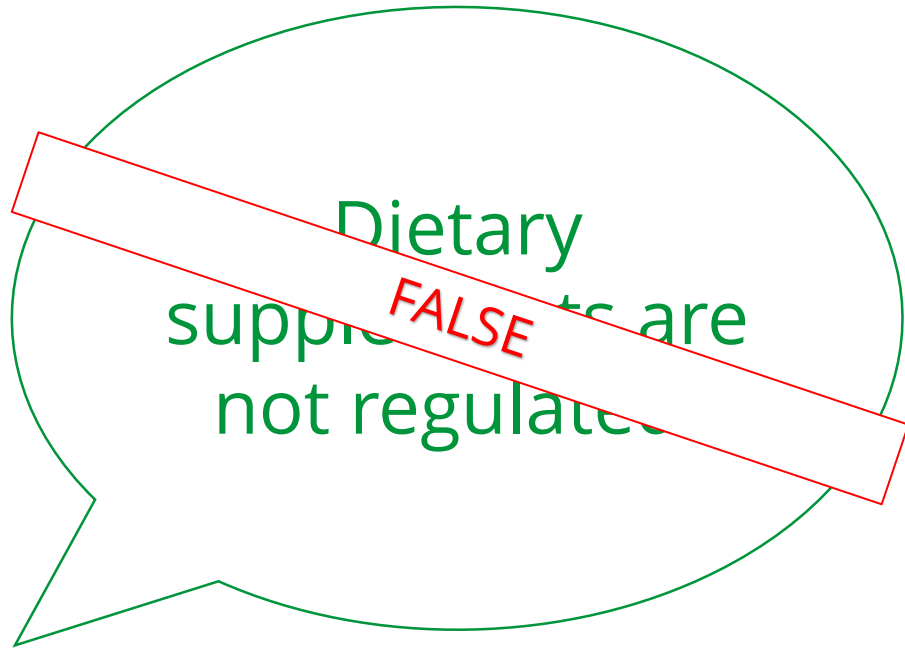
- Regulatory standards
- Labeling
- Undeclared / Illicit ingredients
- Varying ingredient amounts
- Heavy metals

## QUALITY THROUGH COMPOUNDING

- Raw material selection
- Documentation
- Preparatory steps
- Quality control
- Advanced innovations

# CURRENT CONCERNS

## PRODUCT REGULATIONS



- In the U.S., dietary supplements and dietary ingredients are regulated by the FDA under DHSEA.
  - Labeling
  - Label claims and statements of nutritional support
  - New dietary ingredients (ingredients after October 1994)
  - Established Good Manufacturing Practices (21 CFR part 111)
  - Burden of proof on FDA

# CURRENT CONCERNS

## AUDIENCE QUESTION

**Should dietary supplements have the same regulations as prescription drugs?**

☐ Yes

☐ No



- **HOW DO YOU THINK THIS WOULD AFFECT PRICE?**
- **CAN YOU PROPERLY IDENTIFY ALL DIETARY INGREDIENTS?**
- **MISBRANDING AND ADULTERATION?**

# CURRENT CONCERNS

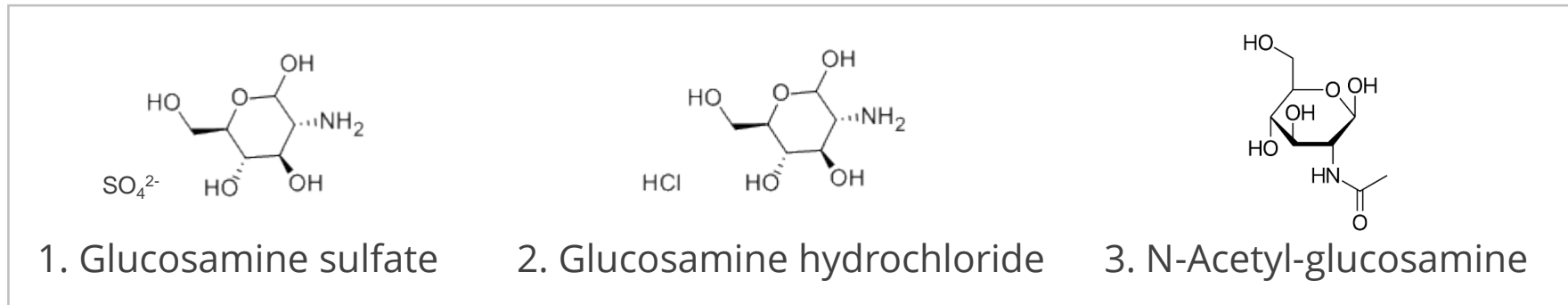
## INADEQUATE REGULATORY STANDARDS

- Certain regulatory standards under DHSEA are **significantly lacking**.\*
- Not required to register their products with the FDA
- Not required to get FDA approval before producing or selling supplements
- No official list of ingredients marketed before October 1994
- Responsibility for product safety is in the hands of the manufacturer

# CURRENT CONCERNS

## MISLEADING OR FALSE LABELING

- Glucosamine exists in three different forms:



- Each form varies in the level of available glucosamine base
- Wide variations exist in the dose of glucosamine depending on the raw material that is sourced
- The type of glucosamine used is not necessarily indicated on the label

# CURRENT CONCERNS

## INADEQUATE LABELING

- Many OTC supplements recommend doses in their label instructions that either vary greatly from one product to the next, or are well below the dose used in clinical trials.
  - E.g., The suggested daily doses of lutein have been reported to range from 0.25 to 22.5 mg.<sup>1</sup>
- Most OTC supplements **do not** include detailed patient information leaflets.
- No regulatory review of product labeling prior to marketing.



# CURRENT CONCERNS

## INADEQUATE LABELING

### Supplement Facts

Serving size: 3x2 tablets

Servings per container: 20

	amount per tablet	amount per serving (6 tablets)	%RDA* per serving
Energy	17,3 kJ / 4,2 kcal	104 kJ / 25 kcal	**
Protein	< 1 g	< 1 g	**
Carbohydrate	< 1 g	3,54 g	**
Fat	0 g	0 g	**
Dietary fiber	0,898 g	5,386 g	
Inulin	0,797 g	4,781 g	**
Orange fiber	0,208 g	1,248 g	**
Orange powder	64 mg	384 mg	**
Vitamin B6	0,066 mg	0,398 mg	28%
Vitamin B12	0,2 µg	1,2 µg	48%
Folic acid	26,4 µg	158 µg	79%

\*RDA – Recommended Dietary Allowance

\*\*No RDA has been established.

Amount per 6 tabs?

Incorrectly labeled

### Supplement Facts

Serving Size: 2 tablets

Servings Per Container: 30

	Amount per serving	% Daily Value
Vitamin C (as ascorbic acid)	110 mg	122%
Thiamin (Vitamin B1)	90 mg	7500%
Folate DFF (333mcg Folic Acid)	200mcg	83%
Vitamin B12 (as methylcobalamin)	200 mcg	8333%
Potassium	120 mg	3%

# CURRENT CONCERNS

## EXPIRATION DATING

### Expiration Date

- Not required to establish an expiration date
- When products do display them, must be supported by stability data
- Requires:
  - Testing
  - Money
  - Time
  - Resources

### Alternatives

- “Date of Manufacturer”
- “Best-By”
- “Use before”

# CURRENT CONCERNS

## EXPIRATION DATING

### Supplement Facts

Serving Size 1 Capsule  
Servings Per Container 30

	Amount Per Serving	% DV
Probiotic Bacteria Blend	<u>25 Billion Viable Cells†</u>	††
Composed of the following strains:		
<i>Lactobacillus rhamnosus</i> R0011		
<i>Lactobacillus helveticus</i> ( <i>L. acidophilus</i> ) R0052		
<i>Pediococcus acidilactici</i> R1001		
<i>Lactobacillus casei</i> R0215		
<i>Bifidobacterium longum</i> BB536		
<i>Lactobacillus plantarum</i> R1012		
<i>Bifidobacterium breve</i> R0070		
<i>Lactococcus lactis</i> ssp. <i>lactis</i> R1058		

† 25 Billion viable cells at time of consumption, under recommended storage conditions and within Best Used Before Date.

†† Daily Value not established.

### Supplement Facts

Serving Size 2 Capsules

Servings Per Container 30

Amount Per Serving		%DV
Vitamin A (100% as Beta Carotene)	2,500 IU	50%
Vitamin C (Ascorbic Acid)	100 mg	167%
Vitamin B6 (from Pyridoxine Hydrochloride)	5 mg	250%
Folic Acid	120 mcg	30%
Vitamin B12 (Cyanocobalamin)	100 mcg	1667%
Organic Fruit Blend	750 mg	*
Organic (Apple, Noni, Orange Peel, Peach, Lemon Peel, Grape, Cranberry, Raspberry, Cherry, Açai, Mango, Elderberry, Black Currant, Pomegranate, Strawberry, Papaya, Banana, Blackberry, Plum, Goji Berry, Blueberry, Pineapple, Prune)		
Lactobacillus Acidophilus	20 mg	*
<u>200 million CFU (at the time of manufacture)</u>		
Fruit Enzyme Blend	13 mg	*
Amylase, Pectinase, Hemicellulase, Cellulase, Protease, Lipase, Glucoamylase, Phytase, Invertase, Maltase		

\*Daily Value (DV) not established

# CURRENT CONCERNS

## UNDECLARED PHARMACEUTICALS

- Alarming amounts of dietary supplements have been found to contain undeclared pharmaceutical ingredients.
- Pharmaceutical found in FDA laboratory testing of products include:
  - Warfarin
  - Phenytoin
  - Sildenafil
  - Propranolol
  - Sibutramine
  - Benzodiazepines
  - Anabolic steroids

# CURRENT CONCERNS

## ILLICIT INGREDIENTS

- Commercial supplements may be subjected to **contamination by illicit ingredients** banned by the World Anti-Doping Agency (WADA).
  - An estimated **14-18%** of all commercial sport supplements contain illicit contaminants that could cause athletes to fail drug tests.<sup>1</sup>
    - In one incident, a commercial product containing the illegal stimulant DMAA left **14 out of 36** product users hospitalized for acute liver failure.<sup>1</sup>

# CURRENT CONCERNS

## VARYING INGREDIENT AMOUNTS

- Actual levels of dietary ingredient dosage strength can vary drastically between commercial products.
- In a study that assessed the dosage strength of DHEA in 17 different over-the-counter (OTC) formulations:<sup>1</sup>
  - 3 formulations contained no DHEA.
  - Most of the remaining dosages contained 58-82% of the amount indicated on the label.



# CURRENT CONCERNS

## VARYING INGREDIENT AMOUNTS

- The variation in **dosage strength** varies drastically between commercial supplements.

Proportion of Products in Compliance with Dosing Quality Standards for a Range of Supplements			
Supplement	Origin	Proportion in Compliance (95-105%)	Range of Contents (% of label claim)
Coenzyme Q10	New Zealand	1/7	100-130
Creatine	USA	1/8	83-106
Creatine	USA	4/6	94-126
Green tea extracts	USA	0/4	9-48

# CURRENT CONCERNS

## HEAVY METALS

➤ Nutraceuticals may be subjected to **heavy metal contamination**.

- Weathering
- Biological activity
- Volcanic activity
- Pesticides and chemical fertilizers
- Wastewater irrigation
- Precipitates from heavy coal combustion & smelter waste
- Residues from mining



# CURRENT CONCERNS

## HEAVY METALS

Heavy Metal	Health Consequences
Arsenic	<ul style="list-style-type: none"><li>• Increased risk for lung, bladder, kidney, and skin cancer</li><li>• Development of skin lesions (e.g., hyperkeratosis) and pigmentation changes</li></ul>
Cadmium	<ul style="list-style-type: none"><li>• Kidney damage</li><li>• Skeletal damage (e.g., osteoporosis and fractures)</li></ul>
Lead	<ul style="list-style-type: none"><li>• Neurotoxic and psychological effects</li><li>• Kidney damage</li><li>• Long term exposure in children can lead to diminished intellectual capacity</li></ul>
Mercury	<ul style="list-style-type: none"><li>• Neurological damage</li><li>• Psychological symptoms (changes in personality, restlessness, anxiety, sleep disturbance, and depression)</li><li>• Contact eczema</li><li>• Especially toxic to a fetus</li></ul>

# CURRENT CONCERNS

## HEAVY METALS – HEALTHY POWDERS?

Raw Ingredient



Powder



# DIETARY SUPPLEMENTS

## THE NUTRACEUTICAL INDUSTRY IS AT A CROSSROADS

- *The demand is high...*
- *But quality control is of growing concern...*
- *At which point will consumers take a step back?*

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## QUALITY THROUGH COMPOUNDING

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- Advanced innovations

# QUALITY THROUGH COMPOUNDING

## BENEFITS OF CUSTOMIZED NUTRACEUTICALS

- Target individual needs
- Modify the dosage form
- Adjust the dosage strength
- Limit unwanted ingredients
- Combine multiple ingredients
- Enhance patient compliance

➤ ADDRESS QUALITY CONCERNS

# QUALITY THROUGH COMPOUNDING

Compounding pharmacists ultimately **maintain power over the quality** of their preparations:

- Patient consultations
- Raw material selection
- Documentation and records
- Preparatory standards and techniques
- Analytical and quality control testing
- Packaging and labeling
- Advanced innovations

# QUALITY THROUGH COMPOUNDING

## PATIENT CONSULTATIONS

Provides an opportunity for personalized consultations and the dissemination of accurate nutritional information.



# QUALITY THROUGH COMPOUNDING

## RAW MATERIAL SELECTION

The first step in producing high-quality compounded preparations is selecting high-quality raw ingredients.

*The quality of your final preparation is only as high as your lowest quality ingredient.*

# QUALITY THROUGH COMPOUNDING

## RAW MATERIAL SELECTION

➤ Things to look for when selecting raw materials:

- ✓ Tested for heavy metals
- ✓ Tested for identity
- ✓ Tested for purity
- ✓ Tested for composition / assay



# QUALITY THROUGH COMPOUNDING

## RAW MATERIAL SELECTION

### CERTIFICATE OF ANALYSIS

MAGNESIUM CITRATE (Tribasic) (Soluble)

TESTS	SPECIFICATIONS	RESULTS
ASSAY (Mg) ON DRIED BASIS	14.5 - 16.4 %	15.5 %
DESCRIPTION	White to off-white fine granular solid or crystalline powder.	CONFORMS
SOLUBILITY	Partially soluble in cold water.	CONFORMS
IDENTIFICATION	Meets the requirements	POSITIVE
LOSS ON DRYING	<= 29.0 %	25.7 %
pH	5.0 - 9.0	6.3
HEAVY METALS	<= 50 ppm	< 50 ppm
ARSENIC	<= 3 ppm	< 3 ppm
IRON	<= 200 ppm	< 200 ppm
CALCIUM (DRIED BASIS)	<= 1.0 %	0.005 %
CHLORIDE	<= 0.05 %	< 0.05 %
SULFATE	<= 0.2 %	< 0.2 %
LEAD	To be reported.	0.01 ppm
ORGANIC VOLATILE IMPURITIES	Meets the requirements	CONFORMS
**PACKAGING and STORAGE**	Preserve in tight containers.	

 MEDISCA®

DISCLAIMER: The above is an example of a certificate of analysis. This is presented for informational and educational purposes only.

# QUALITY THROUGH COMPOUNDING

## RAW MATERIAL SELECTION

- **Medisca** offers over 100 nutraceutical ingredients, all of which undergo identification and heavy metal testing.
- All API classified nutraceuticals are assayed for strength and purity.
- Certificate of Analysis provided with each ingredient.



# QUALITY THROUGH COMPOUNDING

## RAW MATERIAL SELECTION



- Ademetionine Disulfate Tosylate (SAmE)
- Arginine (L), USP
- Ascorbic Acid, USP
- Aspartic Acid, USP
- Biotin, USP (vitamin H)
- Calcium Amino Acid Chelate (30%)
- Calcium Carbonate, USP (Heavy) (Precipitated)
- Calcium Citrate, USP
- Calcium Pantothenate (D), USP
- Carnitine (L), USP
- Chromium Picolinate
- Citrulline (L)
- Collasil OSA
- Cyanocobalamin, USP (Vitamin B12)
- Ferrous Gluconate, USP (Dihydrate)
- Folic Acid, USP
- Glutamic Acid (L), USP
- Glutamine (L), USP (Levoglutamide)
- Glutathione (L) (Reduced)
- Glycine, USP
- Hydroxocobalamin, USP (Vitamin B12A)
- Isoleucine (L), USP
- Lactic Acid, USP (Racemic)
- Leucine (L), USP
- Leucovorin Calcium, USP
- L-Histidine Hydrochloride
- Magnesium Amino Acid Chelate (20%)
- Magnesium Citrate, USP (Tribasic) (Soluble)
- Magnesium Oxide, USP (Heavy) (Powder)
- Manganese Gluconate, USP (Dihydrate)
- Methionine, USP (L-Methionine)
- Methylcobalamin
- Niacin, USP (Nicotinic Acid)
- Niacinamide, USP (Nicotinamide)
- Phytonadione, USP (Vitamin K1)
- Proline (L), USP
- Pyridoxal-5-Phosphate (Monohydrate)
- Pyridoxine HCL, USP (Vitamin B6)
- Riboflavin, USP (Vitamin B2)
- Serine (L), USP
- Taurine, USP
- Thiamine Hydrochloride, USP (Vitamin B1)
- Threonine (L), USP
- Tyrosine (L), USP
- Valine (L), USP
- Vitamin D3 (Powder)
- Vitamin E Succinate (d-), USP
- Etc...



\*For additional Nutraceutical ingredients, visit: <https://www.medisca.com/products/nutraceuticals/ingredients>

# QUALITY THROUGH COMPOUNDING

## STANDARD OPERATING PROCEDURES

The quality of the final preparation depends on compliance with compounding **Standard Operating Procedures**.



# QUALITY THROUGH COMPOUNDING

## MASTER FORMULATION RECORDS

- Ensures consistency and reproducibility of compounded preparations, including:
  - Process development and calculations
  - Preparatory steps
  - Proper equipment and techniques
  - Personnel training



# QUALITY THROUGH COMPOUNDING

## PREPARATORY STEPS

- Use Reliable and Validated Formulas
  - Perform literature searches
  - Rely on scientifically proven information and principles of formulation chemistry
  - For FREE sample formulas, see:



<https://www.medisca.net/technical-services/tss/additional-sample-formulas>



# QUALITY THROUGH COMPOUNDING

## PREPARATORY STEPS

### ➤ Use Reliable and Validated Preparatory Techniques

- Proper trituration
- Proper mixing techniques / blending of powders
- Geometric addition
- Appropriate application of compounding automation can improve manual methods providing superior compounds.



# QUALITY THROUGH COMPOUNDING

## QUALITY CONTROL

### ➤ Verify the End-Product

- Perform weight verifications on solid and semi-solid dosage forms.
- Perform visual inspections (e.g., clarity, homogeneity, color, consistency, odor, volume, etc.)
- Ensure compliance with prescription.
- Ensure appropriate labeling with appropriate instructions.



# QUALITY THROUGH COMPOUNDING

## QUALITY CONTROL

### ➤ Periodically Invest in Analytical Testing

- Verify the purity and strength of your compounded preparation by sending it out for analytical testing.



# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS

*Benefit from specialized innovations that help enhance the quality of final preparations.*

# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – ENCAPSULATIONS

- Portable and stable dosage form
- Versatile use
- Combine several compatible active ingredients
- Minimize the number of dosages to be consumed
- Protect against photosensitive ingredients
- May not be suitable for those with difficulty swallowing



CapsuBlend®

# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – ENCAPSULATIONS



Balances



ProFiller 1100



Densimeter



Inversina

# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – RAPID DISSOLVE TABLETS

- Dissolves quickly in the mouth
- Rapid absorption
- High bioavailability
- Suitable for those with difficulty swallowing
- Many commercial nutraceutical products **fail dissolution**



# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – RAPID DISSOLVE TABLETS

### Medi-RDT Base

- Finely granulated powder with improved flowability
- Paraben-, gluten-, lactose-, and sucrose- free
- Suitable for APIs stable at a temperature of 115°C (239°F)\*
- Fast baking, wetting, and disintegrating time:
  - Baking time: 10-15 mins (versus 30 mins of other commercial bases)
  - Wetting time: 5 sec. (versus 24 sec. of other commercial bases)\*\*
  - Disintegrating time: 93 sec. (versus 287 sec. of other commercial bases)\*\*



# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – RAPID DISSOLVE TABLETS

### Medi-RDT Kit

- Medi-RDT base
- Medi-RDT blister pack
- ProFiller RDT Mold
- Hot hand® protector
- Customized formula
- 50 mesh sieve and receiver pan



# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – GUMMIES

### ➤ Chewable

- Suitable for patients that have difficulty swallowing pills (e.g., pediatrics and geriatrics)

### ➤ Medisca Gelatin Gum Base:

- Compatible with lipophilic and hydrophilic AIs
- Excellent salt compatibility
- Melting range 60-65°C
- Passed USP <51> microbial challenge test
- Processed into small, easy-to-use pieces
- Paraben-free



# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – EFFERVESCENT

- Combines the portability and stability of a capsule with the bioavailability of a solution
- Easy to compound high dose, multiple-ingredient formulations
- Helps improve compliance
- Easier to swallow than capsules or tablets
- Good gastrointestinal tolerance
- Ideal for special patient populations



# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – EFFERVESCENT

### Medisca FizzMix Base™

- Fast dissolution and extended fizzing effect\*
- Versatile and innovative dosage form for a wide range of ingredients
- Excellent solubility & palatability
- Free-flowing and stable
- Lactose-, sugar-, and paraben-free



# QUALITY THROUGH COMPOUNDING

## ADVANCED INNOVATIONS – EFFERVESCENT

- Medisca's Sachet Filling Equipment provides a simple and convenient way of dispensing batch sizes of powder formulation.
- Simply load the pre-mixed powder into the sachet filling equipment for uniform fill weights.



# QUALITY THROUGH COMPOUNDING

## CONTINUING EDUCATION



### **Opportunities in Nutraceutical Customization**

Webinar available on-demand at: <https://education.lp3network.com/>



### **The Role of Nutraceuticals in Epigenetic Regulation**

Webinar available on-demand at: <https://education.lp3network.com/>



### **Nutraceutical Compounding – Laboratory Training**

Register at: <https://education.lp3network.com/live-training/nutraceutical-lab>

# CONCLUDING REMARKS

- The nutraceutical market is growing at an exponential rate.
- Valid scientific data is accumulating in support of the beneficial effects of nutraceuticals.
- With limited regulations enforced, the quality control of manufactured dietary supplements is markedly underwhelming.
- As a compounding pharmacist, you can ultimately control the quality of your final preparation.
- Take advantage of high-quality ingredients, innovative products, and reliable devices to improve your compounding practice.

# ACKNOWLEDGMENTS





**THANK YOU FOR LISTENING**