
## Standard Operating Procedures
Dietary Supplement and Natural Products
Development, Training & Deployment

## ANNOUNCING
## THE *VITAMIN LAWYER* REGULATORY COMPLIANCE CERTIFICATION PROGRAM!

**"Bureaucracy wants to devour your company!"**

This web site, www.SOP*Certification*.com provides access to my Standard Operating Procedures certification program, specially designed for the industry, with special emphasis on small and start-up companies, but any company that has its own labels needs this program!

**You need my 40 years' experience as *The Vitamin Lawyer!***

I can save your company hundreds of thousands of dollars in regulatory costs! Just embrace my *three simple steps* to regulatory compliance:

[1] **PROCEDURE** – I work with your CEO to tweak my Standard Operating Procedures and Good Manufacturing/Marketing Practices for your company

[2] **CLAIMS** – I work with your company for proper claims control, definition & substantiation... and the FDA required S&F Claims Notice.

[3] **TRAINING** - It's not enough to have procedures, says FDA: train your team and *prove* they are qualified - through my Three Step Program: **Presenting, Training, Certifying.**

**That third step is what this Certification program is designed to accomplish: meeting FDA training requirements.**

**Says FDA - "...documentation of employee training is necessary to track which employees have been trained in which operations. Therefore, final Sec. 111.14(b)(2) requires you to keep documentation of training, including the date of the training, the type of training, and the person(s) trained." Federal Register, page 34811**

**The Gold Standard -**
**Vitamin Lawyer Consultancy**
**Certification Program!**

**The SOP Format / Four Webinar / Certification Test Program Synopsis**

**Begins on the next page…**

Presenter:

# Ralph Fucetola JD

## The Vitamin Lawyer

**This Webinar is a Vitamin Lawyer Consultancy Educational Program**

**Designed for Dietary Supplement Label-Owners & Marketers**

**Ten Hour Certification Course**

1. **Preparatory Reading SOP Format . . . . . 3 hrs**
2. **Introductory Webinar . . . . . 2 hrs ***
3. **SOPs in Detail Webinar 1 . . 2 hrs**
4. **SOPs in Detail Webinar 2 . . 2 hrs**
5. **SOP Certification Conclusion Test - Open Book . . . . . 1 hr**
6. **Optional Bonus Webinars**

***PRIVATE CERTIFICATION***

***ISSUED UPON COMPLETION***

*** This is the Introductory Webinar**

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This is the First, Introductory Webinar Overview:

# Webinar Overview

- This Webinar will teach you about:
  - Structuring Your Company for GMP Regulatory Compliance
  - The Contents and Terms of the SOP Document
  - Company Positions that Implement the SOPs
  - Best Practices for Labels, Claims, Manufacturer and Marketing
  - Defendable Record Keeping
  - The Company Core Data Sheet & Substantiation Note Book

The Purpose of Standard Operating Procedures is to Ensure the "purity, identity, composition and strength…" of the dietary supplement food products sold under the provisions of DSHEA – the Dietary Supplement Health and Education Act of 1994.

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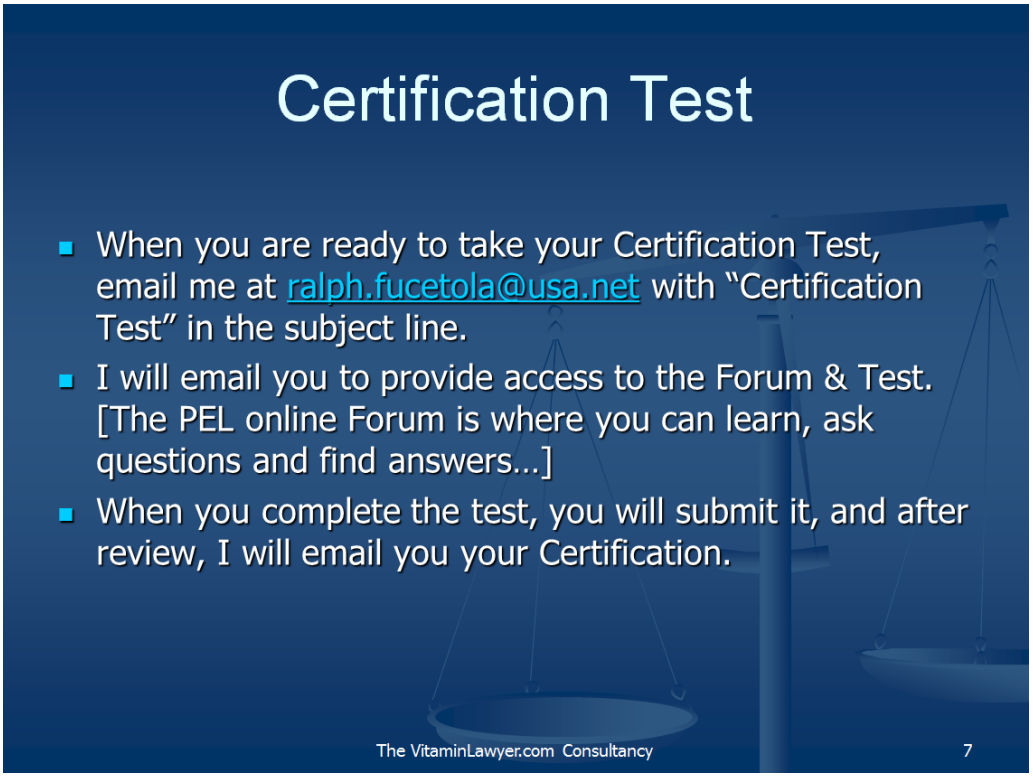
The Second Webinar Overview:


This is the Third Webinar Overview:

The Fourth, Concluding, Webinar Overview


The Program Concludes with the Open Book Certification Test




FDA News.com 3.27.13: **"FDA on the hunt..."**

"Dietary supplement makers: The party's over. The grace period on inspections has expired and the FDA is on the hunt. More warning letters were issued in 2012 than in the previous two years combined. GMP compliance is the FDA's focus..."

"**Dietary supplement manufacturers are facing a high level of regulatory scrutiny from the government** as a result of the study released last week by the U.S. Dept. of Health & Human Services Office of the Inspector General. This study raises new concerns that structure/function claims are not accurate and misleading to consumers. A sample of 127 dietary supplements were reviewed and concluded 'Overall, substantiation documents for the sampled supplements were inconsistent with FDA guidance on competent and reliable scientific evidence.'..." – Natural Products Association

Further from NPA:

**"FDA is concerned with the current lack of GMP compliance and is preparing to take a closer look during inspections.** FDA has also said they are circling back to companies who have already been inspected. Dr. Daniel Fabricant, director of FDA's Division of Dietary Supplement Programs recently stated, "'the majority of inspections [the FDA] have done have resulted in a non-compliance atmosphere, whether resulting in a warning letter or just observations on the 483s.'..." - NPA

Says one FDA Compliance Officer

**"Your company must be in a *state of control* with its training, labels, claims, manufacturer, shipping & customer service…"**

**[Name Redacted] Wellness Company CEO "Alice" - "The FDA showed up unannounced. Said they'd be here for at least 6 days. e showed them the SOPs Counsel Ralph prepared for us. It was comforting to know we could call Ralph Any time during this, and he was there for us."**

# ADDENDUM

**Here is an outline of my SOP format:**