2-DAY VIRTUAL SEMINAR

REGULATORY COMPLIANCE FOR DIETARY SUPPLEMENTS IN THE US, EU AND CANADA

Course Description

A growing public demand for supplements has resulted in a flurry of companies creating and marketing dietary supplements in the United States, EU and Canada. With the regulatory authorities beginning to take a stronger stance on enforcement of regulatory policies, procedures and GMP compliance, it is important for companies to verify that their products comply with the latest regulations and provisions if they plan to market Supplements in these countries

This 2-day interactive virtual seminar will review the regulations that impact Dietary Supplements in the US, EU and Canada and discuss how to verify that products are compliant with these regulations. Differences with food and drug regulation in these countries will be noted as well. We will also cover what qualifies as a dietary supplement or dietary ingredient, how to ensure GMP compliance as well as detailed requirements for labeling and acceptable marketing claims.

Faculty Travis Austin MacKay

Travis MacKay is the Director of Regulatory Affairs for Plexus Worldwide, a leading direct sales company with a range of products dedicated to helping others obtain health and happiness

He currently oversees international regulatory compliance activities driving strategic direction focused on claims development and substantiation strategy

Who Will Benefit

- Executives/Managers within Dietary Supplement or Natural Product companies
- Regulatory Compliance Professionals in the Supplements or Natural Products area
- Quality Assurance or Quality Control Professionals
- Dietary Supplement or Natural Product Manufacturers & Distributors
- Sales/Marketing Personnel in the Supplement or Natural Product Industries

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Agenda Day 01

Dietary Supplement Regulation in the U.S.
- Dietary Supplement Overview
- What is a dietary supplement?
- Supplements vs.
- Pharmaceuticals
- OTC Drugs
- Conventional Foods
- Medical foods
- Natural products
- Herbal medicinal products

Organizations and Regulatory Structure
- FDA Structure regarding Dietary Supplements
- Industry Groups

History of Dietary Supplement Regulation
- Early History
- DSHEA
- Code of Federal Regulations

Manufacturing Considerations
- Company & Facility Registration
- GMP Requirements
- GMP inspections

Dietary Ingredients
- What qualifies as a dietary ingredient?
- Old dietary ingredients vs. New dietary ingredients
- New Dietary Ingredient Notification (NDIN)
- Updated New Dietary Ingredient Guidance from FDA

Labeling Considerations
- Display Panels & Layout
- Supplement Facts Panel
- Labeling Claims
- Health claims
- Disease Claims
- Structure/Function claims
- Disclaimers/Substantiation
- Notification of labeling claims to FDA
- Dietary Supplement Labeling Act

Advertising Considerations
- FDA vs. FTC jurisdiction
- Enforcement
- Expressed vs. Implied Claims
- Exercises & examples
- Disclosures
- Claim Substantiation
- Testimonials

Agenda Day 02

Food Supplement regulation in the EU

Overview
- What is a food supplement?
- Borderline products
- Medicinal Foods

Organizations and Regulatory Structure
- EU Regulatory Structure
- Industry Groups

Supplement Regulation
- Early History
- Food Supplement Directive

Manufacturing Considerations
- Company & Facility Registration
- GMP Requirements

Dietary Ingredients
- What qualifies as a dietary ingredient?
- Ingredient safety
- RDA vs RDI
- DRV vs % Daily Value

Labeling Considerations
- Display Panels & Layout
- Labeling Claims
- Health claims
- Disease Claims
- Reduction of Disease Risk Claims
- Nutrition Claims
- Notification requirements

Advertising Considerations
- Enforcement
- Claim Substantiation

Natural Health Product regulation in Canada

Overview
- What is a Natural Health Product?

Organizations and Regulatory Structure
- Canadian Regulatory Structure
- Health Canada
- Canadian Health Products Directorate

Supplement Regulation
- National Health Products Regulation
- Differences between Canada and US
- Supplements monographs
- Requirements for pre-market approval

Manufacturing Requirements for Natural Health Products in Canada

Dietary Ingredients

Labeling Considerations

Advertising Considerations

Enforcement and Post-Marketing Surveillance

Review of Current Events and other Industry Topics Question and Answers

REGISTRATION FORM

Name _____ **Email** _____

Organization _____ **Department** _____ **Position** _____

Phone _____ **Mobile** _____

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Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
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- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.