

2-day In-person Seminar

Regulatory Compliance for Dietary Supplements in the US, EU and Canada

By: **James Russell**, Director, Regulatory Affairs for RJR Consulting, Inc

Location 1: June 25-26, 2015 | Salt Lake City, UT

Location 2: August 6-7, 2015 | St. Louis, MO



Making better healthcare products possiblesm

Course "Regulatory Compliance for Dietary Supplements in the US, EU and Canada" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.



SPEAKER

James Russell, Director, Regulatory Affairs for RJR Consulting, Inc

Mr. Russell is the Director of Business Development and Regulatory Affairs for RJR Consulting Inc, a leading global regulatory consulting firm servicing the Life Science and Consumer Products industries. Mr. Russell has 13 years of experience in the Life Science field, encompassing foods, dietary supplements, pharmaceuticals and medical devices.

James joined RJR Consulting in 2009 to assist companies with their global regulatory, manufacturing and distribution needs. Prior to RJR, Mr. Russell worked for a large life science distribution company with organizational responsibilities including regulatory, supply chain, business strategy and product data quality. Mr. Russell currently teaches on a variety of regulatory topics and is a participating member of the Regulatory Affairs Professionals Society (RAPS).

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 live 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. An update on current events within the Supplement industry and the potential impacts to Manufacturers and Distributors in the US, EU and Canada will also be presented and discussed.

AGENDA

DAY ONE (8.30AM – 5.00PM)

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

DAY TWO (8.30AM – 4.30PM)

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
Questions and Answers

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



Registration Form

Registration Information:

- Register Online. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
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Seminar Topic: Regulatory Compliance for Dietary Supplements in the US, EU and Canada

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Attendee Details:

Register for 3 and 4th person gets a free pass.

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Attendee 2			
Attendee 3			
Attendee 4			

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