Food, Drug and Cosmetics Division

U.S. FOOD & DRUG ADMINISTRATION

Quality Leadership Network

FDA, Academia, and Industry Working Together to Improve Quality

presents

The First Annual FDA-ASQ-QLN Consortium on DS

Compliance of the Dietary Supplement Industry:

The FDA and Industry Perspective

WHEN:
November 17, 2016

WHERE:

FDA Los Angeles DO
19701 Fairchild, Irvine
CA 92612

Organizing Chairs:

Dr Marlene Garcia-Swider
Quality System Manager
FDA-Los Angeles District Office
QLN Advisor

Nora Dowell, CQM/OE, CQA, CSSGB
VP, Quality/Regulatory Affairs
International Vitamin Corporation
QLN DS Committee Chair
ASQ, FD&C Div- Region 7 Councilor

Rosemarie Christopher
Membership/Regional Councilor Chair
ASQ, FD&C Division
QLN Food Committee Chair

Organizing Members:

Nighat Ansari- Best Formulations
Bel Canosa- Glanbia
Lewis Casey- ASQ
Lance Harding- Herbalife
Joy Joseph- QMS
Andrea Lester- NAI
Kelly Sheppard- FDA
Dan Solis- FDA
Pat Wratschko-Stauber

Program Moderator: Nora Dowell

It has been more than 6 years since the final implementation of 21CFR Part 111, and we continue to see warning letters issued by the FDA to the industry for non compliance with the regulations. This is a clear indication that there is still a need for better understanding of the regulations and alignment between the agency and the industry. At Supply Side West in Las Vegas, last October 6, Cara Welch had made a call to the industry to work together and help FDA in their effforts to implement the regulations. On top of 21 CFR Part 111, there are other regulations that the industry needs to be aware and will need to assess their compliance. At this event, FDA and Industry experts will discuss 1) State of 21 CFR Part 111 compliance; 2) FSMA(Food Safety Modernization Act) including FSVP, its impact on DS and raw material suppliers; 3) NDI (New Dietary Ingredient), new Guidance for the Industry which was extended for comment until December 12, 2016; 4) Prop 65, new warning statements; 5)New labeling .

7:30-7:50	Registration
7:50-8:00	QLN initiatives: **Rosario Quintanilla**- Public Affairs Specialist, FDA
8:00- 8:15	Welcome Address: **CDR Steven Porter**- Los Angeles District Director, FDA
8:15-9:30	***FSMA: FSVP, Impact on DS and Raw Material Suppliers***
	Dan Solis- LA Director of Imports Operations, FDA
	Dr. Teresa Cain - Import Compliance Officer, FDA
	Joy Joseph - President JQMS
9:30-9:45	Break
9:45-10:45	NDI, Draft Guidance : **Cara Welch Ph.D.-** Senior Advisor, Office of Dietary Supplement Programs, FDA
10:45-12:15	***Industry Self Regulation to Safeguard Dietary Supplement Quality and Safety:***
	DS Panel:
	Raw Material Supplier - **Rupa Das**, VP of Global Quality and Compliance-Botanical International
	DS Manufacturer- **Gary Swanson** , Sr. Vice President Global Quality-Herbalife
	Product Owner- **Guru Ramanathan**, SVP & Chief Innovation Officer-GNC
12:15-12:45	Lunch and Networking
12:45-1:45	DS Panel continued….
	Trade/3rd Party Organization - **David Trosin** Business Development Director- NSF
	Testing Laboratory- **Elan Sudberg**, CEO- Alkemist
1:45-2:45	Q&A
	DS Workshop Moderator: Joy Joseph
2:45-3:00	Break
3:00-3:30	Prop 65: **Ann Grimaldi**- Principal Grimaldi Law Offices
3:30-4:10	FDA Update: **Daniel Cline**- Los Angeles District Compliance Division, FDA
4:10-4:50	Compliance with DS Regulations-Investigator's Perspective: **Sarah Dent-Acosta**- Food Specialist, FDA
4:50-5:00	Sponsor's Presentation: **Lewis Casey**- ASQ

Who should attend?
Quality/Regulatory Managers, Directors, Vice Presidents
Company Executives
Supply Chain Personnel
Regulators

Featured Speaker:

Cara Welch, Ph.D.
Senior Advisor, Office of Dietary Supplement Programs, FDA

Cara Welch, Ph.D., came to the Food and Drug Administration in 2014 as a Regulatory Special Assistant and is currently the Senior Advisor for the Office of Dietary Supplement Programs. In this role, Dr. Welch works on new policies and programs involving regulatory compliance matters for the dietary supplement industry. Welch utilizes her background to provide guidance on research throughout the Center applicable to dietary supplements and serves as an expert witness on regulations regarding dietary supplement ingredients, labeling, and manufacturing.
Prior to FDA, Dr. Welch was the Senior Vice President of Scientific and Regulatory Affairs at the Natural Products Association. While there, she was responsible for implementing policies in response to government initiatives in the regulatory arena; advising association members on regulatory, safety, nutrition and health issues; and overseeing the association's certification programs. Welch earned her Ph.D. in Medicinal Chemistry from Rutgers University working with traditional medicinal African plants.