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COMBINATION PRODUCTS SUMMIT

STREAMLINING 21 CFR PART 4 COMPLIANCE

AN INTERACTIVE WORKSHOP PRESENTED BY NSF HEALTH SCIENCES AND FDANEWS

WORKSHOP CHAIRPERSON:

DR. MARY C. GETZ
VP, NSF Health Sciences-Medical Device Consulting

FEATURED INDUSTRY SPEAKERS:

ELAINE MESSA
President, NSF Health Sciences, Medical Device Consulting

OLIVIA WONG
Director, NSF Health Sciences, Medical Device Consulting

FEATURED FDA SPEAKER:

JOHN (BARR) WEINER
Associate Director for Policy and Product Classification Officer, Office of Combination Products

ADDITIONAL FDA SPEAKERS:

FRANCISCO VICENTY, Mechanical Engineer, Division of Analysis and Program Operations, CDRH

DINESH KUMAR, Regulatory Counsel, Office of Orphan Products Development, Office of Policy and Risk Management, ORA

EDWARD PATTEN, Associate Director Manufacturing Science, Office of Medical Products and Tobacco, Office of Compliance and Biologics Quality, CBER

MELISSA BURNS, Senior Program Manager, Office of Combination Products

NOV. 9-10, 2015 | DOUBLETREE BY HILTON BETHESDA, BETHESDA, MD

The regulatory landscape for combination products is more complicated than drug and device products alone and raises unique challenges that affect the entire product lifecycle. Contradicting terminologies, SOPs, GDPs, timelines and budgets, quality control, postmarket modifications and safety concerns make for serious challenges.

Developing a transparent relationship with the FDA can help companies bridge the gap, but how do you go about creating that relationship?

On November 9 and 10, 2015, NSF Health Sciences and FDAnews are presenting a new interactive workshop designed to bridge the gap for drug- and devicemakers: **Combination Products Summit: *Streamlining 21 CFR Part 4 Compliance***.

This hands-on workshop, featuring current and former FDA officials and recognized drug and device industry leaders, will show you how to develop effective GMP approaches and how to execute them. You will work hand-in-hand with instructors and fellow attendees on comprehensive exercises that will take you from theory to practical application.

Here's just some of the specific knowledge you'll gain:

- How to develop integrated cGMPs and regulatory strategies for combination products
- How – and when – to implement 21 CFR 820 requirements for design controls, and how to develop a strategy for legacy products
- Strategies for interacting with the FDA – including how to avoid the mistakes of others
- How to apply 21 CFR 211 requirements for product release, retains, sterility, and stability
- Tested ways to present and justify exemptions or compliance to specific regulations, including human factors and product release testing
- How to set a quality and regulatory strategy for your combination product portfolio
- Important nuances, such as when a container or closure becomes a combination product
- How to leverage quality agreements to support compliance to 21 CFR Part 4

Day 1 Agenda

MONDAY, NOVEMBER 9

7:00 a.m. – 8:00 a.m. | **REGISTRATION & CONTINENTAL BREAKFAST**

8:30 a.m. – 8:30 a.m. | **WELCOME**

8:30 a.m. – 9:45 a.m.

FDA's Expectations for Combination Products Manufacturers – Review of 21 CFR Part 4 Requirements

- How current regulations and guidances define a combination product
- Why the FDA created its final rule and draft companion guidance and what it means for the industry
- Understanding the roles and responsibilities of FDA Centers and Office of Regulatory Affairs

John (Barr) Weiner, Associate Director for Policy and Product Classification Officer, Office of Combination Products, FDA

9:45 a.m. – 10:30 a.m.

FDA and Industry Interactions; Cultivating a Relationship of Transparency

- Communicating with the FDA – a proactive approach to developing a compliant quality system everyone can agree with
- Top 10 best business practices and lessons learned
- Presenting data to justify compliance – or exemptions – to the regulators
- Your combination product portfolio – how to set a quality and regulatory strategy
- You have options – how to balance the right approach for your company
- Planning and prioritizing product/process remediation
- Understanding and managing risk – ensuring a safe, effective and risk-based approach

Christy Skinner, Quality Assurance, W.L. Gore and Associates

Tim Ulatowski, Ulatowski Consulting LLC; former Director of the Office of Compliance, CDRH

10:30 a.m. – 10:45 a.m. | **BREAK**

10:45 a.m. – 12:15 p.m.

FDA and Industry – Expert Panel Discussion - Things That Keep You Up at Night

- Challenges for the industry – how one can approach developing a combination product strategy
- Proactive vs Reactive – if no one has been cited – why do we have to do it?
- Are there other new requirements or guidance that Industry can use as a basis for developing a compliance strategy?
- How do I develop a working relationship when I don't know even know where to start the dialog?

Moderator: Dr. Mary C. Getz, Vice President, NSF Health Sciences, Medical Device Consulting

Panelists:

- John (Barr) Weiner, Associate Director for Policy and Product Classification Officer, Office of Combination Products, FDA
- Tim Ulatowski, President, Ulatowski Consulting LLC; former Director of the Office of Compliance, CDRH, FDA
- Christy Skinner, Quality Assurance, W.L. Gore and Associates
- Francisco Vicenty Mechanical Engineer, Division of Analysis and Program Operations, CDRH, FDA
- Dinesh Kumar, Regulatory Counsel, Office of Orphan Products Development, Office of Policy and Risk Management, ORA, FDA
- Edward Patten, Associate Director Manufacturing Science, Office of Medical Products and Tobacco, Office of Compliance and Biologics Quality, CBER, FDA
- Melissa Burns, Senior Program Manager, Office of Combination Products, FDA

12:15 p.m. – 1:15 p.m. | **LUNCH**

1:15 p.m. – 4:30 p.m.

How and When to Implement 21 CFR 820.30 Design Controls

- I'm pharma -- why do I need to care about a design and development plan or design verifications?
- I'm device -- what do I need to know about containers/closures, yield calculations and expiration dating?
- Top 3 things to know about biocompatibility
- Why do I need to do design validation and process validation?
- Are legacy products grandfathered in?
- Do's and Don'ts of evaluating risk documentation for compliance
- Why do I need to worry about design control if I use off-the-shelf or 510(k) components?

Case Study #1: Understanding PMOA Before Your Product is DOA

You'll learn about subordinate versus primary modes of action (PMOA) and how to determine appropriate design inputs and outputs

Olivia Wong, Director, NSF Health Sciences, Medical Device Consulting

Amit Khanolkar, Director, Combination Products & Emerging Technologies PQM, Johnson & Johnson Janssen Pharmaceuticals

John Karels, Principal, Project Solutions Consultants

4:30 p.m. – 6:30 p.m. | **NETWORKING SOCIAL**

Day 2 Agenda

TUESDAY, NOVEMBER 10

8:00 a.m. – 8:30 a.m. | CONTINENTAL BREAKFAST

8:30 a.m. – 10:00 a.m.

Understanding 21 CFR 211 Laboratory Controls

- Reserve sampling programs – are you practicing representative or insufficient retention?
- The 3 W's of expiration testing: What studies do I need? When to do it? Why do I need to do it?
- Testing and release – have you assured adequate specifications and criteria?
- Stability testing and strategy
  - Is it simply a container/closure or is it part of the combination product?
  - Impact of sterilization on stability, expiration dating and labeling

Case Study #2: Proven Methods for Choosing Specifications for Product Characterization and Stability

You will gain an increased understanding of how to select and choose appropriate specifications for product characterization and stability.

Dr. Dvorah Feder, Director, Analytical Chemistry Research & Technology, Abbott Vascular

Jie Hu, Manager, Material Characterization Lab and Bioanalytical Services, Abbott Vascular

10:00 a.m. – 10:15 a.m. | BREAK

10:15 a.m. – 11:45 a.m.

Purchasing Controls – Quality Begins With Procurement

- Purchasing Agreements – seven critical elements every quality agreement should address
- Benefiting from your supplier's quality system and documentation
- Putting your Original Equipment Manufacturer (OEM) relationship to work – Leveraging OEM product data and design requirements (cont.)
- Understanding requirements for repackaging
- Engaging qualified contractors and consultants – Effectively augmenting your workforce with experienced, reliable, and temporary staff

Case Study #3: Making Effective Supplier Decisions – Using risk-based tools and decision-making to prioritize audits of contractors/suppliers based on criticality

You will learn how to identify and apply the appropriate level of supplier oversight based on various factors: supplier type/service, component and/or product criticality, overall product classification and target population, risk, etc.

Patti Gupta, President, Patti Gupta & Associates LLC

11:45 p.m. – 12:45 p.m. | LUNCH

12:45 p.m. – 3:45 p.m.

CAPA and Nonconformances – FDA Shouldn't Be the Only Investigators

- A comprehensive approach to CAPA systems
- Complaints, adverse events and medical device reporting – how to develop a common approach using yes/no decision tree process
- What is CAPA appropriate? Determining appropriate decisions, documentation and investigations
- Ensuring your non-conformance documentation conforms to requirements
- Risk assessments – it's not just for design controls
- Root cause investigations – getting down to the real root of the matter
- Tracking and trending – what your system is REALLY trying to tell you

Case Study #4: Correction, Corrective Action and Preventive Action – Which is Needed?

You'll gain an understanding of the meaning of these three terms, as well as the various tools available to make effective decisions regarding the significance of a non-conformance.

Gary Gilliam, Operations and Quality Executive, MedPharm Consulting, Inc.

Patti Gupta, President, Patti Gupta & Associates LLC

3:45 p.m. – 4:00 p.m. | BREAK

4:00 p.m. – 4:45 p.m.

Managing Quality From The Top Down -- Sustaining Overall GMP Compliance

- Audit strategy – managing internal and external regulatory authority audits
- How best to present your Quality System program – starting out on the "right path"
- Effective management controls from quality policy to CAPAs and audit execution – the checks and balances to ensure you're maintaining compliance
- 7 things every training program must address
- Overlooked metrics that need your immediate consideration
- Executing management reviews – managers don't know what they don't know
  - Don't tell them what they want to hear, tell them how they can help
  - Understanding your data and its impact on product quality and patient safety

Dr. Mary C. Getz, Vice President, NSF Health Sciences-Medical Device Consulting

4:45 p.m. – 5:00 p.m. | CONCLUSIONS & ACKNOWLEDGEMENTS

Elaine Messa, President, NSF Health Sciences, Medical Device Consulting

Unrivaled Take-Home Materials Support Everything That You'll Learn

You'll receive an absolutely invaluable workshop folder and USB drive with supporting, need-to-have tools and reference documents that you can put to use immediately when you return home. The materials include:

- Copies of all workshop presentations and materials
- Current FDA Regulations
  - 21 CFR Part 4
  - 21 CFR Part 210
  - 210 CFR Part 211
  - 21 CFR Part 803
  - 21 CFR Part 806
  - 21 CFR Part 820
- Hyperlinks to additional online FDA guidance and requirement documents
- White Paper on Combination Products
- List of Guidances used by FDA Investigators
- List of Quality Terms and Definitions
- Tips for Managing an FDA Inspection
- Adverse Event Reporting (AER) Decision Tree
- Risk Matrix Chart
- Design Control Diagrams and Process Flows
- Traceability Matrix Template
- Fishbone Cause and Effect Diagrams
- "5 Whys" Diagram
- Root Cause Impact Assessment
- Corrective Action Risk Impact Assessment
- Sample Management Metrics
- Sample Quality Agreement
- Supplier Criticality Matrix

Who Will Benefit

- Engineering Managers
- Quality Engineers
- Analytical Chemists
- Compliance Managers – Training and Internal Audit oversight
- Purchasing and Supply Chain Managers
- Procurement Agents involved in outsourcing production or processes
- R&D staff – Engineering, and Analytical Lab personnel
- Medical staff evaluating risk, safety, or effectiveness
- Regulatory Affairs Managers
- General/Corporate Counsel
- Directors and Managers responsible for delivery and execution to 21 CFR Part 4 requirements
- Those involved with the day-to-day activities of combination product design, development, validation and production within quality, regulatory, laboratories, engineering, R&D and operations organizations

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STREAMLINING 21 CFR PART 4 COMPLIANCE

☐ **YES!** Sign me up for the **Combination Products Summit: *Streamlining 21 CFR Part 4 Compliance***

Attendee 1: Name _____
Title _____ Email _____ **$1,797**

Attendee 2: Name _____
Title _____ Email _____

Attendee 3: Name _____
Title _____ Email _____

Register at www.FDAnews.com/comboproducts or call toll-free: (888) 838-5578

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CONFERENCE PRICING:

Conference Price	**$1,797**
2-4 attendees – SAVE 10%	**$1,617**
5-6 attendees – 15%	**$1,527**
7-9 attendees – 20%	**$1,438**
10+ attendees – 25%	**$1,348**

HOTEL RESERVATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the **FDAnews Workshop** to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. Hotel may require first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

Dates/Location:
November 9-10, 2015

Doubletree by Hilton
8120 Wisconsin Ave.
Bethesda, MD 20814

Tel: +1 (301) 652-2000
Toll-free: 1- 855-610-TREE (8733)

www.DoubletreeBethesda.com

Room rate: $177.00 plus 13 percent tax
Reservation cut-off date: Oct. 16, 2015

WORKSHOP

Tuition includes all workshop sessions, workshop written materials, two breakfasts, two lunches, reception and daily refreshments.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call +1 (703) 538-7600 for details.

FOUR EASY WAYS TO REGISTER

Online:
www.FDAnews.com/comboproducts

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Mail:
FDAnews, 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

CANCELLATIONS/ SUBSTITUTIONS

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund -- less a $200 administration fee. No cancellations will be accepted -- nor refunds issued -- within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Case Studies You Can't Afford to Miss!

Case Study 1: Understanding PMOA Before Your Product is DOA.

You'll learn about subordinate versus primary modes of action (PMOA) and how to determine appropriate design inputs and outputs. You'll also tackle compatibility issues, risks and mitigation strategies; learn how to recognize critical control points throughout the design process; and get best practices for establishing and maintaining compliant design history files.

Case Study 2: Proven Methods for Choosing Specifications for Product Characterization And Stability.

You will gain an increased understanding of how to select and choose appropriate specifications for product characterization and stability. Plus, how to establish appropriate tolerance levels, beginning in design and development and continuing through to design transfer. Finally, you'll understand the importance of "closing the window" and establishing effective acceptance criteria prior to full-scale production.

Case Study 3: Making Effective Supplier Decisions – Using Risk-Based Tools and Decision-Making to Prioritize Contractor/ Supplier Audits.

Based on hundreds of previous supplier audits, this case study will show how to identify and apply the appropriate level of supplier oversight based on various factors: supplier type/service, component and/or product criticality, overall product classification and target population, risk, etc. You will also gain insight into proven ways of establishing an effective, risk-based auditing schedule that satisfies both business and compliance needs.

Case Study 4: Correction, Corrective Action and Preventive Action – Which Is Needed?

You'll gain an understanding of the meaning of these three terms, as well as the various tools available to make effective decisions regarding the significance of a non-conformance. You'll also play detective in a series of decision-making exercises on non-conformances that may or may not be appropriate for CAPA. Finally, you'll find out the best way to structure effectiveness checks to ensure the adequacy of actions taken.

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300 N WASHINGTON STREET, SUITE 200
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Interactive Workshop Featuring Current
and Former FDA Officials