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2-Day In-Person Seminar:

Change Control Best Practices - Avoiding Unintended Consequences of Changes

By: **Brandy Lewis,** Principal Quality Consultant and Director, Thirteen Consulting Group Inc

Location 1: August 6-7, 2015 | San Francisco, CA **Location 2:** November 12-13, 2015 | Philadelphia, PA

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
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Course "Change Control Best Practices - Avoiding Unintended Consequences of Changes" has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

SPEAKER

Brandy Lewis, Principal Quality Consultant and Director, Thirteen Consulting Group Inc.

Brandy Lewis has 23 years of pharmaceutical quality assurance and quality systems experience in both industry and consulting roles. Ms. Lewis has worked in clinical supply and commercial manufacturing environments, and has experience with integrated manufacturing and contract manufacturing business models. She has extensive expertise in the areas of change control, GMP training, and regulatory inspection preparation and management.

Working with both small and large companies, Ms. Lewis has successfully developed and implemented key quality systems for the appropriate phase of the company. She is an experienced GMP trainer, and has developed and delivered customized interactive training presentations for many companies. She has also provided FDA/FDB/ISO inspection/audit support for several companies and clients, including readiness training, on-site assistance during inspections, and authoring written responses to inspectional observations. Prior to becoming a consultant in 2014, Ms. Lewis was the head of Quality at four (4) companies in the San Diego area.

LEARNING OBJECTIVES

On completing this course on FDA compliance, participants will be able to:

- Understand regulatory requirements and FDA expectations for change control
- Understand the purpose of change control
- Identify what types of changes are /are not subject to change control
- Properly describe a change
- Properly justify a change
- Develop a comprehensive change execution plan
- Conduct a proper change risk assessment
- Accurately execute a change
- Accurately implement a change
- Develop a full change control package
- Utilize critical thinking skills throughout the change control process
- Avoid pitfalls during the change control process

COURSE DESCRIPTION

With FDA citing inadequate change control constantly in its 483s and Warning Letters, the prerequisite to ensure that changes are accurately described, justified, assessed for risk, implemented, and documented has come to the fore. Changes must also be prospectively reviewed by appropriate subject matter experts. Furthermore, certain major changes (e.g. manufacturing, specifications) may require regulatory filings and/or prior regulatory approval.

This seminar will guide all personnel involved in proposing, assessing, and implementing changes to understand and successfully apply the fundamental change control steps and best practices. The key focus will remain on:

- Change proposals
- Justification / risk assessment
- Change execution / implementation

The seminar will focus on changes to equipment, facilities, materials/components, test methods, suppliers, specifications, etc. Document change control will be discussed as a supporting element. Additionally, this practical, how-to course will illustrate and impart:

- The importance of subject matter expertise, proper planning, critical thinking skills, and co-ordination of all change activities.
- Skills needed for applying change controls within an organization.
- Group exercises to allow participants to practice skill sets with feedback from the instructor.
- Practical training by having participant teams complete a full write-up for a mock change control.

AGENDA

Day One (8:30 AM – 4:30 PM)

Registration Process: 8:30 AM – 9:00 AM

Session Start Time: 9:00 AM

- Regulatory Requirements
- FDA Change Control Expectations / Warning Letter Examples
- Purpose of Change Controls
  - What is Change Control?
  - Why Change Control?
  - A Different Way of Thinking
- Change Control Process Model
  - 5 Part Process Model
  - Key Terms and Definitions
- Types of Changes Subject to Change Control
  - Products, Materials, Suppliers, Processes, Facilities, Equipment, etc.
  - Like-for-Like Changes
- Change Proposal
  - Current State / Proposed State
  - Group Exercise - Change Proposal
- Change Justification
  - Science and Compliance Rationale
  - Group Exercise - Change Justification
- Change Execution Plan
  - Key Elements
  - Group Exercise - Change Execution Plan
- Change Proposal Assessment
  - Risk Assessment
  - Validation, Technical, Regulatory, Quality Assessment
  - Group Exercise - Change Risk Assessment

Day Two (8:30 AM – 4:30 PM)

- Executing the Change
  - Key Elements
- Implementing the Change
  - Key Elements
- Change Control Documentation
  - Key Elements
- Putting It All Together: A System Viewpoint
- Change Control Workshop
  - Participant Teams to Write-Up Mock Change Control, Based on Case Studies Provided by Trainer

WHO WILL BENEFIT

This course is designed from a pharmaceutical manufacturing perspective; however, since the main focus is on techniques and practices, the course material may be equally applied to biologics and medical device environments. It will benefit:

- Change proposal authors
- Reviewers / approvers of change controls
- Change control system owners
- Production staff / management
- Engineering staff / management
- Validation staff /management
- QA and QC staff / management
- Regulatory affairs staff / management

Registration Form

GROUP REGISTRATIONS

Send your team for maximum benefit. Get your team up to speed!

2 Attendees	-	Get 10% off
3 to 6 Attendees	-	Get 20% off
7 to 10 Attendees	-	Get 25% off
10+ Attendees	-	Get 30% off

Call Toll Free +1-888-717-2436 if you have any queries.

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.
- Call Toll Free: +1-888-717-2436 (USA), 8000-3570-2845 (Middle East) or Fax your PO: 650-963-2556.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-963-2556

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ Toll Free: +1-888-717-2436 (USA), 8000-3570-2845 (Middle East) or email us @ editor@complianceonline.com

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Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 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 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($200) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline 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.

Seminar Topic: Change Control Best Practices - Avoiding Unintended Consequences of Changes

Date & Location: .....

Attendee Details:

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

	Name	Title	Email
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Attendee 3			
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