An Interactive Workshop
Presented by MSceppa Consulting and FDAnews

Back by Popular Demand: Learn how to evaluate noncompliance activities — with the same criteria used by FDA investigators.

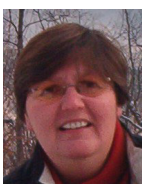
June 18–19, 2014 • Marriott Bethesda North Hotel & Conference Center • Bethesda, MD

Risk-Based Clinical Quality Assurance

Train Your Auditors Like the FDA Does

With a highly charged atmosphere for compliance and enforcement, the FDA is focusing on GCP violations. Register for this must-attend interactive workshop and you will learn how to:

- Structure your site audit just like an actual FDA inspection
- Define distinctions between noncompliance, scientific misconduct and fraud
- Use site staff interview techniques that yield better information — with less resistance
- Balance relationships — QA, clinical and the CRO — at this critical juncture when clinical study outsourcing is on the rise
- And much, much more



MICHELLE SCEPPA, MSceppa Consulting

"Michelle is a great speaker. Her materials are very helpful. She entertains all questions and has answers for you right away. She is very knowledgeable in her field."
— **Catherine Cadogan**, Sr. Clinical Research Associate, GE Healthcare

Visit www.CQAworkshop.com or call (888) 838-5578

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June 18–19, 2014 • Bethesda North Marriott

WORKSHOP AGENDA

DAY ONE

8:00 a.m. – 8:30 a.m. REGISTRATION AND CONTINENTAL BREAKFAST

8:30 a.m. – 10:00 a.m. Starting on the Same Page: Good Clinical Practice Regulatory Requirements and Expectations

- Review of FDA and GCP requirements for conducting a clinical study
- What role does ICH have in good clinical practices?
- Responsibilities associated with institutional review boards and ethic committees (IRB/EC)
- Principal investigator roles and responsibilities
- Essential elements of informed consent agreement
- What is the sponsor's role in the clinical study?
- Understanding the study protocol
- The investigator's brochure — why is it important?

10:00 a.m. – 10:15 a.m. BREAK

10:15 a.m. – 12:00 p.m. GCP Audits: What Audits Are Needed to Maintain a Compliant GCP Program

- What are the fundamentals of a GCP audit?
- Establishing an audit program
- The components of an audit program
- Qualifying a clinical research organization (CRO)
- Central laboratory audits and why they need to be a component of a GCP program
- Auditing clinical sites — who gets the audit and why?
- Why is it important to address the audit observations and follow-up?

12:00 p.m. – 1:00 p.m. LUNCH BREAK

1:00 p.m. – 3:00 p.m. Working with a CRO: Conducting Compliant GCP Studies

- When utilizing the services of a CRO, it is still important to meet and maintain the sponsor's requirements
- When working with a clinical site: Are GCPs being followed and most importantly, are they being documented?
- The "relationships": QA, clinical and the CRO — a tenuous relationship at best
- The audit: aspects and specifics — what is the value of an audit?
- Audit follow-up — always important to conduct the audit, but are the recommendations and corrections implemented?
- Post-CRO assessment — was the relationship with the sponsor and the CRO successful? — A checklist to evaluate the performance

3:00 p.m. – 3:15 p.m. BREAK

3:15 p.m. – 5:00 p.m. Most Commonly Cited GCP Violations at a Clinical Site

- Principles of GCPs at a clinical site
- The areas FDA investigators focus on
- PI responsibilities for the study — why the sponsor and the PI sometimes differ in this area
- Reviewing FDA inspections and the top five GCP violations

5:00 p.m. Session Wrap-Up, End of Day 1

DAY TWO

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

8:30 a.m. – 10:30 a.m. Writing GCP Audit SOPs: Elements of the SOPs

- ☑ **INTERACTIVE EXERCISE!** Writing a clinical site audit SOP; why do you need this SOP; what are the important elements of this SOP?
- ☑ **INTERACTIVE EXERCISE!** Writing a central laboratory audit SOP; why do you need this SOP; what are the important elements of this SOP?

10:30 a.m. – 10:45 a.m. BREAK

10:45 a.m. – 12:00 p.m. Preparing and Setting Up CQA Audits

- Selecting sites to be audited — creating a master audit plan and how to make sure it is met
- Auditing contract research organizations — why it is important to audit a phase 1 unit
- Audits of a central laboratory — why lab data and testing are a critical component of the clinical study
- Managing the audits (logistics, time, etc.) — why managing the logistics of an audit are critical to the audit itself
- Conducting the audits — what makes a "good" auditor?
- The site visit audit report — when and how the report is a valuable tool
- Evaluating the audit findings and implementing corrective actions — whose responsibility is it?

12:00 p.m. – 1:00 p.m. LUNCH BREAK

1:00 p.m. – 5:00 p.m. 5 Tools for CQA Auditors

- Preparing for the audit: A checklist does not make you a good auditor, but it is a useful tool
- The auditor's performance: how to be nice but still maintain professional efficiency
- Interviewing skills
- ☑ **INTERACTIVE EXERCISE!** Interviewing a peer
- Writing skills: report formats most auditors find useful
- ☑ **INTERACTIVE EXERCISE!** Creating a report format
- Postassessment of the study: was it successful and did the "relationships" (clinical, quality and the CRO) work?

5:00 p.m. Workshop Adjourns

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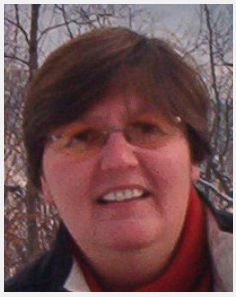
Hotel & Conference Center • Bethesda, MD

YOUR EXPERT INSTRUCTOR



MICHELLE SCEPPA, principal and founder of MSceppa Consulting, has more than 25 years of experience in quality assurance and regulatory compliance in the pharmaceutical and medical device industries. As a lead auditor, she has conducted and managed more than 300 internal and external audits for drug, biologics and medical device firms in the U.S. and Europe. Ms. Sceppa has implemented and managed preclinical, clinical and manufacturing quality assurance programs for numerous clients. Knowledgeable in the details of compliance with all U.S. federal regulations — including Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) for drugs, biologics and medical devices — Ms. Sceppa is also certified in the Q7A regulations for the manufacture of active pharmaceutical ingredients. Since 2002, Ms. Sceppa has been a faculty member of the Parenteral Drug Association's Training and Research Institute (PDA-TRI) in Baltimore, MD.

WHAT YOU WILL LEARN

- The basic principles of GCPs and international regulations
- How to determine if GCPs are being followed and what needs to be documented
- Balancing the relationships — QA, clinical and the CRO — in the ever-changing economy where clinical study outsourcing is common
- Defining responsibilities with outsourced clinical trials and the role communication plays in maintaining compliance
- Strategies for deciding who to audit
- Audits of a CRO or central laboratory — who and how do you audit these specialized providers
- Managing the audits (logistics, time, etc.) — understanding the management of the audit is essential to assuring completion of everything that needs to be done
- Conducting the audits — what do you do and what interviewing skills are needed
- The site visit audit report — writing a report is sometimes the hardest thing to accomplish
- Evaluating the audit findings and implementing corrective actions — once the report is written, the audit is not over
- FDA inspections and the top five GCP violations

WHO SHOULD ATTEND

- Clinical quality assurance managers and auditors
- Clinical site directors
- Clinical research associates/ coordinators
- Regulatory affairs
- IRB administrators

COURSE BINDER MATERIALS

- Slides from PowerPoint presentations
- Case review worksheets
- Interactive exercise worksheets
- SOPs, forms, templates for CQA audits; site, CRO and central laboratory
- Copies of applicable FDA/ ICH regulations and guidances

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LOCATIONS AND HOTEL ACCOMODATIONS

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. The hotel may require the 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.

Lodging and Conference Venue:

June 18-19, 2014
Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Road
North Bethesda, MD 20852
Toll free: (800) 859-8003 • Tel: +1 (301) 822-9200
www.bethesdanorthmarriott.com
Room rate: $199 plus 13% tax
Reservation cut-off: May 27, 2014

TUITION

Tuition of $1,797 includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

CANCELLATIONS AND 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 of 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.

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 (888) 838-5578 for details.

FOUR EASY WAYS TO REGISTER

Online: www.CQAworkshop.com
Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600
Mail: **FDAnews,** 300 N. Washington St., Suite 200 Falls Church, VA 22046-3431 USA

☑ **YES!** I want to attend **Risk-Based Clinical Quality Assurance: *Train Your Auditors Like the FDA Does*** on June 18-19, 2014, at Bethesda North Marriott Hotel & Conference Center, Bethesda, MD

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300 N. Washington St., Suite 200
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