An interactive workshop presented by
Cerulean Associates LLC and FDAnews

"Companies must provide truthful and accurate information in their marketing applications…The American public expects and deserves no less."
— Janet Woodcock, M.D., Director, CDER

FDA Data Integrity

From Data Creation to Long-Term Archive

Dec. 8-9, 2015

Embassy Suites Raleigh-Durham Airport/Brier Creek • Raleigh, NC

FDA data integrity requirements are among the most strenuous that regulated industries have to comply with. Your electronic records must be trustworthy and reliable across their entire data lifecycle — from initial data creation through long-term archival.

In the FDA Data Integrity workshop you will learn the following:

- The types of data integrity violations identified during recent FDA inspections
- FDA expectations for review of electronic laboratory data
- What actions to take if data integrity concerns are identified within your company or at a contractor
- What is really required by the FDA, EMA, Health Canada and other regulating agencies
- How to quickly parse warning letters for data integrity expectations
- FDA investigator tactics and questions to expect about your data integrity
- The eight practical elements of data integrity
- What to look for when conducting quality audits of data integrity
- How to map your data flow
- How to incorporating data integrity compliance into the day-to-day operations
- How to qualify record and archival storage vendors
- How to develop a media migration strategy

John Avellanet
Founder, Cerulean Associates LLC,

"John takes on complicated regulation and breaks it down into easily managed steps and projects applicable to any company."
— Jeffery Taylor, Manager, Quality Systems and Validation

"John is not only a subject matter expert, he is also a great speaker. He understands how to keep the audience engaged by encouraging their participation. Thumbs up to John."
— Johanna Stamates, Executive Director Research Compliance and Quality Assurance, University Of Miami

Visit www.fdanews.com/FDADataIntegrity or call (888) 838-5578

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WORKSHOP AGENDA

DAY ONE
TUESDAY, DEC. 8, 2015

8:30 a.m. – 9:00 a.m.
REGISTRATION & CONTINENTAL BREAKFAST

9:00 a.m. – 9:15 a.m.
INTRODUCTION AND WELCOME

9:15 a.m. – 10:45 a.m.

I. **Data Integrity: What's Really Required?**
   - a. Core regulatory requirements — FDA, EMA, Health Canada and more
   - b. Overlooked guidances — what you don't know will hurt you
   - c. How to quickly parse warning letters for data integrity expectations
   - d. FDA investigator tactics and questions about your data integrity
   - **e. Interactive Hands-On Exercise:** Attendees act as FDA investigators in different company types to find the data integrity controls FDA expects during an inspection

10:45 a.m. – 11:00 a.m. REFRESHMENT BREAK

11:00 a.m. – 12:00 p.m.

II. **Suppliers and Data Integrity: Who's Actually Accountable?**
   - a. FDA's view — accountability versus responsibility
   - b. Dealing with your regulated data at critical suppliers
   - c. Contractual components to address data integrity risks
   - d. Handling SaaS providers, hosted IT systems and cloud computing
   - e. Managing data integrity with CROs and outsourced clinical sites
   - f. Overseeing data integrity at your CMO and contracted services
   - g. Addressing data from suppliers of raw materials
   - **h. Interactive Hands-On Exercise:** Attendees act as FDA investigators to review the data integrity controls from several case study companies have in place over their suppliers — should the sponsor/purchaser get a warning letter?

12:00 p.m. – 1:00 p.m. LUNCH

1:00 p.m. – 2:15 p.m.

III. **Practical Realities: The Business Costs of Poor Data Integrity**
   - a. Real world business costs of poor data integrity
   - b. Legal pitfalls for senior management from poor data integrity
   - c. Practical quality costs of poor data integrity
   - **d. Interactive Hands-On Exercise:** Attendees review several case studies to determine costs and dangers of poor data integrity

2:15 p.m. – 2:30 p.m. REFRESHMENT BREAK

2:30 p.m. – 4:30 p.m.

IV. **Critical Data Integrity Elements to Prove Compliance**
   - a. Eight practical elements of data integrity (ALCOA+ in practice)
   - b. Narrowing the scope
   - c. Risk-based data integrity controls — a simplified approach
   - d. Verifying data integrity controls at suppliers
   - e. Qualifying personnel — from CV to training
   - f. Defining roles and responsibilities
   - g. Conducting quality audits of data integrity — what to look for and why
   - h. Monitoring, metrics and communication
   - i. Policies and SOPs to consider
   - j. Scanning, true copies and source data
   - **k. Interactive Hands-On Exercise:** Using case studies, attendees identify likely risks and select the most appropriate controls for each situation

4:30 p.m. – 5:00 p.m.

V. Day One Wrap Up and Review
   - **a. Interactive Hands-On Exercise:** Attendees identify 3 compelling reasons for their own company to adopt data integrity controls now

DAY TWO
WEDNESDAY, DEC. 9, 2015

9:00 a.m. – 9:15 a.m.
WELCOME AND QUICK LEARNING RECAP

9:15 a.m. – 10:30 a.m.

VI. **Modern Validation Protocol**
   - a. Validation by risk level — it's all about the data
   - b. Sampling and test cases — FDA's view
   - c. FDA's view of supplier-provided validations
   - d. Taking advantage of the traditional DQ\IQ\OQ\PQ format
   - e. Example FDA-"approved" test cases for data integrity-based validation
   - **f. Interactive Hands-On Exercise:** Attendees review case study validation tests to see if data integrity is actually being verified

10:30 a.m. – 10:45 a.m. REFRESHMENT BREAK

10:45 a.m. – 12:00 a.m.

VII. **Mapping Your Data Chain-of-Custody**
   - a. Data mapping defined
   - b. Steps to map your data flow across the data lifecycle
   - c. Benefits to mapping your chain-of-custody — business and the FDA
   - **d. Interactive Hands-On Exercise:** Work in teams to data map a sample data flow from several case studies (one cGCP and one cGMP)

12:00 p.m. – 1:00 p.m. LUNCH

1:00 p.m. – 2:15 p.m.

VIII. **Advanced Tactics to Cut Costs and Reduce Your Workload**
   - a. Change management — from preapproved to emergency
   - b. Containing costs with cross-functionality
   - c. Incorporating data integrity compliance into the day-to-day operations of departments and supervisors
   - d. Creating a site master data integrity compliance plan
   - e. Data integrity governance
   - **f. Interactive Hands-On Exercise:** Draft a communication to be sent out by

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MEET YOUR INSTUCTOR

John Avellanet is an award-winning FDA compliance expert known for his business-savvy, pragmatic advice and engaging speaking style.

Mr. Avellanet was the lead author of several certification courses on Good Manufacturing Practices (GMP) and Quality System Regulation (QSR) supplier management for the US Regulatory Affairs Professional Society.

Last year he co-authored the book *Pharmaceutical Regulatory Inspections* with several current and former regulatory agency officers, and his industry classic, *Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine*, was featured highlight of BIO 2011.

Prior to founding his lean compliance consulting firm, Cerulean Associates LLC, Mr. Avellanet was a former Fortune 50 combination device C-level executive who created, developed, and ran his company's compliance programs to achieve ISO, DEA, BIS and FDA compliance. During his career, he had to defend decisions to investigators, auditors, and litigators alike. He now brings his hard-won, real-world expertise and practical advice to his corporate clients worldwide. A former FDA and US Department of Justice prosecutor has said of Mr. Avellanet, "He is the best in the business. Period."

your senior team to all company employees about good data integrity that will actually lower your workload and encourage self-compliance

2:15 p.m. – 2:30 p.m. REFRESHMENT BREAK

2:30 p.m. – 3:30 p.m.

IX. **Data Integrity, Recordkeeping and Archival Controls**
   a. Records to retain to prove good data integrity controls
   b. Basics of bit rot and other risks to archived data
   c. Developing a media migration strategy
   d. Qualifying record/archival storage vendors
   e. Interactive Hands-On Exercise: Attendees work in teams to outline a sample set of data integrity controls and auditing plans for several case study companies

3:30 p.m. – 4:00 p.m.

X. **Building Your Business Case for Defensible Data Integrity**
   a. Quick tips for talking to senior management about data integrity
   b. A sample data integrity action plan — nine brainstorming questions
   c. Interactive Hands-On Exercise: Attendees work with the expert instructor to draft their own personal, business case and prioritized plan for implementing a data integrity control framework at their company

4:00 p.m. – 4:30 p.m.

XI. Wrap Up and Final Questions

4:30 p.m.

XII. Adjournment

YOUR COURSE MATERIALS

Each participant will receive a folder and flash drive packed with tools and reference materials in a combination of both electronic and hard copy format you can put to use right away, including:

- Presentation slides
- A set of detailed handouts including examples and hands-on exercises
- Two sample policies – ready for you to implement now
- One sample SOP and form – ready for immediate implementation
- Eight sample checklists – ready for you to use right away
- Two quick guides and templates – ready for you to use immediately
- And more….

WHO WILL BENEFIT

- Executive management
- Regulatory affairs
- Quality assurance/quality control
- Legal and compliance officers
- Clinical research directors
- Consultants/service providers
- CAPA specialists
- Compliance information managers
- GMP compliance officers
- GMP training managers
- Heads of internal audits
- QA documentation managers
- QA/QC managers and directors
- Quality systems managers
- Systems analysts
- Training personnel

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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:

Dec. 8-9, 2015
Embassy Suites Raleigh-Durham Airport/Brier Creek
8001 Arco Corporate Drive
Raleigh, NC 27617
Toll Free: (800) EMBASSY
+1 (919) 572-2200
www.RaleighDurhamAirportBrierCreek.EmbassySuites.com
Room rate: $179.00 plus 12.75% tax
Reservation cut-off date: Nov. 20, 2015

TUITION

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

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.

TEAM DISCOUNTS

Significant tuition discounts are available for teams of three 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/FDADataIntegrity
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 **FDA Data Integrity: *From Data Creation to Long-Term Archive*** I understand the fee of $1,797 includes all workshop sessions, workshop materials, two breakfasts, two luncheons and daily refreshments.

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(Please see "Team Discounts" above for tuition discounts when you send a team of three or more.)

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