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IN THIS ISSUE

Trade Group Cautions on Adding Payment Data to Medicare Site

AdvaMed is urging the Centers for Medicare & Medicaid Services not to include data on device company payments to clinicians on its Physician Compare website.

The appeal comes in response to a comprehensive proposed rule revising the physician fee schedule and other Medicare Part B payment policies. As part of the proposed rule, CMS sought stakeholder feedback on including Open Payments data on Physician Compare.

As part of a package of comments, AdvaMed says, CMS should include only general information or reference the Open Payments website on Physician Compare, which helps patients choose doctors who are enrolled in Medicare.

"[I]ncluding on Physician Compare a reference or link to the Open Payments website, as opposed to Open Payments data, is

(See **CMS**, *Page 2)*

Industry Protests Higher Fees at Brazil's ANVISA

Brazil's Agência Nacional de Vigilância Sanitária is facing criticism from the medical device industry for hiking surveillance inspection fees as the country faces tough economic times.

ANVISA maintains the fee increase — the first in the regulator's 16-year history — is not a tax, but a restoration of purchasing power established by the nation's legislature that had depreciated over time, but device groups disagree.

Brazilian industry group ABIMO says devicemakers are making strides and developing innovative, cost-effective products, despite the adverse economic environment, and is examining legal action.

Under the new fee scheme, a good manufacturing practices certificate for companies in Brazil or Southern Common Market

(See **Brazil**, *Page 2)*

CMS, *from Page 1*

appropriate because the Physician Compare website and the Open Payments website are separate programs created for different purposes.

"As a result, information and data from the two websites cannot and should not be combined after the fact," the group says.

In the proposed rule, CMS notes that consumers have indicated that "this level of transparency is important to them and access to this information on Physician Compare increases their ability to find and evaluate the information."

If CMS ultimately decides to include payment data on eligible providers' profile pages, it should ensure the data match what's on the Open Payments website, particularly since there is a disputes and corrections policy to fix inaccuracies, AdvaMed says.

More than 2,000 Comments

The trade group was one of nearly 2,300 stakeholders across a range of industries to comment on the proposed rule.

The Medical Imaging & Technology Alliance expressed support for a plan to develop appropriate use criteria to specify when a diagnostic imaging service should be used, but said industry should have a seat at the table in AUC development.

To ensure transparency, the group says identities of devicemakers that work with provider-led entities should be made public.

CMS defines PLE as "a national professional medical specialty society or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare."

The association says in its comments that it agrees with this definition.

AdvaMed's comments are available at: www.fdanews.com/091515-advamed.pdf. MITA's may be found at: www.fdanews.com/091515-MITA.pdf. — Elizabeth Hollis

Brazil, *from Page 1*

member countries will jump from about U.S. $3,900 to more than $11,000 for the biggest firms. Foreign manufacturers face an even greater increase — from $9,684 to more than $28,000 — irrespective of size.

The new fees took effect Sept. 9. Manufacturers that didn't meet the Sept. 8 deadline to pay the old fees must pay the difference.

A document on the ANVISA website details the fees, breaking them down for microenterprises, small companies, medium and large companies.

Roberto Rodrigues, an attorney at Licks Legal, says the fees affect a range of regulated industries and could bring in as much as $350 million.

A technical note explaining the fees is available here: www.fdanews.com/091515-anvisa.pdf.

The document breaking down the fees is available at www.fdanews.com/091515-ANVISA-fees.pdf. — Elizabeth Hollis, Jonathon Shacat

FDA to Review First-Ever Digital Medicine NDA

The FDA has agreed to review an application for Otsuka Pharmaceutical and Proteus Digital Health's novel digital medicine combining Abilify with a digital tracking mechanism.

The drug/device combination embeds an ingestible Proteus sensor in Otsuka's blockbuster antipsychotic Abilify (aripiprazole), allowing data to be sent to a wearable patch that records individualized treatment information.

The information is sent to the patient's mobile phone and, with consent, to doctors or caregivers.

Otsuka hopes to boost drug therapy compliance with the combination. "By increasing overall patient compliance rates even modestly, health outcomes can be improved for many and healthcare costs can be reduced significantly," spokeswoman Kimberly Whitefield tells *IDDM*. — Victoria Pelham

SEC Accuses Trio of Violating Law To Profit from GE-Clarient Deal

Three men have agreed to settle U.S. Securities and Exchange Commission charges that they engaged in insider trading ahead of GE Healthcare's 2010 purchase of Clarient, a cancer diagnostics company.

According to documents filed in the U.S. District Court for the Northern District of California, businessman John McEnery III allegedly tipped off his son, John McEnery IV, and a close friend, Michael Rawitser, about the acquisition.

The elder McEnery had been informed by a senior director at Clarient — a woman whom he had dated on and off since the 1990s — about the buyout. "Given their history, pattern and practice of sharing confidences, the Clarient Insider expected McEnery III to keep the information regarding the Clarient acquisition confidential," court documents state. Instead he "misappropriate[d] the information about the Clarient acquisition to unlawfully enrich himself and others."

The SEC accuses McEnery of "knowingly and/or recklessly" trading on the information and encouraging his son and friend to do the same. The three began purchasing shares of Clarient and sold them for a profit after the merger was announced, reeling in more than $50,000.

The three have agreed to pay a combined sum of approximately $170,000 to settle the charges, without admitting or denying the accusations. The settlement is subject to the court's approval.

"Individuals who obtain confidential information through a relationship of trust with a corporate insider are prohibited from using that information to trade securities," says Joseph G. Sansone, acting co-chief of the SEC's Market Abuse Unit. "These traders violated such a trust by using highly sensitive information to reap illicit trading profits." — Elizabeth Hollis

FDA Looks to Boost Transparency By Enhancing Device Data Availability

With an eye toward spurring innovation and advancing research, the FDA has added a vast amount of information to a website geared toward researchers and other parties looking to gain insight into the agency's activities.

Launched in 2014, openFDA is intended to serve as the go-to source for information on products regulated by the agency, including medical devices. The new application programming interface will expand upon adverse event and recall data made available over the past year by incorporating information from the total product lifecycle.

The website incorporates four decades of device-related data, allowing stakeholders access to information on 30,000 device approvals and approval supplements and 141,000 clearances through the 510(k) process and *de novo* process. It also includes 9,500 device recalls dating to 2002 and 4.2 million adverse events reports going back to 1991. Other data include 100,000 device listings, 6,000 classifications and 24,000 company registrations.

"This API is the latest in a series of openFDA releases that has made publicly available data easier to access," according to a blog post by Taha A. Kass-Hout, chief health informatics officer and director of FDA's Office of Health Informatics, Roselie A. Bright, who manages openFDA within the Office of Health Informatics, and Ann M. Ferriter, director of analysis and program operations in CDRH's Office of Compliance. "FDA believes that you can use these tools to create innovative products that could help protect and promote public health. In fact, over the last year, there have been dozens of tools created using openFDA resources." — John Bechtel

Canè Gets Warning Letter Over Infusion Pump Procedures

The FDA handed Italian devicemaker Canè S.p.A. a warning letter for not including a software validation procedure in a Form 483 response, after the agency determined that production of the Crono S-PID-50 infusion pump did not comply with current good manufacturing practices.

According to the July 29 letter, the company didn't have a protocol for performing code testing on software used to control infusion pumps and didn't document test results, including a list of software defects found during code testing.

The 483 and warning letter followed a Feb. 16 to 19 inspection of Canè's Rivoli-Turino, Italy, plant.

The FDA also dinged Canè for failing to establish procedures for receiving and reviewing complaints. For example, 26 of 30 repair and maintenance report records of primary immunodeficiency pumps reviewed during the inspection stemmed from complaints, but there was no evidence the complaints were investigated or evaluated for MDR reporting. Canè's corrective and preventive action procedures also were deemed inadequate, as they didn't describe how the company would evaluate all sources of quality data to identify existing and potential nonconforming product.

The FDA chides the company for not establishing and maintaining adequate procedures for quality audits. The firm's quality audit procedure requires auditors to be independent, but the firm allowed an assistant quality manager to audit an area without appropriate background or training to assess firmware verification or validations. The company's 483 response failed to include an updated quality audit procedure, the letter says.

Canè did not respond to a request for comment by press time. View the warning letter at www.fdanews.com/09-08-15-cane.pdf.
— Michael Cipriano

FDA to Shine Light on Personalized Medicine During Workshops

Looking to advance personalized medicine and customize patient care, the FDA is seeking stakeholder input on the challenges and opportunities of next-generation sequencing-based clinical tests to guide its regulatory approach toward these products.

That feedback will help shape discussions during two back-to-back workshops on NGS tests, scheduled for Nov. 12 and 13 at the agency's White Oak campus in Silver Spring, Md. Both workshops are aimed at advancing the White House's Personalized Medicine Initiative, which President Barack Obama introduced earlier this year. The goal is to approach disease treatment and prevention with an individual's genes, environment and lifestyle in mind.

The workshops will build on findings from a February meeting that convened a range of experts on NGS technology.

The first workshop will focus on analytical performance evaluation standards that developers can use to ensure the accuracy and reliability of their tests' results. According to a *Federal Register* notice, topics for discussion include an example of a possible performance standard and a general framework that utilizes existing guidelines.

Day two will examine current challenges in the clinical validation of NGS tests and how stakeholders can develop curated databases that associate genetic changes with different conditions and diseases, such as diabetes.

"A single company, lab, or institution is unlikely to have enough information to definitively determine the clinical importance of test results," say Adam Berger, senior staff fellow on CDRH's personalized medicine staff, and Zivana Tezak, associate director for science in the Office of In Vitro Diagnostics, in an *FDA Voice* blog.

"The aggregation of clinical information in curated databases will create a 'data commons' that could serve as a reliable source of scientific evidence that test developers could use to demonstrate that NGS test results are relevant to a person's disease or outcome."

The FDA plans to post papers ahead of the meetings detailing its thinking on issues slated for discussion.

Interested parties may submit comments on both workshop topics through Nov. 25. Read the *Federal Register* notices here: www.fdanews.com/FDA-NGS-Day1.pdf and here: www.fdanews.com/FDA-NGS-Day2.pdf. — Elizabeth Hollis

IMDRF Meeting to Feature Update On EU Device Regs, FDA Initiatives

Ahead of this week's meeting in Kyoto, Japan, members of the International Medical Device Regulators Forum have offered a sneak peek into what they will discuss during the event.

Scheduled for Sept. 14 to 18, the meeting will feature presentations from member states and industry organizations. The individual regulators have posted their presentations on IMDRF's website, providing status updates on various initiatives.

The EU will provide an update on the medical device and *in vitro* diagnostic device regulations, which are expected to go to trialogue next month (*IDDM*, June 19). Topics slated for discussion among the European Parliament, European Commission and Council of Europe include premarket control of high-risk devices, reprocessing of single-use devices and counseling and informed consent for genetic tests.

Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, will update stakeholders on the center's strategic priorities, providing an overview of key guidance documents issued over the past few months.

A representative from Brazil's Agência Nacional de Vigilância Sanitária will discuss an agreement that grants it access to the Global Medical Device Nomenclature Agency's database of accepted terms to identify medical devices. — Elizabeth Hollis

FTC Redoubles Efforts to Block Steris Acquisition of Synergy

The Federal Trade Commission continues to try and put the brakes on Mentor, Ohio-based Steris' proposed buyout of Synergy Health, claiming Synergy's proposed strategy to use X-ray to sterilize medical products was abandoned in the wake of a commission investigation into the deal.

Last October, Steris — which offers gamma irradiation, ethylene oxide sterilization and laboratory services for devicemakers and other industries — announced its intention to buy UK-based Synergy for $1.9 billion in cash and stock, citing it as a way to accelerate international growth.

Steris and rival Sterigenics currently are the sole contract providers of gamma radiation services in the U.S.

Using gamma is the only feasible method for "sterilizing large volumes of dense and heterogeneously packaged products," the FTC says.

Synergy's X-ray method could prove highly disruptive to this market and perhaps served as a temptation to Steris, the commission says.

The FTC alleges that the acquisition would violate antitrust laws by significantly reducing future competition in the gamma and X-ray radiation markets.

The commission has sought a preliminary injunction in the U.S. District Court for the Northern District of Ohio.

While the companies maintain that using X-ray was not a sound financial strategy, the FTC disagrees.

The commission points to encouraging board reports and presentations, positive communications between senior executives and other Synergy actions that demonstrate the company's ongoing commitment to X-ray prior to the FTC's probe.

In fact, the device community has seen the appeal of using X-ray. "Potential customers continue to express interest in Synergy's U.S. x-ray business," court documents say.

"Indeed the 'big fish' of medical device customers, Johnson & Johnson, is prepared to move its Surgicel product to x-ray, 'paving the way for further conversions.'" Zimmer-Biomet has also expressed interest in learning more about the method.

"But for the FTC investigation, Synergy would be promoting x-ray for the United States, preparing to advertise the anticipated conversion of J&J's Surgicel to x-ray, and nearing conversions of other products for other customers, all in anticipation of entry as early 2016," the commission asserts.

Companies Respond

Steris and Synergy have rebuffed the FTC on all of charges, asserting that there were a number of documented problems with the X-ray strategy — problems that the commission maintains could be fixed.

One issue is that the business model would fail to meet financial requirements and could pose an unusually high risk to Synergy, the companies say.

They hold that J&J's interest in X-ray for Surgicel was noncommittal and note that J&J manufactures and sterilizes the product outside the continental U.S.

"[T]here is no evidence to suggest that J&J intends to relocate sterilization of Surgicel away from where it is manufactured," the firms say.

As far as the FTC investigation, the companies deny that the probe was the impetus for the project's demise.

Synergy would not have been able to enter the U.S. with its X-ray method within a reasonable timeframe, regardless of the merger, they say. — Elizabeth Hollis

BRIEFS

St. Jude Unveils Line of Succession

Michael Rousseau, chief operating officer of St. Jude Medical, is slated to take the helm at the device giant following the retirement of Daniel Starks, who has served more than 11 years as the company's chairman, president and CEO. Starks will still play a role at the company as executive chairman of its board of directors, assisting with key stakeholder relationships. Rousseau — who steps up to CEO on Jan. 1 — started at St. Jude in 1999 as senior vice president for cardiac rhythm management global marketing. He went on to lead the company's realignment of its supply chain management and helped broaden its global customer service operations.

Teleflex Recalls Endobronchial Tube

Following 78 customer complaints, Wayne, Pa.-based Teleflex has recalled its Hudson RCI Sheridan Sher-I-Bronch endobronchial tube. The Class 1 recall affects 233 lots across 12 product codes and comes in the wake of reports that the double swivel connector may crack or separate on the endobronchial tube, potentially causing respiratory distress. No injuries have been reported.

Smiths Looks to Prevent Needle Jabs

In the wake of legislative initiatives to prevent needle stick injuries in healthcare professionals, Smiths Medical has added its Edge safety device technology to both the Portex Pro-Vent and Portex Pulsator arterial blood sampling syringes in the EU. The product works by issuing audible clicks to the user when the safety mechanism is engaged and ready for disposal in a sharps container. "The recent safety legislation enactment in the EU has created greater awareness and demand for device-based protection for clinicians," says Shrikant Rahalkar, vice president for global product management and safety solutions. "Incorporating Edge safety device technology into our ABS blood sampling syringes provides an additional level of protection for patients as well as clinicians."

Asuragen, Illumina Team Up

Molecular diagnostics company Asuragen has inked an agreement with Illumina on the development and commercialization of sequencing-based companion diagnostics for pharma and biotech partners. Asuragen will use its Quantidex NGS platform for customized companion diagnostics for its partners on the Illumina MiSeqDx instrument. In July, Asuragen launched its Quantidex Pan Cancer Kit for research purposes. The panel integrates reagents, controls, and a novel bioinformatics suite for the sequencing of 21 genes relevant to a diverse set of human cancers, according to the company.

Hill-Rom Completes Welch Allyn Buy

Another $1 billion-plus deal in the device world has closed, with Hill-Rom snapping up Welch Allyn, maker of diagnostic devices and patient monitoring systems. With the deal's closing, Welch Allyn shareholders will receive more than $1.6 billion in cash and approximately 8.1 million newly issued shares of Hill-Rom common stock. Hill-Rom makes hospital beds, surgical equipment and wound therapy solutions.

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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

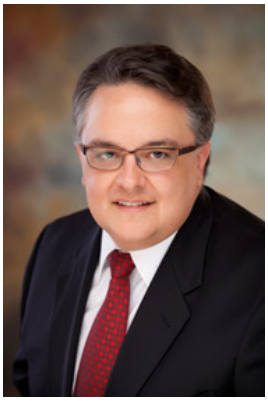
Dec. 8-9, 2015

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

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FDA Data

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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

Integrity

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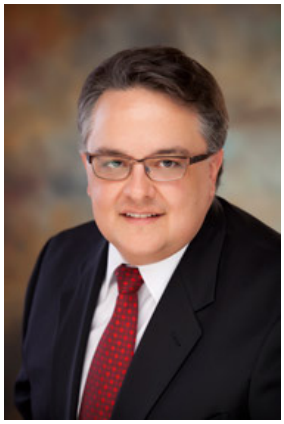
MEET YOUR INSTUCTOR



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

FDA Data Integrity

From Data Creation to Long-Term Archive

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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
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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.

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