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IN THIS ISSUE

CDRH Outlines Regulatory Science Priorities for Upcoming Fiscal Year

Collecting and using patient preference data as part of the regulatory decision-making process and ensuring the proper reprocessing of reusable medical devices are two top challenges the FDA's Center for Devices and Radiological Health hopes to tackle as part of its regulatory science priorities for fiscal year 2016.

Developed by a CDRH subcommittee, the list names regulatory science needs/gaps identified by center personnel. It includes 10 items of equal importance.

"The regulatory science priorities serve as a precept for making strategic intramural research funding decisions to ensure that CDRH research is focused on issues/gaps/needs that are relevant and critical to the regulatory science of medical devices and radiation-emitting products," according to a report detailing the priorities.

(See **CDRH**, *Page 2)*

IMDRF Finalizes Document Addressing QMS Application

The International Medical Device Regulators Forum has unveiled a document it hopes will help industry understand how quality management can play a role in ensuring the proper functioning and safety of devices that rely on software.

Posted to the IMDRF website earlier this month, the document outlines good software and engineering principles and reviews medical device quality principles that should form the backbone of effective software as a medical device quality management system. It is intended for current and future SaMD developers, software development organizations unfamiliar with medical device QMS requirements and organizations that work within established systems to communicate the link between medical device quality systems practice and software development practices.

Among the topics covered by the document is SaMD leadership and organizational support; lifecycle support processes such as

(See **IMDRF**, *Page 2)*

CDRH, *from Page 1*

Device reprocessing has taken center stage after complex duodenoscopes came under scrutiny in the wake of being linked to the transmission of antibiotic-resistant infections. To prevent future infections, CDRH recommends taking a comprehensive approach to addressing reprocessing techniques. Approaches should incorporate device design, human factors, validation methods and surveillance of reprocessed devices in healthcare facilities, among other considerations.

CDRH also has made it a priority to incorporate patient preferences in regulatory decision-making. The FDA issued draft guidance earlier this year that discusses the main factors sponsors and other stakeholders should consider when collecting patient preference information for use in applications (*IDDM*, May 15). The remaining items on the regulatory science priorities list are:

- Leveraging "Big Data" for regulatory decision-making;
- Leveraging evidence from clinical experience and employing evidence synthesis across multiple domains in regulatory decision-making;
- Developing computational modeling technologies to support regulatory decision-making;
- Enhancing performance of health information technology and medical device cybersecurity;
- Incorporating human factors engineering principles into device design;
- Modernizing biocompatibility/biological risk evaluation of device materials;
- Advancing the methods to predict clinical performance of medical devices and their materials; and
- Advancing the use of patient-reported outcome measures in regulatory decision-making.

The full report is available here: www.fdanews.com/102615-CDRH-priorities.pdf. — Elizabeth Hollis

IMDRF, *from Page 1*

product planning, risk management and document and record control; and SaMD realization and use processes.

In terms of risk management, the document recommends that organizations chart sources of hazards, including the following:

- User-based: Are there hazards related to age or physical ability of the user?
- Application based: Should the SaMD application be available on only certain devices?
- Device-based: Does the smaller screen of a smartphone allow for the correct usage of the intended application?
- Environment-based: Will background noise of loss of network connectivity affect safety?
- Security-based: Is a company analyzing security threats to an SaMD's product code during manufacturing, maintenance and in-service use?
- The document also refers readers to the standard ISO 13485:2003 covering QMS requirements.

Lisa Simone recommended that industry study the IMDRF document for potential insight into the next steps the agency could take during a recent FDAnews workshop covering software and cybersecurity risk management for medical devices. Simone is software review team lead and policy adviser, Office of Blood Research and Review at the FDA's Center for Biologics Evaluation and Research.

She emphasized that the FDA wasn't going to automatically adopt everything in a document, but it does illustrate some of the agency's thinking and could point to where it will be headed with software as a medical device.

Her comments came as the FDA continues to feel pressure from legislators. "We're being pressured by Congress to reduce our oversight of software," she said. At the same time, there have been recent media reports of cybersecurity issues posing potential risks to patients. "It puts us in a tough spot," she added.

The IMDRF document is available here: www.fdanews.com/10-26-15-imdrf.pdf. — Elizabeth Hollis

Brazil, French Officials Meet To Strengthen Transparency

Officials from the Agência Nacional de Vigilância Sanitária met with health and economic representatives from France last week to discuss the economic regulation of medical products and pricing models in Brazil.

ANVISA officials learned details of the French model of regulation of the product market for health in support of the activities of the Grupo Interministerial de Órteses, Próteses e Materiais Especiais.

This group is investigating ways to stop abuse in the orthotics and prosthetics sectors, as well as to develop strategies to restructure and expand transparency in this market.

The meeting came after calls by Brazil's House of Deputies and Senate to investigate.

A January ministerial decree created the interagency task force, which includes representatives from the Ministries of Health, Finance and Justice.

ANVISA officials intend to take lessons learned from the meeting and continued cooperation with French officials to develop similar economic policies related to pricing and regulatory measures in Brazil. — Elizabeth Hollis

INVIMA Updates GMP Resolution For External Orthopedic Devices

Colombia's Instituta Nacional de Vigilancia de Medicamentos y Alimentos has updated regulations governing the sanitary requirements related to laboratories developing external orthopedic prosthetics and orthotics.

In a Sept. 14 notice posted to INVIMA's website this month, the regulator informs labs that they must comply with a resolution issued in August that covers good manufacturing practices for these types of devices.

Establishments manufacturing external orthopedic technology and orthotics must register with INVIMA during the last quarter of the year. Facilities must include information, such as the owner's name and the address of the establishment, legal representation, department codes and the municipality, telephone number and email address.

The resolution also explains that it is incumbent upon the facility to request an authorization inspection from an INVIMA representative. After a successful inspection, it may open and conduct operations.

In the first quarter of 2016, INVIMA will establish a procedure to request an authorization to operate. It will identify the documents to request verification visits and the duration of inspections, among other activities.

Since INVIMA has yet to establish new rates for these inspections, companies are asked to refrain from requesting them until the prices are updated.

The resolution updates a 2010 decree, Resoultion 1319, that defined the technical and health requirements that manufacturers must meet. Previously, no such regulations existed.

As part of the earlier resolution, providers had to be on an INVIMA list to provide prosthetics and orthotics to patients. However, the government decided to give providers more time to comply.

Organizations including the International Committee of the Red Cross sat on a working group to amend the Resolution 1319, according to the organization's *Physical Rehabilitation Program 2013 Annual Report*. The ICRC has provided physical rehabilitation support as part of a mine action program.

Read the August resolution here: www.fdanews.com/102615-invima-resolution.pdf. The circular is available here: www.fdanews.com/102615-invima-circular.pdf. — Elizabeth Hollis

FDA Releases Document to Clear Up Confusion over PMA Supplements

The FDA has provided its thinking on when medical device companies must submit a PMA supplement as a result of a manufacturing site change.

With draft guidance released Oct. 21, the FDA aims to define what constitutes a manufacturing site change, as well as when a company should submit a related PMA supplement. In addition, it describes the documentation that should be submitted as a result of the change and what factors the FDA intends to consider when determining whether to conduct an inspection prior to the approval of the site change. The document doesn't cover manufacturing site changes for devices cleared under the 510(k) process.

The document, written in a Q&A format, informs industry that the agency intends to consider such a change to have occurred when the site was not approved as part of the original PMA, or if it were part of the original PMA but for different manufacturing activities.

"Under these circumstances, the different site would have no experience with either the process or the technology, or a similar process or technology, for manufacturing the same or a similar device, and FDA would not have had the opportunity to evaluate the change," according to the draft document.

With such a change, the company would have to submit a 180-day supplement, according to the FDA.

If a site is among those already approved, changes may be submitted as 30-day notices. The same applies to changes that are for performance of the same or similar activities or devices as those at the PMA-approved site.

The agency offers examples of when it expects a site change supplement and when a 30-day notice is appropriate.

In addition, the agency provides 13 items it would like to see included in a site change supplement, including a diagram of the proposed new manufacturing, processing, packaging and distribution sites and a description of the equipment and processes that would be affected by the site change.

Need for Inspection

The document also lists factors the agency will consider when determining whether to conduct an inspection related to a site change:

- The dates of the last inspections of the current and new sites;
- The classifications of those inspections;
- The relevance of the last QS regulation inspection to the moved manufacturing, processing or packaging activities; and
- The risk to the safety or effectiveness of the device association with the manufacturing activities performed at the new site.

The document replaces earlier draft guidance, *Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval*, which was unveiled in 1999. A copy of the draft guidance document is available here: http://www.fdanews.com/10-26-15-site-change.pdf. — Elizabeth Hollis

Russian Authorities Tout Progress Combating Fakes, Improving Quality

Russia's device authority is taking a strong stand against counterfeit and unregistered products, according to representatives at separate events this month.

Speaking at a conference on combating fake medical products, Maria Migeeva, deputy head at Roszdravnadzor, said the health regulator has suspended the use of 28 medical devices and confiscated 201 unregistered medical products along with three that did not conform to quality requirements.

Further, during the first half of the year, the regulator has logged 678 reports of

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Russia, *from Page 5*

administrative offenses and imposed fines totaling about U.S. $145,000.

Separately, Roszdravnadzor organized a conference last week in Moscow that included an overview of state regulations of medical devices. FarmMedObraschenie 2015 was attended by a number of international organizations, including U.S. Pharmacopeial Convention, Japan's Pharmaceuticals and Medical Devices Agency and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan.

During the event, which was named as part of the Ministry of Health's scientific activities for 2015, Deputy Minister of Health Igor Ghahramanyan said inspection and supervisory activities have improved in recent years, as evidenced by the number of fines collected. He added that body also has beefed up inspections of regulated industry.

Mikhail Murashko, head of Roszdravnadzor, added that the strengthened regulatory powers provided by the government has allowed his agency to crack down on those producing counterfeit medical products through enhanced penalties. — Elizabeth Hollis

Chembio Earns Grant, Signs Diagnostics Deal with German Firm

Fresh off winning a grant to develop a point-of-care diagnostic test to identify febrile diseases from a single drop of blood, Medford, N.Y.-based Chembio Diagnostics has signed an agreement with Berlin, Germany's opTricon, a developer of mobile analysis devices for rapid diagnostic tests.

Under the agreement, Chembio will launch the DPP micro reader, a point-of-care instrument, to help in the detection of sexually transmitted diseases, certain febrile diseases and a specific form of cancer.

Chembio chief science and technology officer Javan Esfandiari says the company intends to combine the micro reader with assays currently in development. One of these assays is being developed with help from a 12-month, $2.1 million grant from the Paul G. Allen Ebola Program.

With the grant, Chembio will use its DPP technology to develop a first-to-market multiplex assay that can simultaneously detect malaria, Dengue, Ebola, Lassa, Marburg and Chikungunya from a single fingerstick blood sample. During the Ebola outbreak that struck West Africa last year, healthcare workers were quick to notice a problem. It is hard to differentiate between febrile diseases, as they have similar symptoms, as John Sperzel, Chembio's chief executive, tells *IDDM*.

"The overwhelming majority that presented with the symptoms of Ebola didn't have Ebola," Sperzel explains. That forces clinicians to guess what subsequent test to run on the patient.

Having a single test for these febrile diseases can eliminate this guesswork, potentially saving lives. "We're well on our way on the development of the assay," Sperzel tells *IDDM*.

Sperzel adds that Chembio has other tests in the works, including one being developed with Perseus Science Group to detect traumatic brain injury. In addition, the company has regulatory approvals in Mexico and Brazil for a test to detect HIV and syphilis. It was first to market in both countries, says Sperzel, adding that the company expects to launch a clinical trial in the U.S. for the test during this quarter.

The company also is working with the Bill & Melinda Gates Foundation to develop a DPP Ultra-Sensitive malaria assay, as well as the Centers for Disease Control and Prevention to develop a DPP Ebola assay and a malaria-Ebola combination assay. It has another agreement to develop a DPP Dengue fever assay. — Elizabeth Hollis

NICE Plans to Recommend Device for Sickle Cell Patients

An advisory committee of the U.K.'s National Institute for Health and Care Excellence has issued a preliminary recommendation that the Spectra Optia, a blood component separator, could be cost effective for sickle cell anemia patients who require regular transfusions.

Manufactured by Terumo, the Spectra Optia apheresis system, which has a CE mark as a Class 2b medical device, offers advantages to patients and the National Health Service versus manual red blood cell exchange, a commonly used treatment, according to NICE.

"The evidence considered indicates that the device benefits patients by making the red blood cell exchange process faster and less frequent, and could save the NHS money, with the size of the saving depending on the patient's condition and the equipment already owned by the NHS," says Carole Longson, director of the NICE Center for Health Technology Evaluation.

One potential advantage is that Spectra Optia could help patients who are iron overloaded. Some blood transfusion treatments can raise the amount of iron in a person's body, potentially leading to liver disease or heart failure. Those receiving treatment must undergo chelation therapy to strip out excess iron; however, that treatment can make some patients feel sick. The committee heard from experts that Speactra "is the only reliable iron-neutral transfusion therapy currently available," thus reducing the need for chelation therapy.

Still, there are some unknowns. "Uncertainties in the cost model for adopting Spectra Optia lead to a wide range of estimated cost consequences," NICE says in a consultation document. The cost consequences range from roughly $150,000 per patient per year in savings, to imposing an additional cost of about $9,400 per patient per year compared with manual exchange. The highest costs are seen in patients with severe iron overload.

In addition, the healthcare costs regulator wants to see more data on the outcomes of treatment with Spectra Optia. Specifically, it sees the need for long-term data on the impact of automated and manual exchange on iron overload status and the subsequent need for chelation therapy.

To guide discussions, the committee is seeking stakeholder feedback on the following questions:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence?
- Are the provisional recommendations a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

Interested parties may submit comments through Nov. 16 ahead of a second advisory committee meeting scheduled for Dec. 17. The consultation document is available here: http://www.fdanews.com/10-26-15-spectra-optia.pdf. — Elizabeth Hollis

Tanzania: All Devices Subject To Registration Rules in 2016

Tanzanian health regulators are reminding stakeholders that the second phase of registration for medical devices starts in less than three months.

Beginning Jan. 1, 2016, medical device companies looking to market in Tanzania will need to apply for registration. It extends the mandatory registration list, which went into effect in 2009, according to a notice on the Tanzania Food & Drugs Authority's website.

Devices covered in the first phase were auto-disable syringes, surgical sutures, examination and surgical gloves, scalp vein set, intravenous cannulae, catheters and tubes, contraceptives, needs, administration sets, blood collection bags, surgical dressing, internal prosthetics replacements, orthopedic implants, bone cements, drug-eluting stents and intraocular lenses.

Read the notice here: http://www.fdanews.com/10-26-15-Tanzania.pdf. — Elizabeth Hollis

BRIEFS

ANVISA Selects New Director

Fernando Mendes Garcia Neto has been named a director of Brazil's Agência Nacional de Vigilância Sanitária. His term will run through March 31, 2017. Neto fills the vacancy left by former director Jaime Cesar de Oliveria Moura, who resigned in April. Neto joins four other members, who vote on decisions for the agency, including newly installed Director President Jarbas Barbosa da Silva Júnior.

Danish MoH Seeks Director General

In an effort to reach a broader range of candidates, Denmark's Ministry of Health has readvertised the position to helm the new Danish Medicines Agency. In August, the DoH announced it was establishing four new agencies so each could focus on its area of competence: the Danish Medicines Agency; Danish Health Authority; Danish Patient Safety Authority; and Danish Health Data Authority. One of the tasks will be pharmacovigilance and medical devices. The four agencies officially launched Oct. 8, and new websites for each will launch in January 2016.

Office of Women's Health to Provide Update

The FDA has scheduled a Nov. 30 meeting, during which representatives from the Office of Women's Health will discuss progress made on identified strategic priorities and initiatives. The meeting will take place at the AARP Cy Brickfield Center in Washington, D.C. The event is free, but attendees must preregister. Seating is limited to 25 participants. More information is available from an Oct. 19 *Federal Register* notice here: www.fdanews.com/102615-womens-health.pdf.

MDA, ASEAN Committee to Hold Seminar

The Malaysian Medical Device Authority has scheduled a Nov. 30 seminar to shine a light on potential hurdles industry might encounter while adhering to the Medical Device Act 737 of 2012, among other topics. Put on jointly with the Association of Southeast Asian Nations' Consultative Committee on Standard and Quality – ASEAN Medical Device Committee, the seminar will touch on updates to the ASEAN Medical Device Directive and the MeDC@St modules for medical device registration. The seminar will be held just outside Kuala Lumpur. Interested parties must register by Nov. 9 via email to seminar@mdb.gov.my. Seating is limited to 100 people.

Allergan Completes AqueSys Buy

Dublin, Ireland-based Allergan has wrapped up its acquisition of AqueSys, an Orange County, Calif.-area device company focused on developing implants that reduce intraocular pressure associated with glaucoma. The all-cash transaction included a $300 million upfront payment and potential regulatory approval and commercialization milestones related to the lead product, XEN45, which has received a CE mark. It is in late-stage development in the U.S., with a fully enrolled IDE clinical trial. The company expects the FDA will give its nod to the implant by late 2016 or early 2017 through the 510(k) pathway.

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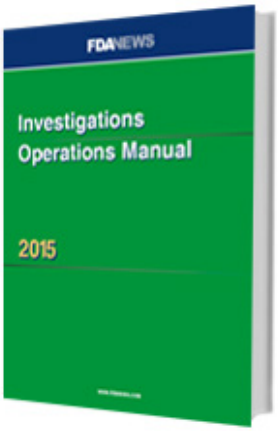

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FDA Data Integrity

From Data Creation to Long-Term Archive

Dec. 8-9, 2015

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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.

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- 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."
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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

Dec. 8-9, 2015 • Embassy Suites Raleigh-Durham Airport/Brier Creek • Raleigh, NC

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
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Phone: Toll free (888) 838-5578 (inside the U.S.)
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Mail: **FDAnews,** 300 N. Washington St., Suite 200
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☐ **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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