DEVICES & DIAGNOSTICS LETTER®

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## INSIDE THIS ISSUE



## First De Novo Panel Meeting Ends With Thumbs Down on Stroke Tool

The first-ever FDA advisory panel meeting to discuss a de novo application ended in disappointment for sponsor CoAxia as panelists decided evidence did not support the safety and effectiveness of NeuroFlo as a treatment for ischemic stroke.

The Neurological Devices Panel met Dec. 10 to discuss NeuroFlo's ability to increase cerebral blood flow in patients with ischemic stroke. Maple Grove, Minn.-based CoAxia filed the de novo petition after the FDA deemed its 510(k) submission not substantially equivalent (NSE) to an FDA-cleared device. CDRH later upheld the NSE finding, but agreed to get panel input on the de novo request. CoAxia has appealed the NSE decision.

*(See* **CoAxia**, *Page 2)*

## Defense Attorneys Predict No FDA Action On *Caronia*, but Off-Label Guidance Crucial

President Barack Obama's administration is unlikely to challenge the recent off-label marketing decision in *U.S. v. Caronia* because it only applies in three states and is in line with other recent off-label precedents, industry defense lawyers say.

In *Caronia*, the U.S. Court of Appeals for the 2nd Circuit ruled the government cannot prosecute manufacturers for speech promoting the lawful, off-label use of an FDA-approved product (*D&DL*, Dec. 10).

Government lawyers would face a "difficult burden" in convincing the U.S. solicitor general that the case will dramatically impact FDA enforcement efforts and should either be reheard by the U.S. Court of Appeals for the 2nd Circuit or directly appealed to the Supreme Court, John Fleder of Hyman, Phelps & McNamara said late Wednesday. "The case stands; it will not be changed," Fleder predicts.

*(See* **Caronia**, *Page 4)*

**CoAxia,** *from Page 1*

The NeuroFlo catheter is identical to the company's FloControl, which was cleared to stop or control blood flow in the peripheral vasculature in 2003. In 2005, the FDA granted NeuroFlo a humanitarian device exemption for use in treating cerebral ischemia after brain hemorrhage in patients who do not benefit from medical therapy.

That same year, CoAxia applied for a clinical trial to demonstrate that NeuroFlo plus medical management leads to improved neurological outcomes in stroke patients compared to medical management alone. That trial, Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke, or SENTIS, missed its primary effectiveness endpoints — a factor that seemed to weigh heavily on the minds of the 12-member panel.

**Safety Endpoint Met**

NeuroFlo did meet its primary safety endpoint, causing fewer adverse events overall than were seen in a control group, and the panel agreed it was safe for use in the proposed population. But some panelists expressed concern that the difference in adverse event rates — 177 in the control arm versus 174 in the NeuroFlo group — wasn't significant. Panelists were also inclined to disregard the device's success on certain endpoints designated after the study concluded, such as stroke-related mortality, saying they could not be sure the post hoc data analysis was reliable.

"The panel's sense seems to be that the effects identified are exploratory" and in need of further study, said panel chair Robert Hurst, University of Pennsylvania.

The panelists also did not feel the benefits of NeuroFlo outweighed the risks. But "if this was compassionate use and it's the only thing to use, it's reasonable," said patient representative Philip Posner, who generally sided with the rest of the panel. The consensus was that further animal and human studies of NeuroFlo are needed before it can be approved.

CoAxia CEO Andy Weiss expressed disappointment in the decision, saying it reflects both an unfavorable panel makeup bereft of practicing stroke neurointerventionalists and a lack of clarity from the FDA on medical evidence requirements for de novo petitions for products that are already cleared for other indications.

Unfounded concern over adverse events was one way those factors played out, Weiss said. "They are comparing groin puncture issues to salvaging the brain," he told *D&DL*. "And there was a complete dismissal of our medical evidence of a two-fold reduction in stroke-related mortality."

Weiss said CoAxia will continue to work with the FDA to secure Class II designation and a stroke indication for NeuroFlo. — Elizabeth Orr

## Device Complexity Leads MHRA To Suggest Upping Device Trial Fees

Devicemakers would pay about $1,300 more for regulatory activities related to clinical trials under revised user fees proposed by the UK's Medicines and Healthcare products Regulatory Agency (MHRA).

The increased fees are due to the growing complexity of medical technology and the corresponding bump in resources required to review trial applications — particularly those related to software and biological safety, the MHRA said. Overall fee income needs to increase by about $83,000 in order to cover today's review costs, the agency said.

According to a recent consultation letter, fees for trials of Class I, IIa or IIb devices would rise from about $4,800 to about $6,100. Fees for Class IIb implantable or long-term invasive, Class III and active implantable devices would climb from about $6,700 to about $8,000.

Fees for renotification in the event of an objection would increase by about $1,300 for all devices.

The proposed changes, the first since 2009, would be implemented through an amendment to the UK's 2002 device regulations and take effect April 1, 2013. — Zachary Brennan

## Democratic Senators Press for Delay In Device Tax Implementation

Industry praised efforts by some Democratic senators to delay implementation of the 2.3 percent medical device excise tax, but said they do not go far enough.

Previous attempts to repeal or delay the tax — set to take effect Jan. 1 — have been Republican-led efforts that quickly died in the Democrat-controlled Senate (*D&DL*, July 2). But on Dec. 4, Sens. Amy Klobuchar (D-Minn.) and Kay Hagan (D-N.C.) wrote Senate Majority Leader Harry Reid (D-Nev.), citing the size and success of the device industry and lack of government guidance on how to comply with the tax. The letter was co-signed by 14 other Democratic senators and two senators-elect.

"As we work together to develop a long-term solution to help move our economy forward, reduce our debt and reform our tax code, we urge you to support delaying enactment of this provision in a fiscally responsible manner," the letter states.

AdvaMed's J.C. Scott, senior executive vice president for government affairs, praised the bipartisan support shown in the letter but said it is not enough. "Delay of the tax is an important step, but Congress must fully address the device tax," he said. The Medical Imaging and Technology Alliance echoed that sentiment.

Since the letter was drafted, the Internal Revenue Service has issued a final rule and draft implementation guidance on the tax (*D&DL*, Dec. 10). It was not clear at press time if that was enough to assuage Klobuchar and Hagan's concerns.

View the letter at www.fdanews.com/ext/files/12-17-12-taxletter.pdf. — Elizabeth Orr

## Compliance Programs May Minimize Chance of Park Doctrine Liability

Companies should develop a comprehensive compliance program to minimize corporate officers' liability for trial deficiencies under the Park Doctrine, a legal expert says.

Once the program is in place, staff should be trained to ensure it is implemented fully, said Darshan Kulkarni, principal at The Kulkarni Law Firm. The aim is for upper management to show regulators they are proactively trying to prevent problems.

Kulkarni noted a recent uptick in FDA use of the 1975 Park Doctrine. In one recent example, four former Synthes executives were sent to prison for their part in deaths that occurred during an illegal clinical trial (*D&DL*, June 25).

The compliance program should take into account the primary factors FDA considers in applying Park:

- Whether the violation involves actual or potential harm to the public;
- Whether the violation is obvious;
- Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- Whether the violation is widespread;
- Whether the violation is serious;
- The quality of the legal and factual support for the proposed prosecution; and
- Whether the proposed prosecution is a prudent use of agency resources.

If problems arise during the course of a trial, sponsors will have demonstrated that they created, managed and participated in a comprehensive and legitimate compliance program that failed to prevent noncompliance despite their good intentions, Kulkarni said.

The Park Doctrine states corporate officers may be held liable for misdemeanors and felonies under the 1938 FD&C Act despite there being no proof that the official acted with intent or negligence, and even if they lacked any knowledge of the specific offense. Prosecutors don't have to prove the accused had intent to commit a crime, only that they had a duty to prevent it.

*(See* **Park**, *Page 6)*

**Caronia**, *from Page 1*

That means the agency's primary response could be to bring only cases in which off-label claims are clearly false or misleading, he added. Fleder spoke at the Food and Drug Law Institute's Enforcement, Litigation and Compliance Conference in Washington, D.C.

The FDA has not yet said if it will ask Justice Department lawyers to act on the 2nd Circuit decision. But one FDA official has said the *Caronia* case ruling could be catastrophic for the agency.

Robert Temple, deputy director for clinical science in the Center for Drug Evaluation and Research, said that the decision could so burden the agency that its off-label enforcement efforts would screech to a halt.

**Little Recourse Beyond 'Misbranding'**

"If we have to go case by case and rebut each piece of evidence, as we did prior to the 1938 FD&C Act and 1962 efficacy amendments, the ability to regulate off-label use would become almost impossible, too costly in terms of the effort required," Temple told *D&DL* Thursday.

Federal regulations prohibit devicemakers from promoting products for unapproved uses; however, the FD&C Act provides little recourse beyond "misbranding" statutes. The lack of lucidity in the law has caused confusion in the drug and device industries, and existing FDA guidance on the issue also lacks clarity on what is permissible, Fleder said.

Regardless of how the *Caronia* case evolves, additional FDA guidance is needed to bring clarity to the issue of off-label promotions, said Fleder and Jennifer Bragg of Skadden, Arps, Slate, Meagher & Flom. Current guidance "doesn't even begin to answer all of the questions" that the *Caronia* case presents, Fleder added.

*Caronia* is just the latest court decision to blunt the agency's off-label enforcement tools. The ruling cited speech protections in these recent cases:

- *U.S. v. Caputo*, a medical device case in which the presiding judge in his ruling urged the FDA to make explicit in product approvals what companies can and cannot promote (*D&DL*, Jan. 29, 2007); and
- *U.S. v. Harkonen*, in which a federal court judge concluded that former InterMune CEO W. Scott Harkonen was not indicted for promoting Actimmune for an unapproved use but because he made false and misleading statements.

The *Harkonen* case was initially decided in 2009 but was argued in an appellate court Dec. 6. The three-judge panel of the 9th Circuit is expected to rule on the case in the coming weeks.

Bragg noted the *Caronia* ruling is unlikely to curb *qui tam* actions filed under the False Claims Act because the majority are not filed by the federal government. — Johnathan Rickman

## FDA on Right Track for MDRs But Still Has a Ways to Go: OIG

Recent FDA steps to improve device adverse event reporting jibe well with Office of the Inspector General recommendations, a new OIG report shows.

The report compiles recommendations the OIG has made that have not yet been put into practice. One such recommendation was the FDA "develop a clear protocol for reviewing adverse event reports that specifically addresses following up with manufacturers who routinely submit reports late or with incomplete information."

The OIG also suggested the FDA work with facilities to reduce adverse event underreporting and advocate for legislation that would end requirements making facilities submit multiple annual reports. The recommendations were made in 2009, after OIG research found facilities weren't submitting adverse events to the FDA in a timely manner and the agency wasn't documenting its follow-up of adverse events (*D&DL*, Nov. 2, 2009).

Since the 2009 report came out, the FDA has announced plans to revamp its adverse event reporting using a new database, the FDA Adverse Event Reporting System (FAERS), which is scheduled to launch by the end of 2014 (*D&DL*, June 25). OIG believes FAERS will allow for easier follow-up of adverse events reports. However, more progress is needed on follow-up with devicemakers that report adverse events late and on legislation to minimize redundant reporting, the new report concludes.

No other CDRH-specific recommendations are contained in the report, but a handful of device- and diagnostics-related suggestions are directed at the Centers for Medicare & Medicaid Services. They include:

- Performing more unannounced visits to independent diagnostic testing facilities, which OIG inspectors have found often are not open during regular business hours;
- Tracking accumulated repair costs of capped rental medical equipment to prevent improper payments for repairs that exceed the total cost of the device;
- Instituting stronger record reviews to ensure the medical necessity of power wheelchairs, durable medical equipment, prosthetics, orthotics and other supplies at high risk of fraud or abuse;
- Ensuring that claims for pressure-reducing support surfaces meet coverage criteria; and
- Taking multiple steps to stop improper payments for lower-limb prostheses.

View the full OIG report on unimplemented recommendations at www.fdanews.com/ext/files/12-10-12-OIG.pdf. The FDA section begins on page 135. — Elizabeth Orr

## FDA: User, Environmental Concerns Key to Good Home-Use Device Design

Companies making medical devices for home use should develop a risk-management plan that describes the process for identifying hazards, evaluating and controlling known risks, and monitoring how well the controls are working, according to a new FDA draft guidance.

This risk-management plan should "strive for the highest level of risk mitigation possible by designing risk out of the system to the greatest extent possible," the guidance states. Stating risks in product labeling is not sufficient for the home environment because users may ignore or not understand safety precautions, the document adds.

The draft, released Thursday, is in response to growing demand for home use devices as the U.S. population ages and more individuals are cared for at home, the agency said.

Devicemakers should pay special attention to environmental considerations when designing home-use products, the draft guidance says. These include the potential for electromagnetic interference, contaminants such as pets and tobacco

*(See* **Home Use**, *Page 6)*

## Park, *from Page 3*

The resurgence in use of Park is due to the government's frustration over what it perceives as sponsors' failure to take the rules seriously, Kulkarni said, adding companies treat fines as a cost of doing business. To change that attitude, the FDA and Justice Department are shifting from targeting companies to targeting individuals "so the message gets through," he told *D&DL*.

Under the doctrine, the FDA can hold the CEO, chief compliance officer, chief legal officer, chief medical officer and appropriate middle managers of multibillion-dollar devicemakers and healthcare systems responsible for a principal investigator's or study coordinator's actions. Anyone who is involved in clinical research or trial design can be liable under Park, he said.

To avoid potential violations and liability, Kulkarni recommends sponsors follow guidance issued by HHS' Office of Inspector General. The OIG guidance lists seven fundamental elements of a sound compliance program:

- Written policies and procedures;
- A designated compliance officer and compliance committee;
- Effective training and education;
- Effective lines of communication;
- Internal monitoring and auditing;
- Standards that are enforced through well-publicized disciplinary guidelines; and
- Prompt response to detected problems and need for corrective action.

Most large devicemakers have dedicated compliance teams, Kulkarni noted, adding that more mid- to small-sized companies also are hiring compliance officers. But there are still a surprising number with no designated personnel, he said.

If deficiencies arise despite instituting a well-planned compliance program and regulators decide to come after officials with Park, the best thing sponsors can do is mount the "impossibility defense," Kulkarni said. That argues the requirements were objectively impossible.

In *U.S. v. Park*, the Supreme Court ruled "The government's policy is to prosecute only those individuals who are in a position and who have an opportunity to prevent or correct violations, but fail to do so." This puts the onus on the prosecution to prove a certain level of negligence on the part of the defense, Kulkarni said. — Ferdous Al-Faruque

## Home Use, *from Page 5*

smoke, and variations in temperature, air flow and humidity. Portability, tamper-resistance and child-proofing should also be considered.

Designs should also consider the potential range of users' physical, sensory, cognitive and emotional capabilities and disabilities. For example, the device interface should be visible under ambient lighting, the guidance says. Because the primary user may be a family member assisting a loved one who is unable to use the device alone, devices should not cause the user to feel overwhelmed or anxious, the guidance adds.

The FDA recommends devices be designed with minimal need for calibration and enough mechanical strength to survive drops onto hard surfaces. If a device uses wireless technology, coexistence with other wireless devices deserves careful consideration, the guidance says. And any alarms should be loud enough to be heard in an "uncontrolled noise environment" by someone who may have a hearing impairment.

Companies should perform human factors testing "early in the device process and then several more times as the design evolves," the guidance states. As a special concern, the FDA suggests user training outline the responsibilities of the family caregiver and discuss the need to clean, calibrate and maintain the device.

Comments are due to docket no. FDA-2012-D-1161 by March 13. View the draft guidance at www.fdanews.com/ext/files/12-17-12-homeuse.pdf. — Elizabeth Orr

## Kansas Distributor Files Antitrust Suit Against Cardinal, Owens & Minor

Suture Express has filed a $200 million complaint against medical supplies giants Cardinal Health and Owens & Minor, alleging the larger companies unfairly manipulated prices to keep competitors out of the market.

The lawsuit, filed Dec. 5 in the U.S. District Court for the District of Kansas, charges the defendants with five counts related to establishing an illegal monopoly.

Specifically, the Overland Park, Kan., distributor maintains that Cardinal and Owens & Minor threatened healthcare facilities with higher distribution rates on other products if they bought suture and endomechanical supplies through Suture Express. The larger companies also priced medical and surgical bundles below cost to encourage loyalty, the complaint states.

"Were it not for defendant's actions, Suture Express' revenues and profits would be substantially greater than they are today," the complaint states.

**Defendants Deny Claims**

Because Suture Express is so narrowly focused, it can offer lower prices and faster delivery on specialty suture products than larger distributors, CEO Brian Forsythe told *D&DL*. The defendant's actions threaten the customer with a "prohibitive financial penalty on the other 90 percent of what they need to buy," he said.

The $200 million in damages Suture Express is seeking is based on an economist's estimate of business lost over the last four years, Forsythe said. Because Cardinal and Owens & Minor are similar in size and market dominance, he added, it's impossible to say which company was more at fault in terms of establishing the unfair monopoly. That's for the courts to sort out, he said.

Cardinal and Owens & Minor together control about 70 percent of the suture market, compared with Suture Express' 8 percent share, according to Forsythe.

Cardinal Health spokeswoman Corey Kerr called the allegations meritless.

"We are absolutely confident that our practices comply with the law," said Truitt Allcott, a spokeswoman for Owens & Minor.

Both companies said they plan a vigorous defense. — Elizabeth Orr

## Presubmission Guidance Progresses To OMB, Last Step to Publication

The FDA is in the final stages of clearing guidance on presubmission meetings with devicemakers, a Tuesday *Federal Register* notice states.

According to the notice, "Guidance on Medical Devices: Pre-Submission Program and Meetings with FDA Staff" has been submitted to the Office of Management and Budget (OMB) for review and clearance — the last step before it can be put into effect. A draft version of the guidance came out in July (*D&DL*, July 16).

CDRH's presubmission program allows devicemakers to request and obtain feedback on specific questions before they formally submit an application. It was originally open only for investigational device exemption submissions; however, over time, companies began informally seeking advice on PMA and 510(k) applications as well to avoid unnecessary delays down the road, the notice explains. During last summer's negotiations on the medical device user fee and FDA reform package, the agency committed to putting a structured presubmission system in place.

The FDA anticipates about 2,544 presubmission packages a year and expects to spend about 137 employee hours processing each request. Per-package costs to manufacturers are estimated at roughly $20,550. Total annual costs to industry should be around $52.3 million.

Comments on the collection of information are due Jan. 10 to Docket FDA-2012-D-0530. View the *Federal Register* notice at www.fdanews.com/ext/files/12-17-12-meetings.pdf. — Elizabeth Orr

# BRIEFS

## FzioMed Files Citizen's Petition

San Luis Obispo, Calif.-based FzioMed has filed a citizen's petition against the FDA claiming the agency's denial of its PMA for a gel used in lumbar spinal surgery was scientifically unfounded. CDRH ruled Oxiplex not approvable in January 2010, and the FDA upheld the decision on review in October 2012, saying there was not enough scientific evidence to demonstrate safety and efficacy. FzioMed disagreed, pointing to two U.S. and two foreign clinical trials showing the gel enhanced efficacy in surgeries and lacks a significant risk. The devicemaker is requesting the independent Medical Devices Dispute Resolution Panel review the petition. View the petition at www.fdanews.com/ext/files/12-17-12-Fziomed.pdf.

## HUD Reporting Adjusted to Fit FDASIA

The FDA is putting into effect a clause in last summer's FDA reform legislation that will allow humanitarian use devices intended primarily for pediatric use to turn a profit as long as they're used in fewer than 4,000 people a year. The agency announced the change to HUD reporting requirements in a notice slated for the Dec. 17 *Federal Register*. About six HUD applications are expected yearly, with three of those intended for pediatric populations; however, the agency expects very few, if any, to trip the 4,000-device threshold based on past history with HUDs. Comments are due to FDA-2012-N-1203 by Feb. 15, 2013. View the notice at www.fdanews.com/ext/files/12-17-12-HDE.pdf.

## 'GETAROUNDKNEE' Suit Settled

Stryker has settled its lawsuit against Wright Medical Technology for alleged patent infringement of Stryker's GETAROUNDKNEE trademark, an order filed Dec. 10 in the U.S. District Court for the District of New Jersey shows. The Sept. 27 complaint charged Wright with launching a website using a slight variant of the name shortly after Stryker had begun using GETAROUNDKNEE last spring (*D&DL*, Oct. 29). Financial terms of the settlement were not disclosed.

## Mobile Device Security Site Launches

The Office of the National Coordinator for Health Information Technology has launched a website aimed at educating healthcare providers about protecting patient information on mobile devices. The site, www.HealthIT.gov/mobiledevices, includes videos, fact sheets and posters promoting security.

## Head-Cooling System Recalled

Natus Medical's Olympic Cool-Cap system is the subject of a voluntary Class I recall due to reports the screen of the system's control module may freeze, meaning no cooling treatment is being provided. The Cool-Cap is used to cool the heads of newborns with hypoxic-ischemic encephalopathy, while simultaneously warming the rest of the body. The company is warning customers on how to recognize and correct the screen freeze. It also is replacing an unreliable power supply module in some affected units.

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## WORKSHOP AGENDA

### DAY ONE

**8:00 A.M. – 9:00 A.M. REGISTRATION/ CONTINENTAL BREAKFAST/NETWORKING**

**9:00 a.m. – 12:00 p.m.**

- **Training — a cost or investment?**
  - The state of training in our industry and beyond
  - The connections between training, quality and other benefits
  - Is yours a learning or a training organization?
  - ☑ INTERACTIVE EXERCISE! **Issues affecting training programs today**
- **Regulatory expectations for training**
  - Expectations — what they are and where they come from
  - Examples of training-related expectations from US, Canada, EU, and WHO for the pharma industry
- **Compliance failures and training — identifying the causes**
  - Where firms have fallen short of the expectations
  - Recent citations for inadequate training
  - Root and contributing causes of training failures
- **Training is not the answer to all your problems**
  - ☑ INTERACTIVE EXERCISE! **Ways to waste time, money and opportunity through training**
  - Thinking about performance solutions in your CAPAs, not just training
  - Knowledge in the head, knowledge in the world or both?
- **Competency-based training**
  - What is it?
  - How it differs from more traditional types of training

**12:00 p.m. – 1:00 p.m. LUNCH**

**1:00 p.m. – 4:00 p.m.**

- **A quick look at learning theories: how we learn**
  - ☑ INTERACTIVE EXERCISE! **Characteristics of the learning theories and what they mean for trainers**
- **Building a successful learning program**
- **Learning plans or curricula**
  - How they are used
  - Benefits
- **Considering the learners as part of the training solution**
  - Characteristics of adult learners
  - The learners of today and the learners of tomorrow
- **What qualifies a trainer?**
- **What is an expert?**
  - Developing expertise
- **Approaches used to design and develop training courses**
  - ADDIE (Analysis, Design, Development, Implementation and Evaluation)
  - Rapid Prototyping
  - Problems with the ADDIE model
  - Writing active learning objectives for your courses
  - ☑ INTERACTIVE EXERCISE! **Case study: How could you make this better?**
- **Authentic learning — matching learning methods to the job to increase success**
  - ☑ INTERACTIVE EXERCISE! **Creating an authentic activity**

### DAY TWO

**8:00 a.m. – 8:30 a.m. CONTINENTAL BREAKFAST/NETWORKING**

**8:30 a.m. – 12:00 p.m.**

- ☑ INTERACTIVE EXERCISE! **Keys to a successful training system – quick review**
- **Assessment and evaluation — how can you measure success?**
  - What can your quality system tell you about the effectiveness of your learning program?
  - Formative or summative – what are the differences?
  - The Kirkpatrick and Philips models
  - What about return on investment?
  - How far do you go?
  - ☑ INTERACTIVE EXERCISE! **What would evaluation and assessment look like for this course?**
- **Alignment: making sure all the pieces fit**
  - What is "alignment"? Why is it so important?
- **Other ways to get people involved**
- **The connection between training and procedures**
  - Why are there failures in following procedures? Is it always training?
  - ☑ INTERACTIVE EXERCISE! **The amount of detail in a procedure**
  - Ways to promote consistent performance using an SOP
  - Use of job aids

**12:00 p.m. – 1:00 p.m. LUNCH**

**1:00 p.m. – 4:00 p.m.**

- **Tools that support performance**
  - Job aids
  - Putting knowledge into the work environment
- **Evidence of training and performance**
  - Training records
- **Evaluating and enhancing YOUR training program**
  - What metrics are you using?
  - ☑ INTERACTIVE EXERCISE! **What are some ways it can be improved?**
  - Making the case to management to support and enhance training

**SUMMARY/CLOSING**

# mproving GMP Performance

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## WHO SHOULD ATTEND

- Compliance officers
- Consultants/service providers
- Engineering and design control teams
- Executive management
- Managers
- Manufacturing directors and supervisors
- Procedure writers
- Pharmaceutical and cGMP auditors
- QA/QC personnel
- R&D staff
- CAPA specialists
- Training personnel
- Instructional designers and technologists

## COURSE MATERIALS BOOK

- Examples of training-related 483 citations and warning letters
- Instructional design checklist
- Action/behavioral words used in writing objectives
- Sample evaluations and assessments
- Checklist for evaluating eLearning courses
- Recommended resources

## WHAT YOUR COLLEAGUES HAVE TO SAY

*"It's obvious James has a lot of experience and knowledge on the subject. His approach makes it easy to respond and share information. Great job, James!"*
Christine Koenig, Manager, QA Compliance, Alcon Surgical

*"I really enjoyed and feel that I Learned a great deal from the instructor, Jim Vesper, he has an engaging quality especially when describing real-life stories when reinforcing a training concept."*
Monica MacInnis, Senior Quality Systems Trainer/Auditor, Fresenius Medical Care North America

*"A fantastic conference! The tools Jim taught is will be incredibly valuable to my training department."*
Ivan Odegard, GMP Training Specialist, Paddock Laboratories

## YOUR EXPERT INSTRUCTOR

JAMES VESPER designs and develops instructional courses and workshops for pharmaceutical and medical device companies. He established and is president of the firm LearningPlus, Inc., and has had more than 30 years' experience in the pharmaceutical industry.

Mr. Vesper worked eleven years at Eli Lilly and Co. His first assignment was as corporate industrial hygienist, followed by three years in corporate quality assurance. He was responsible for issues concerning the manufacturing and testing of parenteral products made at Eli Lilly facilities and third parties worldwide. His last assignment at Lilly was project leader of GMP education and instruction, establishing the department and its mission.

Since 1991, Mr. Vesper has been creating innovative instructional training products for the pharmaceutical and healthcare industries using video and computer technologies as more effective and efficient delivery media. Working as a consultant with a wide variety of clients, his firm creates integrated curricula for personnel and customized training courses targeted to specific needs. He presents papers and workshops at various international technical and professional meetings, including those of the International Society for Pharmaceutical Engineering, GMP TEA, PDA, Pharmaceutical Sciences Group and PharmTech. In 2001, he was awarded the PDA's Agallaco Award for Excellence in Training. He is also an advisor to the World Health Organization's Global Learning Opportunities/Vaccine Quality group, and has mentored, designed and developed learning programs that are in use worldwide.

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## LOCATIONS AND HOTEL ACCOMMODATIONS

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 avail-able 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.

### Lodging and Conference Venue:

**Feb. 25–26, 2013**
Embassy Suites Raleigh - Durham Airport/Brier Creek
8001 Arco Corporate Drive
Raleigh, NC 27617
Toll Free: (800) 362-2779
+1 (919) 572-2200
www.RaleighDurhamAirportBrierCreek.EmbassySuites.com
Room rate: $159 plus 12.75 percent tax
Reservation cut-off date: Feb. 4, 2013

**Aug. 19–20, 2013**
Sheraton Philadelphia University City Hotel
3549 Chestnut Street
Philadelphia, PA 19104
Toll Free: (888) 627-7071
+1 (215) 387-8000
www.PhiladelphiaSheraton.com
Room rate: $179 plus 15.2 percent tax
Reservation cut-off date: July 29, 2013

## TUITION

Tuition 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.TrainingToLearning.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 U.S.A.

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☑ **YES!** I want to attend *From Training to Learning: Improving GMP Performance.* I understand the fee of $1,897 includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

**FDANEWS**
300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 U.S.A.

**Choose Date/Location** ❒ Feb. 25–26, 2013 • Raleigh, NC ❒ Aug. 19–20, 2013 • Philadelphia, PA

Attendee 1 Name: _____ Title _____ Email _____

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Email address (so you can receive order acknowledgements, updated news, product information and special offers)

**Company Information**

Organization_____

Address_____

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**Payment Options**

❒ Check enclosed, payable in U.S. funds to **FDAnews**

❒ Charge to: ❒ Visa ❒ MasterCard ❒ American Express

Credit card no. _____

Expiration date _____

Total amount $ _____

Signature _____
(Signature required on credit card and bill-me orders.)

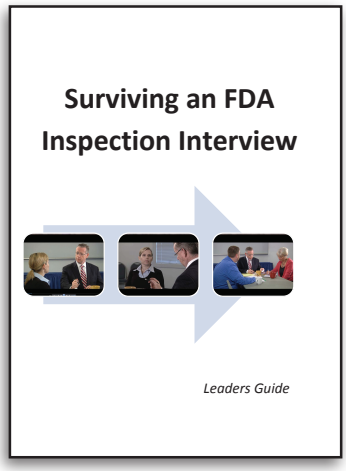
Print name _____

❒ Bill me/my company $ _____

Purchase order # _____
(Payment is required by the date of the conference.)

FDANEWS

# Surviving an FDA Inspection Interview




Ever want to take your employees inside an FDA inspection interview to show them exactly what can go wrong – and how to avoid these mistakes? Now you can. This time-tested solution to one of the biggest inspection prep challenges any company faces will lead your employees through the scenarios that can take an inspection off-track – and show them the right way to handle the situations they'll face when sitting across the interview table from the FDA.

This instructional guide and DVD creates a powerful, hour-long training event that shows employees the types of questions and tactics they'll face during inspection, and gives them the confidence to respond correctly. Participants will learn:

- How to respond to a question when they don't know or are unsure of the answer.
- How to handle a lull or a gap in the conversation.
- How to communicate confidence with words and body language.
- How to respond to a question completely but concisely.
- How to respond when they don't understand the question or the question is very broad.

**Training DVD and Workbook:**

At just $595 for the complete training package, ***Surviving an FDA Inspection Interview*** costs just a fraction of what you'd pay to hire a consultant to come to your facility to train employees. Boost your inspection preparation now by ordering today.

**Surviving an FDA Inspection Interview Includes**

- 15-Minute Training DVD
- Leader Guide to Surviving a Regulatory Interview
- Trainer Script: Surviving a Regulatory Interview
- Alternate Trainer Script: Surviving a Regulatory Interview
- Interviewing Issues Worksheet
- Interviewing Issues Worksheet Answer Key
- Knowledge Assessment
- Knowledge Assessment Answer Key

**FOUR EASY WAYS TO ORDER**

1. **PHONE:** Toll free (888) 838-5578
   or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/40899
3. **FAX:** +1 (703) 538-7676
4. **MAIL:** FDAnews
   300 N. Washington St., Suite 200
   Falls Church, VA 22046-3431

☑**Yes!** Please send me ____ copy(ies) of ***Surviving an FDA Inspection Interview*** at the price of $595.

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

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METHOD OF PAYMENT

❑ Check enclosed (payable to FDAnews)

❑ Bill me/my company. Our P.O.# _____

❑ Charge my credit card:
❑ Visa ❑ MasterCard ❑ American Express

Credit card no. _____

Expiration date _____

Signature _____
(Signature required on credit card and bill-me orders)

Add $10 shipping and handling per DVD shipped to the U.S. and Canada, or $35 per DVD for DVDs shipped elsewhere. Virginia customers add 5% sales tax.

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