INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

Vol. 1, No. 14
April 6, 2015

IN THIS ISSUE

Industry Seeks Greater Clarity On De Novo Classification Process

Devicemakers are urging the U.S. FDA to clarify its definitions of risk levels and what qualifies a medical device for de novo process in draft guidance on the approval pathway.

As currently written, the agency's definition of "low to moderate" risk is vague and open to interpretation, the Orthopedic Surgical Manufacturers Association says in comments on the draft. "It would be useful for a sponsor to know FDA's threshold for what could be a low-moderate risk device and what is a high-risk device," the group says.

Increasing clarity around de novo criteria could save both the FDA and sponsors time and resources by eliminating submissions that are doomed to fail, OSMA adds.

The trade group also asks the FDA to provide examples of what it expects to see in the way of benefits with a de novo device, since traditional 510(k)s tend to focus on risks rather than benefits.

Practical Examples

AdvaMed recommends adding practical information and examples of issues that can hurt a de novo submission's chances of approval, to aid sponsors considering this pathway. Given the relatively low number of applications that succeeded in getting a de novo classification, there may not be a strong incentive to apply, AdvaMed says.

The group also wants the FDA to clarify the criteria it uses to determine whether a de novo submission for a device previously found to be not substantially equivalent to a predicate will be granted de novo status or placed in Class III.

AdvaMed suggests adding a "scope" section as well to clarify that in vitro diagnostic products are included under the guidance. OSMA and AdvaMed were among 16 organizations and individuals that commented on the August 2014 draft guidance.

In its guidance, the FDA encourages presubmission meetings between devicemakers and the agency and warns that applications filed without a presubmission meeting will be more closely scrutinized. The agency will be looking to see that the sponsor's search for a potential

(See **De Novo**, *Page 2)*

De Novo, *from Page 1*

predicate was thorough, that it identified any risks and special controls that might be needed, and that it collected sufficient data to support claims of safety and effectiveness.

Members of the Patient, Consumer and Public Health Coalition on Draft Guidance expressed concern that the de novo process could be used to lower premarket standards for high-risk devices. "To protect public health and ensure that medical devices provide a reasonable assurance of safety and effectiveness, the draft guidance must unambiguously describe when the de novo process may and may not be used to clear a medical device," the group says.

The de novo route is available to novel technologies that are not considered high risk and not the subject of a pending 510(k) or PMA.

View the draft guidance at www.fdanews.com/ext/resources/files/08/08-18-14-denovo.pdf. The comments can be accessed at www.regulations.gov/#!docketBrowser;rpp=25;so=DESC;sb=postedDate;po=0;dct=PS;D=FDA-2011-D-0689. — John Bechtel

White House Plan Will Streamline Antibiotic Susceptibility Testing

By 2020, the U.S. FDA will update criteria on antibiotic susceptibility testing devices use to guide appropriate antibacterial drug treatment, under an action plan released by the White House on March 27.

The plan calls for the FDA to adopt criteria developed by standards development organizations rather than include interpretive guidelines on labels. The agency will also provide technical assistance within one year on legislative proposals being considered to streamline the updating of interpretive criteria for AST devices, the plan says.

The plan outlines federal activities over the next five years to develop and deploy next-generation diagnostics.

The effort is part of President Barack Obama's $1.2 billion fiscal year 2016 budget, which nearly doubles funding for combating and preventing antibiotic resistance.

(See **White House**, *Page 3)*

White House, *from Page 2*

With support from the National Institutes of Health and other funding agencies, researchers are taking advantage of new technologies to develop rapid "point-of-need" diagnostic tests, the White House says. These tests can reduce unnecessary antibiotic use by helping healthcare providers quickly distinguish between viral and bacterial infections, making it easier to recommend targeted treatment, the administration adds.

Read the plan at www.fdanews.com/03-27-15-Antibioticplan.pdf. — Jonathon Shacat

Petition Alleges Essure Trial Fraud; FDA Investigating

Bayer Healthcare's Essure female contraceptive is facing new U.S. FDA scrutiny in the wake of a citizen's petition alleging fraud on the part of the manufacturer.

The Center for Devices & Radiological Health has agreed to investigate the allegations in the petition, which accuses Bayer of misrepresenting its premarket approval application by altering the medical records of patients in Essure clinical trials, including crossing out or changing affirmative findings of pain and adverse events. The company also allegedly changed at least one trial participant's birthdate, apparently to meet an FDA request for more data on older women.

In addition, Bayer did not report eight instances of internal perforation caused by Essure, nor has the company notified the FDA of 16,047 complaints received since 2011, the petition claims.

Attorney March Susen, with Koch Parafinczuk & Wolf in Ft. Lauderdale, Fla., who filed the petition on Feb. 20, says Bayer violated the conditions of its PMA approval and federal law around the manufacture and marketing of Essure. He also disputes a claim in Essure's marketing materials that there were no pregnancies in clinical trials, saying there were four. And while the brochure claims Essure is more effective than tubal ligation or a vasectomy, Bayer never performed comparative clinical trials, Susen says.

Susen is asking the FDA to remove Essure from the market until a new PMA is submitted, force Bayer to publicly admit to the alleged violations and amend Essure's labeling to include a black box label warning that the PMA has been suspended.

In its March 26 response, the FDA says it has referred the complaint to CDRH's compliance office.

The allegations are similar to ones made in lawsuits Koch Parafinczuk filed against Bayer, says Bayer spokeswoman Rosemarie Yancosek, adding the company will cooperate with the FDA investigation.

View Susen's petition at www.fdanews.com/04-06-15-petition.pdf and the FDA's response at www.fdanews.com/04-06-15-response.pdf. — Elizabeth Orr

EU Ombudsman Seeks Further Inquiry Into Greek Hospital Procurement Case

The EU ombudsman is urging the European Commission to reexamine allegations that Greek hospitals violated procurement laws to favor certain suppliers, saying the country has a history of flouting the law.

The complaint was filed in January 2013 by a Greek importer who claimed the country didn't ensure that its hospital procurement procedures follow EU law after hospitals refused to buy its CE-marked suture devices. The importer also accused the Commission of failing to force Greece to comply.

Not only did hospitals not change their practices, but they put in place additional specifications that allowed them to continue to favor their preferred supplier, the complainant alleged. The preferred supplier, a large multinational company, held a near-monopoly on sales to Greek hospitals, according to a draft recommendation

(See **Greece**, *Page 5)*

Robust Simplicity.

EtQ features the most comprehensive Compliance Solution that is completely configurable to your business needs

- Automated processes such as Corrective Action, Audits, Risk Management, Complaint Handling, Document Control, and more
- Flexible to adapt to unique business processes, without programming
- Scalable solution that integrates with other business systems
- Make any application mobile and access your data from anywhere, anytime

EtQ
info@etq.com
800.354.4476
http://www.etq.com/fda

Greece, *from Page 3*

issued March 26. When the importer filed injunctions against calls for tenders that included those specifications, Greek officials increased the fees for filing an injunction.

The Commission concluded that Greece was in compliance with EU law and, in July 2014, the ombudsman proposed a "friendly solution" to the matter, asking the Commission to reexamine the complaint file concerning Greece's compliance with EU procurement legislation for medical devices.

The Commission responded that it could not continually monitor the way member states apply EU law or keep complaints open indefinitely, the ombudsman says.

Further Sanctions

In her draft recommendation, Ombudsman Emily O'Reilly faults the Commission for failing to fully examine the complainant's allegations, which she says are well-reasoned and substantiated.

If the Commission considers the evidence insufficient, "it should act upon the complainant's offer to provide clarifications and additional information," she says. If infringement of EU procurement laws is found, the Commission should consider referring Greece back to the EU Court of Justice for further sanctions, the ombudsman says, citing a 2006 decision involving the same issues.

The Commission has until June 30 to issue a detailed opinion explaining how it will implement the recommendation.

Erik Vollebregt, with Axon law firm in the Netherlands, says the case is reminiscent of procurement fraud in earlier Commission investigations into general healthcare corruption. The supplier has two options in addressing such situations: challenge the hospital's decision via EU procurement law or sue for fraud.

Using procurement law can be tricky, however, "because there is no way to make the hospital comply if it really doesn't want to," Vollebregt says, which may drive suppliers in this situation to file fraud claims.

View the draft recommendation at www.fdanews.com/04-06-15-greece.pdf. — Elizabeth Orr

Is Your Device Up for Ad Com Review? FDA Has Some Tips

New guidance from the U.S. FDA's medical devices center aims to help manufacturers get the most benefit from meetings with agency advisory committees by explaining the uses of committee meetings and steps firms can take to prepare.

The Medical Devices Advisory Committee consists of 17 advisory panels whose topics range from plastic surgery devices to radiological products. These panels provide advice on regulatory issues, such as reclassification of preamendment devices, and premarket submissions.

Timelines

Premarket submission meetings are where most devicemakers will come into contact with MDAC and its panels.

The meetings typically involve a single device for which the manufacturer seeks marketing authorization — such as premarket approval applications, de novo requests and humanitarian device exemptions. Committee panelists give specific advice on the device under review and address scientific, clinical and public health issues that are relevant to the review.

The FDA will request a panel review when there is uncertainty about the risks versus benefits of the device or if there are major data quality or integrity issues with the submission, such as missing data and protocol deviations, the draft guidance says.

The guidance also describes what the FDA will do to prepare expert panelists for a meeting

(See **Advisory Committees**, *Page 6)*

Advisory Committees, *from Page 5*

and sets a timeline for interactions between the agency and the sponsor leading up to the meeting.

Panel members will receive a packet with the meeting's planned agenda, the agency's summary of the issue, questions for the panel's consideration, appropriate sections or excerpts from the device submission and other relevant information, such as scientific literature.

About 55 business days before the meeting, the FDA will send an information letter to the sponsor with an outline of the material it intends to include in the panel pack. Then, 42 days out the company should submit two versions—one complete and one redacted—of its proposed materials for the pack.

Between then and 22 days ahead of the meeting, the FDA will review the unredacted materials and provide feedback to the sponsor. This is the time to call out errors and correct the final version that will go into the panel pack, the guidance notes.

Between two and three weeks before the meeting, the FDA will send a final unredacted panel pack to panelists and the sponsor.

Slides to be viewed during the meeting should be exchanged five days prior to the meeting, and two days before the meeting the FDA will post the redacted briefing materials on its website.

The guidance also discusses panel deliberations and voting. While panel recommendations aren't binding, the FDA often follows their advice.

All panel meetings include a public session during which interested parties can comment.

Comments on the draft guidance are due June 1. Read it at www.fdanews.com/04-01-15-CDRH.pdf. — Charlotte Astor

With Little Movement on Device Regs, EU States Turn to Joint Action Plan

Lack of progress on medical device reform legislation has spurred some EU countries to use last year's joint immediate action plan to improve device oversight.

Regulators using the joint plan will stay within the boundaries of existing legislation while coordinating vigilance activities such as recalls — something that has rarely happened in the past, says Erik Vollebregt, with Axon law firm in the Netherlands.

A joint market surveillance pilot program proposed in the 2014 action plan also seems to be moving forward and will allow member states to monitor postmarket experience "at an acceptable level," Vollebregt adds.

The Joint Action Plan, issued last June, is best known for having permitted notified bodies to perform unannounced audits of manufacturers.

However, it also established monthly vigilance teleconferences between member states and directed the European Commission's Joint Research Center to analyze trends in medical device incident reports.

The medical device regulations, proposed in September 2012, have been stalled since last year as the Council of Ministers struggles over a controversial premarket scrutiny mechanism and other provisions. It's currently unclear when the legislation might move forward.
— Elizabeth Orr

Survey Will Help Indian Devicemakers ID QS Issues Ahead of U.S. Inspection

Devicemakers in India that exceed the U.S. FDA's quality system expectations would receive fewer inspections and other incentives, under a pilot program announced last month.

The new approach would not only offer reduced inspection frequency or intensity, but also a more predictable pathway to implementing manufacturing-related postapproval changes, FDA spokesman Jeff Ventura tells *IDDM*.

A questionnaire being developed will not only note problems, but could allow the FDA to document where a facility's quality management system exceeds what would be required to meet regulatory compliance.

The pilot is not directly related to the quality metric collection program that the FDA has recently publicized, Ventura says. He declined to provide further details, citing the agency's policy not to discuss internal procedures until they are finalized.

The program was highlighted during a recent trip by FDA officials to meet with Indian counterparts and conduct site visits at several facilities. The officials discussed progress with respect to addressing GMP violations in India, with a shared focus on quality (*IDDM*, March 27).
— Jonathon Shacat

U.S. FDA Grants Class II Status to Urethral Inserts With Pump for Bladder Drainage

The U.S. FDA issued a final rule today placing urethral inserts with pumps to facilitate bladder drainage in Class II with special controls, including biocompatibility testing.

Firms submitting a 510(k) for premarket clearance must show the device is safe and effective in clinical testing and that it performs as intended. They must also document the device acceptance rate and its adverse event profile.

Adverse events associated with these devices include tissue irritation, infection, renal damage, trauma to the bladder wall, urgent urination, urine leakage, and device encrustation, migration or malfunction.

Devicemakers must also verify that components that contact the urinary tract are biocompatible and sterile, the FDA says. Performance data must support the shelf life for continued sterility of the product, its package and its use.

(See **Urethral Inserts**, *Page 8)*

Urethral Inserts, *from Page 7*

Nonclinical data should look at urine flow rate, valve integrity, bladder neck force retention, pump/valve endurance, encrustation and mechanical reliability, under the final rule.

The rule also spells out requirements for product labeling, such as warnings, recommended treatment regimen and a summary of complications.

The reclassification was requested by Vesiflo for the inFlow Intraurethral Valve-Pump and Activator.

Read the final rule, effective immediately, at www.fdanews.com/04-15-FDA-Order.pdf. — Jonathon Shacat

Expert Encourages Devicemakers To Use China's Trial Exemptions

While China's year-old medical device regulations require clinical trials for Class II and Class III devices, there are some defined exceptions and regulators are in the process of finalizing guidance to help companies take advantage of them, an expert says.

Devices that are demonstrated to be equivalent to ones already on the market, with equivalent safety and efficacy, may be exempted from clinical trials, under the new rules, says John Balzano, special counsel for Covington & Burling's food and drug practice group.

Exemptions also are available for devices whose safety and effectiveness can be evaluated nonclinically and ones that can be evaluated on the basis of existing clinical data.

The China Food and Drug Administration has prepared catalogues to help devicemakers determine classification and whether exemptions apply, Balzano notes. The agency has also issued draft guidance on clinical trials guidance that, once finalized, should help firms use the exemption catalogue and compare product names, descriptions and intended uses.

While parts of the draft need clarifying, it is a step forward in terms of offering guidance, the lawyer says.

The regulations were adopted in March 2014 and took effect Oct. 1.

Before devicemakers apply to register their devices, they should perform testing to ensure that their products conform to CFDA technical requirements, says Balzano, who discussed the new regulations during an FDAnews webinar.

Firms must also determine the device's class. Classification is a key process because it determines many requirements, such as whether a trial is necessary or if a trial must be preapproved, as is the case with certain high-risk Class III devices, Balzano notes.

Classification also determines which accredited trial site will be used for a particular type of device, Balzano says. As with preregistration testing, applicants must conduct trials at state-accredited clinical trial institutions such as state-run hospitals.

The CFDA has released a draft regulation outlining how it will accredit medical institutions that conduct clinical trials for devices (*IDDM*, Jan. 23). — Jonathon Shacat

FDANEWS

Customer Service
(888) 838-5578 • +1 (703) 538-7600
customerservice@fdanews.com

Editor: Elizabeth Orr
(703) 538-7652
eorr@fdanews.com

Ad Sales: Jim Desborough
(703) 538-7647
jdesborough@fdanews.com

300 N. Washington St., Suite 200 • Falls Church, VA 22046-3431 • Phone: (888) 838-5578 • +1 (703) 538-7600 • Fax: +1 (703) 538-7676
www.fdanews.com

Reporters: Lena Freund, Kellen Owings, Jonathon Shacat, Charlotte Astor, Jason Scott

President: Cynthia Carter; **Content Director:** Dan Landrigan; **Editor-in-Chief:** Meg Bryant; **Managing Editor:** John Bechtel

FDANEWS PRESENTS THE

Multi-attendee discounts are available!

BUILDING A WORLD-CLASS ADVERTISING AND PROMOTION REVIEW PROGRAM

AN INTERACTIVE WORKSHOP PRESENTED BY PHILLYCOOKE CONSULTING AND FDANEWS

YOUR EXPERT SPEAKER:

DALE A. COOKE
Owner, PhillyCooke Consulting

Mr. Cooke's practice specializes in helping FDA-regulated companies develop compliant promotional tactics and improve the promotional review. He is the author of ***Effective Review and Approval of Digital Promotional Tactics*** and is currently at work on a book about compliant social media usage for prescription product manufacturers.

This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

MAY 13-14, 2015

EMBASSY SUITES RALEIGH-DURHAM AIRPORT/BRIER CREEK

2 Days, 200 Tips For Improving Your Advertising and Promotion Review Program

FDA marketing scrutiny no longer is limited to magazine and TV ads. Now the agency is poking around, checking signage in tradeshow booths… checking in on Twitter and Facebook….and listening to the physicians and other healthcare professionals you've paid to speak or train.

Come to Raleigh in May for two days of intense learning. You'll arrive back home with a bag full of tricks and tips to keep all your marketing efforts squeaky-clean.

- **Understanding Pre-Approval Communications** Don't get on the FDA's or SEC's radar screens before your product is even approved. Learn how to properly disclose information and remain in compliance.
- **How To Maximize Disease Awareness Communications** Take away valuable tips and tricks for using disease awareness communications pre- and post-approval.
- **Hurray! You're Approved** Building the most aggressive – but compliant – campaign from first day of approval to commercial launch.
- **Assuring Your Promotions Meet FDA Off-Label Standards** Successfully navigating 4 major traps that can earn you a warning letter fast.
- **Itching To Do More With Social Media?** Discover how to get your message out there … without crossing the line.

DAY ONE | MAY 13

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. - 9:45 a.m.

Pre-approval Communications

- How to meet your SEC requirements for disclosing information while not running afoul of FDA pre-approval promotion prohibitions

9:45 a.m. - 10:30 a.m.

Disease Awareness Communications

- A review of FDA's help-seeking guidance
- Keys for using disease awareness communications prior to approval. Essential information for continuing communications efforts post-approval compliantly.

10:30 a.m. - 10:45 a.m.

Break

10:45 a.m. - 11:15 a.m.

From Day of Approval through Commercial Launch

- Understanding the timeline and key dates for communications
- Minimizing the pain, while maximizing the impact of initial promotional communications

11:15 a.m. 12:00 p.m.

Essential Advertising & Promotion Regulations

- A review of all of the requirements for product promotion, including product name usage, fair balance, directions for use

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. - 1:45 p.m.

Format-Specific Promotional Requirements

- DTC television promotion
- Brief summary requirements for print promotion

1:45 p.m. - 2:30 p.m.

Substantial Evidence & Other Standards

- A review of the substantial evidence standard, what fails to meet that standard, and when other standards apply

2:30 p.m. - 2:45 p.m.

Break

2:45 p.m. – 4:00 p.m.

Off-Label Information

- Avoiding off-label promotion
- Scientific exchange exemption
- Responding to unsolicited requests
- Distributing off-label reprints

4:00 p.m. - 4:30 p.m.

The Promotional Review Process

- An overview of a the standard promotional review process
- Essential traits for any effective process
- Key decisions in establishing or improving performance
- Effective use of metrics for evaluating performance

4:30 p.m.

Session Wrap-Up, End of Day One

DAY TWO | MAY 14

8:30 a.m. – 9:00 a.m.

Continental Breakfast

9:00 a.m. - 9:45 a.m.

Integrating Digital Promotion

- Key considerations for evaluating the compliance of digital promotional tactics and their integration into the overall promotional mix

9:45 a.m. - 10:15 a.m.

Social Media Part 1

- Overview of the platforms, issues, and a review of the status of FDA guidance

10:15 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:30 p.m.

Social Media Guidances

- A review of the three social media guidances released in 2014: 2253 Filing, Presenting Risk Information in Space-Limited Contexts, & Correcting Misinformation on Third-party Sites

12:30 p.m. - 1:30 p.m.

Lunch

1:30 p.m. - 3:15 p.m.

Promotional Review Board Practicum

- Workshop participants will apply the lessons from the earlier part of the workshop to specific product promotions. They will work in teams to evaluate specific promotional tactics, determine what (if any) parts of the promotion are problematic, and how to provide direction to a brand marketer to make the promotions compliant.

3:15 p.m. - 3:30 p.m.

Break

3:30 p.m. - 4:15 p.m.

Continuing Regulatory Intelligence: Staying Abreast of Ad/Promo News

- Ad/Promo is an area of ongoing developments. This session will cover the most prominent sources for keeping up with these developments.

4:15 p.m. - 4:30 p.m.

Wrap-up and Adjourn Workshop

"Dale was very engaging and informative. I like the interactive portion where we reviewed actual ads."

— 2014 Workshop Attendee

WHO WILL BENEFIT?

- Advertising and marketing managers
- Social media teams
- Promotion review committee members
- Medical affairs
- Continuing education and tradeshow organizers
- Regulatory compliance officers
- PRC coordinators
- Legal counsel
- Compliance
- Executive management
- Outside ad agencies and marketing consultants

"[Dale is] an animated speaker who seems to know something about everything and has no shortage of opinions. This is potentially very dry and dull material. Dale brings out the exciting and humorous aspects especially well. It's an engaging two days."

— Michael Benedetto, Editorial Group Leader, FCB Health

"This is normally a dry topic, but with Dale it was anything but dry. Dale gave one of the best, most engaging presentations. Dale is highly knowledgeable and also very entertaining."

— Ellen Derrico, Global Head, Market Development - Life Sciences & Healthcare, QlikTech

"As a fellow regulatory professional, Dale is one of the most deeply knowledgeable experts I've heard on this complicated subject. As the pharmaceutical industry is experiencing, digital promotional tactics can trip up even experienced regulatory professionals, but Dale showed how basic principles can be applied to develop compliant promotional materials."

— Kathleen Koons, Sr Regulatory Affairs Manager, DJA Global Pharmaceuticals Inc.

Course Binder Materials:

Full slides from the PowerPoint presentations

Reference documents:

FDA Advertising & Procedural Guidances

- Help-Seeking Guidance
- DTC Broadcast Guidance & Q&A
- FDAAA Pre-Dissemination Review Requirements
- Product Name Guidance (All three versions from 1999, 2012, and 2013)
- Presenting Risk Information Guidance
- Social Media Guidances
  - Postmarketing Submissions Requirements
  - Responding to Unsolicited Requests for Off-label Information
  - Presenting Risk Information in Space-limited Contexts Correcting Third-party Misinformation
- Distributing Off-Label Reprints

Relevant Sections of Code of Federal Regulations

Form 2253

PhRMA Principles on DTC Advertising

PhRMA Principles on Interactions with Healthcare Professionals

Pre-approval Promotion Checklist

Effective Review & Approval Process Checklist

Keys to Evaluating Promotional Review Systems List of Key Resources for Continuing Education

Articles by Dale Cooke

- Developing Compliant Search Engine Marketing Campaigns (Publication Date of September 2014)!
- Industry Standards for Linking Disease Awareness Websites to Product Promotion!
- Patient Testimonial Videos: FDA Actions on Risk Information Presentation!
- Presenting Risk Information on Websites!
- Where Things Stand on FDA Guidance on Social Media (Publication Date of September 2014)

FDANEWS PRESENTS THE

BUILDING A WORLD-CLASS ADVERTISING AND PROMOTION REVIEW PROGRAM

☐ **Yes!**

Sign me up for the **Building a World-Class Advertising and Promotional Review Program**

	Complete Workshop	Subtotal
Name ..... Title..... Phone ..... E-mail	**$1,797**	
Name ..... Title..... Phone ..... E-mail	Call for Discounts	
Name ..... Title..... Phone ..... E-mail	Call for Discounts	

www.fdanews.com/advertisingpromotion

Toll-free: (888) 838-5578

TOTAL: _____

INFORMATION:

Name _____

Title _____ Company _____

Address _____

City _____ State _____ ZIP_____

Phone _____ Fax _____

Email _____

PAYMENT OPTIONS:

☐ **Check Enclosed:** payable in U.S. funds to FDAnews

☐ **Charge my**: ☐ Visa ☐ MasterCard ☐ AmEx

Card # _____ Exp. Date _____

Signature _____

HOTEL INFORMATION INFORMATION:

May 13-14, 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: $169.00 plus 12.75% tax
Reservation cut-off date: April 28, 2015

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. Multi-attendee discounts are available and will be calculated at check out.

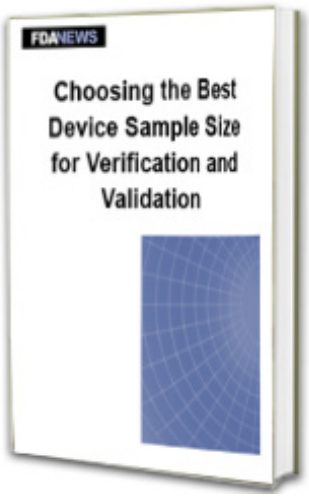
2-4 attendees – 10%
5-6 attendees – 15%
7-9 attendees – 20%
10+ attendees – 25%

TUITION:

Tuition includes all conference presentations, conference materials, two breakfasts, two lunches and refreshments.

CANCELLATION AND SUBSTITUTION:

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.



Choosing the Best Device Sample Size for Verification and Validation

If you're like many manufacturers, you understand the essence of the *21 CFR 820.30* requirement: you must run enough test samples of a product so its test results can be successfully applied to full-scale production runs. And, like many manufacturers, you've probably had trouble for years determining exactly how many units of a product you should test to satisfy the FDA.

Choosing the Best Device Sample Size for Verification and Validation will help you select the right statistical methods to make this determination. With it, you'll learn how to get the right sample size to ensure that user requirements are met in the product design. This management report will also help you understand how to:

- Examine the discrete or continuous statistical data you collect.
- Look at variability, including variation from unit to unit or from batch to batch, as well as variation in their measurement systems.
- Design verification and validation tests, particularly regarding choice of sample size.
- Fully understand the requirements for statistical techniques, including how different techniques can affect the design control process.
- And much, much more.

Finally, you can gain a clearer understanding of how to put together a statistical methods program for design verification and validation that will satisfy FDA auditors.

Order your copy today!

FOUR EASY WAYS TO ORDER

1. **PHONE:** Toll free (888) 838-5578 or +1 (703) 538-7600
2. **WEB:** www.fdanews.com/46876
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 ***Choosing the Best Device Sample Size for Verification and Validation*** at the price of $397 each for the format I've selected: ❑ Print ❑PDF

Name _____

Title _____

Company _____

Address _____

City_____ State _____ Zip code _____

Country _____

Telephone _____

Fax _____

Email _____

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 book for printed books shipped to the U.S. and Canada, or $35 per book for books shipped elsewhere. Virginia customers add 6% sales tax.

15FLYR-N