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2015 FDAnews Media Kit

Every day, thousands of pharmaceutical, medical device and diagnostics executives visit FDAnews.com. An average of 40,000 visitors per month get the very latest industry news, use the archives to research specific issues, make plans for upcoming industry conferences and purchase books, webinars or subscription products.

- The headlines on the home page give readers an inside line to our newsroom — we post the hottest news affecting the drug and medical device industries each business day.
- Users who need to get a handle on a particular topic quickly use the search feature to find all relevant articles and products.
- Many visitors come to the site specifically to purchase products, making this a great opportunity for you to get your message to your prospect while they are ready and willing to purchase.
- Thousands of our newsletter readers choose electronic delivery and access their current and archived issues through the website.

These information-hungry visitors come to the site specifically to find solutions to the compliance issues they face.

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Tagline goes here

NEW eLearning Library From FDAnews!

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About Us Form 483s Webinar Training Pass Newsletters Store Events White Papers Contact Us Advertising/Sponsorships

Texas Dismisses Biotech-Backed Biosimilar Substitution Bill
Texas this week became the 12th state to reject legislation pushed by biotech giants Amgen and Genentech restricting the use of biosimilar drugs.
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Establishing a Pharma Supplier Audit Program: A Risk-Based Approach
The FDA leaves it to you to determine supplier risk and reliability, via audits that you conduct. But make a wrong call and you could face a Form 483, a warning letter or, even worse, liability lawsuits. So here's the question of the day: Are you doing your best job on audits? If the answer is no... or even maybe... get timely help from FDAnews.

Pharmaceuticals

Pharmaceuticals

PDF Edition - Making Excel Spreadsheets Compliant: Foolproof

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For more information contact Jim Desborough (703) 538-7647 or jdesborough@fdanews.com 1

Demographics and Readership

Choose Your Audience

Advertising in our newsletters and eNewsletters gets your message to a broad cross section of readers, and the maximum number of people. You can also target your message to those interested in particular subject areas through specific newsletters.

READERSHIP BY PUBLICATION		
Pharmaceutical Industry		
Publication Title	Frequency	Readership
FDAnews Drug Daily Bulletin	Daily	47,000
The QMN Weekly Bulletin	Weekly	16,000
Drug GMP Report	Monthly	5,010
Generic Line	Biweekly	2,995
Clinical Trials Advisor	Monthly	3,740
International Pharmaceutical Regulatory Monitor	Monthly	3,295
Drug Industry Daily	Daily	4,250
Executive Briefing Series	Monthly	1,780
483s Alert	Weekly	4,689
Medical Device and Diagnostics Industries		
Publication Title	Frequency	Readership
FDAnews Device Daily Bulletin	Daily	25,000
The QMN Weekly Bulletin	Weekly	16,000
The GMP Letter	Monthly	3,980
International Devices & Diagnostics Monitor	Weekly	6,847
483s Alert	Weekly	4,689

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Demographics and Readership

Target Top Decisionmakers

FDAnews provides you with access to top executives and managers in the pharmaceutical and medical device industries. Nearly 20 percent of **FDAnews** customers are in CEO or senior executive positions and another 46 percent are regulatory affairs and quality assurance professionals. Readers also include attorneys, clinical and scientific professionals, and operations and manufacturing managers. Eighty-two percent of **FDAnews** customers are based in the U.S., with most of these professionals located in New Jersey, New York, Pennsylvania, Washington, D.C., or California, mirroring industry demographics.

JOB FUNCTION BY PUBLICATION

	<i>Drug GMP Report</i>	<i>Generic Line</i>	<i>The GMP Letter</i>	<i>Clinical Trials Advisor</i>	<i>Executive Briefing Series</i>	<i>International Pharmaceutical Regulatory Monitor</i>	<i>International Devices & Diagnostics Monitor</i>	<i>Drug Industry Daily</i>
Quality Assurance/Quality Control	37%	26%	34%	33%	14%	36%	32%	31%
Regulatory Affairs/Compliance	27%	23%	28%	22%	14%	37%	34%	24%
Senior Executives	13%	19%	5%	9%	23%	6%	13%	15%
President/CEO	5%	14%	13%	11%	0%	6%	9%	10%
Attorney/General Counsel	1%	2%	0%	0%	5%	1%	1%	0%
Technical/Validation	4%	4%	3%	0%	5%	2%	1%	0%
Clinical/Scientific	5%	5%	9%	12%	5%	2%	1%	0%
Library	8%	7%	13%	13%	34%	10%	9%	20%
Research	0%	0%	0%	0%	0%	0%	0%	0%
Marketing	0%	0%	0%	0%	0%	0%	0%	0%

Publications

Get in Front of Tens of Thousands of Executives Every Day

Over 80,000 pharmaceutical, medical device and diagnostics executives receive at least one of our eNewsletters every day — many receive more than one. Readers know how important it is to keep up with changes and find solutions to their compliance challenges. Advertisers have seen proven success in promoting upcoming conferences and timely technologies, products and services in these cost-effective vehicles.

eNewsletters

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FDANEWS DRUG DAILY BULLETIN

Reasons why **OVER 200 Companies** Trust TrackWise as their Enterprise Quality and Regulatory Compliance Management System...

Vol 5, No. 207 Wednesday, Oct. 22, 2008

In this issue...

- Survey: Sites, Sponsor Face Cost, Communication Hurdles in Trials
- OSD Guidance Being Drafted for Manufacturers
- Bayers Requests FDA Approval for Joint Damage Drug World Daily
- Pharma Bids War

Survey: Sites, Sponsor Face Cost, Communication Hurdles in Trials

The top obstacles researchers face when considering whether to conduct a clinical trial are cost, patient recruitment and delays caused by difficulties with supplies and intellectual property, according to a survey by the RxTrails Institute. Other roadblocks include inadequate sponsor funding, poor communication, including expectations, and protocols that are poorly written and subject to change by sponsors.

ETQ Industry Daily

FREE MEDICAL DEVICE CONTROL & RISK MANAGEMENT AND MORE ETQ

Webinar: Risk Management and Drug Safety Success

FDANEWS DRUG DAILY BULLETIN

Each day you'll receive targeted FDA regulatory, legislative and business news briefs in the pharmaceutical and biologics industries. Plus, you'll get a snapshot of international news relevant to your business. In just a few minutes you can scan major headlines and click through to read the stories you want. Sign up today and receive your first **FDAnews Drug Daily Bulletin** the next business day.

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FDANEWS DEVICE DAILY BULLETIN

Reasons why **OVER 200 Companies** Trust TrackWise as their Enterprise Quality and Regulatory Compliance Management System...

Vol 5, No. 207 Wednesday, Oct. 22, 2008

In this issue...

- Lawmakers Expand Probe Into Ties Between Industry and Educators
- Experts: Clear Patent Strategies Can Maximize Value of Investments
- Device World Daily

Lawmakers Expand Probe Into Ties Between Industry and Educators

Two Senate committees are investigating medical device industry ties to Columbia University and the Cardiovascular Research Foundation (CVRF). In their letter to CBO Chairman Greg Stone, the lawmakers say they are concerned that funding from the medical device industry may influence the activities of non-profit organizations that purport to be independent in their reports and actions.

FREE MEDICAL DEVICE CONTROL & RISK MANAGEMENT AND MORE ETQ

Webinar: Risk Management and Drug Safety Success

FDANEWS DEVICE DAILY BULLETIN

Keep track of important FDA regulatory, legislative and business news developments in the medical device industry. Plus, you'll get a snapshot of international news affecting the medical device industry. You can scan major headlines and click through to read the stories you want. Sign up today and receive your first **FDAnews Device Daily Bulletin** the next business day.

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QMN WEEKLY BULLETIN

Greater Quality and Compliance... Less Risk.

Medical Device Risk Management

An Interactive Workshop Presented by Onus Enterprises and FDAnews

Sept. 27-22, 2010 • Hyatt Regency Minneapolis • Minneapolis, MN

Vol. 2, No. 30 Friday, July 23, 2010

In this issue...

- Language Is Problem for Companies Seeking Brazil GMP Inspection
- Cardinal Health Cited in Form 483 for Investigation Deviations
- Artisan Warned for GMP Issues, Complaints at Locking Packaging
- Manufacturing World Roundup

Language Is Problem for Companies Seeking Brazil GMP Inspection

An OEM's makers, suppliers and importers scramble to meet Brazil's new GMP certification regulation, the biggest problem has been language barriers.

"We had reports of audits that were perfect and some others [that] had interpretation and language problems," Robert Lujan, director of Latin & Associated in Sao Paulo, said. "As everything is so new, we will have to wait to see the real results in two or three months."

Portuguese is the country's official language.

The regulation requires all local and foreign device companies that are registering or re-registering a product in Brazil to undergo an on-site audit before entering the market.

THE QMN LETTER

Cardinal Health Cited in Form 483 for Investigation Deviations

An FDA inspection has found several investigation deviations at a Cardinal Health Pl. Lauderdale, Fla., facility.

For example, the company's quality control manager said that all of the observations were corrected.

Schumacher said.

OSD GMP Issues

Artisan Warned for GMP Issues, Complaints at Locking Packaging

The packaging team, which is responsible for the product's appearance, was notified of the problem.

Clearly Better Compliance

Download FREE whitepaper

Opportunities in Emerging Markets

Download FREE whitepaper

THE QMN WEEKLY BULLETIN (Pharma and Medical Device)

By reading the Quality Management Network's *QMN Weekly Bulletin* you can keep track of the latest from the FDA, Congress and industry experts in the world of cGMP's for pharmaceutical and medical device manufacturers. Each issue delivers crucial information on regulatory changes and inspection trends, as well as a wrap-up of the major quality management news from around the world. Sign up today and start receiving *The QMN Weekly Bulletin*.

Immediate Access Instant Answers

483s ALERT

Dear Subscriber:

The following 483s have been added to 483sOnline.com in the past week. To access all available 483s, visit us at: <http://www.fdanews.com/store/product/detail/productid=36408>.

DRUGS

JFC Technologies Region: Central Inspector: Jose H. Cayula

Issued: 06/08/2011

Observations: Major equipment was found without records of use.

COMPLIANCE NOW

MSD International GmbH (Puerto Rico Branch), LLC

Issued: 03/31/2011 Region: Southeast Inspector: Ramon A. Hernandez

Observations: Preserve samples from representative sample lots or batches of drug products subjected to stability testing.

483s Alert

Every day, FDAnews editors are busy tracking down drug- and device-maker 483s from the latest FDA inspections and adding them to our online database. Keep track of what's added to the site with a free subscription to *483s Alert*. Sign up now to receive this weekly ezine each Wednesday, and you'll never miss an update.

FDANEWS

Publications continued

Proven Industry Resources

For more than 30 years, **FDAnews** has been the premier provider of newsletters to help pharmaceutical, medical device and diagnostics executives understand how regulatory changes affect their business. Readers pay as much as \$1,995 for bottom-line, impact-oriented news and analysis to help them meet the regulatory challenges they face. These proven buyers are looking for solutions to stay in compliance with the FDA's complex and ever-changing regulations and international standards.

Pharmaceutical Industry Newsletters



DRUG INDUSTRY DAILY

This daily electronic briefing delivers coverage of what's happening on Capitol Hill and at the FDA, FTC, HHS, NIH and other key agencies and decision making bodies that affect the pharmaceutical industry. Each issue gives you hard reporting on top issues, such as patent exclusivity, DTC advertising, medication errors, program funding, FDA appropriations, bioterrorism, warning letters, recalls, approvals and more. Written by **FDAnews'** veteran staff of reporters, you get the news as it happens with the added perspective that only seasoned reporters can provide. It's the fastest, most reliable way to make sure you're an industry expert.

Daily, 250 issues, subscribers pay \$1,995



CLINICAL TRIALS ADVISOR

Clinical Trials Advisor is devoted to helping pharmaceutical manufacturers, clinical researchers, IRBs and investigators improve clinical trial operations and GCP compliance. You'll get the latest regulatory and international news, as well as practical advice for maximizing your clinical investments. No other resource provides such valuable reporting and training applicable to every area of clinical trials. From ethics to information technology, training to patient recruitment, accreditation to disclosure — if it impacts clinical trials, *CTA* covers it.

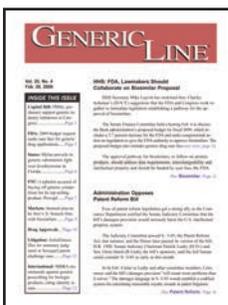
Monthly, 12 issues, subscribers pay \$645



DRUG GMP REPORT

Drug GMP Report delivers in-depth coverage of technical quality control issues that affect drug development and production processes. Each issue provides concise, easy-to-read explanations of key regulatory trends and advice to make GMP compliance easier.

Monthly, 12 issues, subscribers pay \$995



GENERIC LINE

More than \$30 billion of branded drugs are coming off patent. With *Generic Line*, the only newsletter devoted exclusively to the generic drug industry, readers stay on top of Medicare and Medicaid prescription programs, patent developments and all the crucial business, regulatory and legislative changes affecting generic opportunities and threats.

Biweekly, 24 issues, subscribers pay \$997

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Publications continued

Pharmaceutical Industry Newsletters continued



INTERNATIONAL PHARMACEUTICAL REGULATORY MONITOR

Stay on top of key changes in pharmaceutical regulation around the world with this monthly resource for rules and standards flowing from the FDA, the European Medicines Agency, Health Canada, Australia's Therapeutic Goods Administration, the International Conference on Harmonisation and other agencies in Europe, Japan and elsewhere. In addition to a comprehensive briefing, you get actual full official English-language texts of important, hard-to-obtain proposals, regulations, rules, directives, guidances and other documents, to help you prepare better-documented, properly formatted drug applications for fastest processing.

Monthly, 12 issues, subscribers pay \$795



EXECUTIVE BRIEFING SERIES

This new monthly series by the editors of The Food & Drug Letter will give you in-depth reporting and analysis on a variety of topics that impact your industry and decision making.

Monthly, 12 issues, subscribers pay \$4,995

Medical Device & Diagnostics Industries Newsletters



THE GMP LETTER

The GMP Letter helps readers stay on top of FDA's interpretation and enforcement of the Quality System Regulation — and know what changes their firm must make to comply. Each month, *The GMP Letter* provides an informed report of key regulatory developments, tips on what executives can do to prepare for FDA inspections, proven ways to improve design control procedures, how to correct violations and tips on creating more effective GMP training programs.

Monthly, 12 issues, subscribers pay \$985



INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

International Devices & Diagnostics Monitor is a one-stop resource that brings you a complete, global picture of the medical device regulations that affect your business. Nowhere else will you find a more comprehensive collection of all the regulatory changes in the US, EU, Asia, Latin America, the Middle East, Australia and the rest of the world. Your subscription includes a weekly newsletter to keep you up to date with global regulations as changes happen, including complete text of all government documents. In addition, you will also receive a quarterly update with expert analysis on key device and diagnostic issues from around the world.

Weekly, 50 issues, subscribers pay \$1,247

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Advertising Opportunities

Place your ad in these newsletters for a more targeted, content-specific promotion opportunity than other more broad-based outlets. Your full-page, half-page or quarter-page ad runs black-and-white in printed distribution and four-color in PDF distribution.

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Email Database

FDANEWS is the premier provider of regulatory, legislative and business news for clinical, pharmaceutical and medical device professionals. This database includes top executives at clinical, pharmaceutical and medical device companies who subscribe to paid and free newsletters, buy reports, books and training programs, download whitepapers as well as attend conferences on need-to-know clinical, pharmaceutical and medical device regulatory and manufacturing topics.

The clinical selects include both site and sponsor companies.

The regulatory selects include regulatory affairs professionals from both drug and device companies.

The individuals that make up the separate device, drug, and drug & device selects are a large selection of RA, QA, and QC professionals as well as other top executives.

Total Database	53,000
Updated	Monthly

Industry Selects

Clinical	10,000
Regulatory	8,000
Device	10,000
Drug	15,000
Drug and Device	10,000

Minimum Order

Minimum Quantity	5,000
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Pricing

Pricing	\$400/K
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White Paper Program

The FDAnews White Paper Program offers one of our strongest direct lead generation programs available.

FDAnews will host your White Paper and launch an outbound promotional program including:

- ❖ **Website ads**
- ❖ **eNewsletter ads**
- ❖ **eBlasts**
- We guarantee 150 leads.
- Client is given all prospect contact data on a weekly basis.

Rate: \$7,500 for each White Paper. Discounts available for two or more White Papers.

Webinar Services

Want to host a webinar, but don't have the time or manpower to do it?

FDAnews has years of experience of putting together and running webinars. You can now take advantage of this experience for your company.

You select the topic, send us the supporting documentation & provide the speaker, we do the rest.

We create marketing program, which would include, standalone emails, banners for the website and newsletters. Inclusion in our webinar marketing for upcoming events, Twitter, Facebook and press releases.

You have complete approval of all marketing collateral.

FDAnews will create the landing/registration page, send out the acknowledgements. We will monitor and host the webinar, with live operators, on our platform (WebEx), handle the Q&A and have a technical back up team to handle any problems/questions that should arise during the webinar.

A survey is conducted after the seminar on basic info about what they thought about the seminar/speaker/topic, etc.

You will receive the following: registrant's, attendee's, survey and MP4 file of the webinar.

eNewsletter Marketing

FDAnews is read by thousands of Pharmaceutical and Medical Device executives every day.

You can advertise to them via our e newsletters and publications. Banner ads or text ads are available.

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For more information contact Jim Desborough (703) 538-7647 or jdesborough@fdanews.com 8

Website Marketing

Banner ads are available on all the FDAnews webpages.

Copy Writing

FDAnews has been communicating with our readers since 1978. We know how to engage them to get the most out of our subscribers.

FDAnews will write the copy for any of the above, if you do not have the resources or time to do so.

Call for pricing.

Sponsored DVD and eLearning

FDAnews will customize any DVD in our library for you. We will add your logo and slides into our DVD and allow you to send it out to your prospect/customer. This is a great sales aid for your sales force.

Call for pricing.

2015 FDANEWS Conferences and Sponsorship Opportunities

Medical Device Complaint Management

Feb. 25-26 • Boston, MA

12th Annual

Medical Device Quality Congress

March 17-19 • Bethesda, MD

10th Annual

FDA Inspections Summit

Nov. 4-6 • Bethesda, MD

Elevate your company awareness and connect with your potential customers at FDAnews conferences! There is no faster way to meet your top potential customers than exhibiting at an FDAnews conference. Our conferences are just the right size to allow you to quickly and easily identify the connections you need. We offer a variety of sponsorship packages to meet your marketing goals.

Sponsorship packages range from \$5,000 to \$10,000, and your package may include:

- Table Top Booth
- Conference Passes
- Logo on all Marketing Materials
- Pre and Post Conference Email to Attendees
- Acknowledgment on Conference Signage
- Seat Drop of your Brochure
- e-Brochure loaded on Flashdrive
- Lunch Break Sponsor
- Lanyard Sponsorship
- Cocktail Reception Sponsorship

Banner and Ad Rates

eNewsletters

- FDAnews *Device Daily Bulletin*
- FDAnews *Drug Daily Bulletin*
- *The QMN Weekly Bulletin*
- *483s Alert*
- *Drug Industry Daily*

** Only Text ad 1 available

	Weekly	Monthly
Text ad "A" or Horizontal Banner Ad	\$650	\$2,250
Text ad Space 1 or 2	\$500	\$1,500
Text ad Space 3 or 4	\$450	\$1,350
Text ad Space 5 or 6	\$350	\$1,050
Text ad Space 7	\$300	\$950

Newsletters

- *Clinical Trials Advisor*
- *Drug GMP Report*
- *Executive Briefing Series*
- *Generic Line*
- *International Pharmaceutical Regulatory Monitor*
- *International Devices & Diagnostics Monitor*
- *The GMP Letter*

	1X	3X	6X	12X
1/4 Page	\$495	\$475	\$450	\$425
1/2 Page	\$775	\$750	\$725	\$700
FULL PAGE	\$1,475	\$1,425	\$1,375	\$1,350

FDAnews.com

	Monthly	Quarterly	Annually
Header	\$1,100	\$2,640	\$9,300
Space 1 or 2	\$800	\$2,200	\$7,500
Space 3 or 4	\$700	\$1,900	\$6,000
Solution Center	\$600	\$1,600	\$4,750

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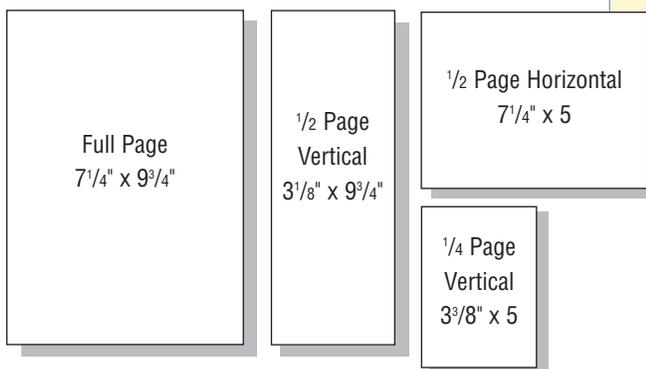
Publication **Specifications**

eNewsletters

<ul style="list-style-type: none"> • FDAnews <i>Device Daily Bulletin</i> • FDAnews <i>Drug Daily Bulletin</i> • <i>The QMN Weekly Bulletin</i> • <i>483s Alert</i> 	DRUG AND DEVICE DAILY HORIZONTAL BANNER AD	612 px wide by 80 px high
	QMN WEEKLY HORIZONTAL BANNER AD	742 px wide by 90 px high
	TEXT ADS	60-word description including live link

Newsletters

<ul style="list-style-type: none"> • <i>Clinical Trials Advisor</i> • <i>Drug GMP Report</i> • <i>Executive Briefing Series</i> • <i>Generic Line</i> • <i>International Pharmaceutical Regulatory Monitor</i> • <i>International Devices & Diagnostics Monitor</i> • <i>The GMP Letter</i> 	SPACE ADS	<ul style="list-style-type: none"> • Include print and PDF distribution • CMYK image format (PDF, TIFF, EPS) • Note: CMYK images will be converted to grayscale for print distribution, and used as color in PDF distribution. • All fonts supplied • Resolution — 300 dpi • Include placed images where applicable
		<p>Full Page — 7¹/₄" x 9³/₄"</p> <p>1/2 Page Vertical — 3¹/₈" x 9³/₄"</p> <p>1/2 Page Horizontal — 7¹/₄" x 5</p> <p>1/4 Page Vertical — 3³/₈" x 5</p>



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HEADER	<ul style="list-style-type: none"> • 640 px wide x 78 px high • High Res. RGB image format (GIF or JPEG) • No larger than 7K at 72 dpi at finished size 	SOLUTION CENTER	<ul style="list-style-type: none"> • 300 px wide x 100 px high • High Res. RGB image format (GIF or JPEG) • No larger than 7K at 72 dpi at finished size
SPACES 1–4	<ul style="list-style-type: none"> • 300 px wide by 100 px high • RGB image format (GIF or JPEG) • No larger than 7K at 72 dpi at finished size 		

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