

Edata Integrity Report

Healthcare Industry Best Practices, Case Studies, Analysis & News

EDC GETS MIXED GRADES FROM CROs, SPONSORS

First in a three-part series

Love it. Hate it. Either way, Electronic Data Capture (EDC) in clinical trials isn't going away anytime soon.

"It's coming: CROs have to embrace it," said Scott Houlton, President of Clinical Packaging and Logistics at Aptuit. CROs that "stick their head in the sand will be bypassed."

"Old school data managers" who don't accept EDC will "have to find something else to do" in another line of work, suggested Jim Rogers, CEO of Nextrials.

Anecdotal evidence and recent surveys and predictions generally bear them out about the rise of EDC in clinical trials.

DON'T WAIT FOR FDA TO DEFINE RISK — THE AGENCY ISN'T

First in a series

Weaving risk assessment and management in at the very outset of a medical product's development cycle can prevent major headaches down the road, experts stress to *EIR*.

"We were kind of amazed [to see

Half of all new clinical trials will use EDC in 2007, says a new report from market research and analysis firm Health Industry Insights (HII). "We're now in an era where paper-based data capture is the exception versus the norm," said Scott Lundstrom, vice president of research at HII.

But many, at least half by some accounts, of all CROs are still resisting EDC. Some downplay its potential or say it overhypes its promises, others just try to avoid it by pushing paper data collection.

FastTrack CEO Ed Seguire said he still hears regularly in his travels that many CROs "jump at the

(Continued Page 8)

how clearly] risk analysis should be in all phases of the development life cycle," said David Vogel, President, Intertech Engineering Associates. His view evolved as he worked for three years as one of the authors in AAMI's workgroup that produced a landmark 2004 report on

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Volume 1, Issue 1

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Next Issue...

- A full report from DIA's Contemporary Pharmacovigilance and Risk Management Strategies Conference
- Part II: What's Working, What's Not in EDC & CROs with Ed Seguire, Fast Track, Bill Cooney, Medpoint, Jim Rogers, Nextrials, and others.

Mandates, Incentives Raised at FDA Esubs Meeting

FDA regulated life sciences companies would probably adopt Esubmissions faster if the agency offered up a mixed “carrot and stick” approach, attendees at last month’s open meeting told FDAers.

The agency signaled it expects “fast action” on esubs, Janet Woodcock said at the opening of the meeting. But for the FDA that may mean several years, attendees at the meeting told *EIR*.

“Janet Woodcock introduced the meeting and said from her point of view the intention was to advance an all esubmissions environment,” said Nancy Smerkanich, Vice President, Regulatory Affairs at Octagon Research Solutions. “The agency is definitely moving toward this,” Smerkanich said. Swift action “doesn’t mean five years to me.” She was one of more than a dozen presenters at the Dec. 18 open meeting (see box).

The agency’s commitment to moving forward may have been demonstrated by the fact that the open hearing was a Part 15 meeting. That means it can take the place of any pre-rulemaking activities. “They can come out of this with a final rule,” Smerkanich told *EDR*.

Embracing esubmissions may be toughest for what Smerkanich called Tier 2 companies, those she defines at medium size pharmas with annual revenue between \$500 million and \$1 billion. “The big boys can just reallocate money from someplace else, while the smaller guys don’t need a lot of money because they are not retooling big systems,” she noted.

“Making the transition from paper to electronic submissions is hard work,” said David Hardison representing the Clinical Data Interchange Standards Consortium (CDISC). Hardison is also Vice President, Life Sciences for SAIC.

CDISC called on the agency to adopt the Operational

Data Model (ODM) for electronic CRF data submissions, in addition to using it as a transport format for define.xml metadata and SDTM and analysis data.

Big companies may need a mandate to push them toward esubs, smaller companies may need financial incentives, Smerkanich said.

A final note: There were no dissenting voices at the open meeting, Smerkanich noted. “It seems everybody wants to go forward” with esubmissions.

Comments can be sent until Feb. 16. To submit one go to:

<http://www.accessdata.fda.gov/scripts/oc/dockets/commentdockets.cfm>, or for additional info email Paula McKeever, Office of Critical Path Programs, at paula.mckeever@fda.hhs.gov.

FDA PART 15 ESUBS MEETING PARTICIPANTS

A partial list of those who presented comments to the FDA at the Dec. 18 meeting:

S. Albert Edwards, Pharm.D. Director, Regulatory Affairs, TAP Pharmaceutical Products

Thomas W. Littlejohn, M.D., Medical Director, Piedmont Medical Group

Doug Pierce, President, Piermed

Ron Celeste, Thin Spring

David Hardison, Vice President, Life Sciences, SAIC

Wayne Kubick, Senior Vice President, Lincoln Technologies

Kristine Jacobson, Surety

Nancy Smerkanich, Vice President Regulatory Affairs, Octagon Research Solutions

Marc J. Scheineson, Alston & Bird

Debra Bremer, Vice President Development and Medical Informatics, Pfizer

Diana McKenzie, Executive Director, IS, Amgen

Ed Tripp, Program Director, eSubmissions, Abbott Laboratories

Bill Rosen, Executive Director, eHealth Policy and Standards, Pfizer Global R&D

LEVERAGE RISK, EXPERTS ADVISE...(from Page 1)

risk for medical devices, “AAMI TIR-32: Medical Device Software Risk Management.”

The 65-page report “could have been three times that length but we had to hack it down,” Vogel said.

“What came out of that, and changed the way we do business here, was seeing clearly the value of starting very early doing preliminary risk analysis and risk management planning,” Vogel said. “It is amazing how much valuable information you can get early on in risk analysis and management that will help you avoid having to go back and do a lot of redesign work,” Vogel said.

Vogel now works with a mix of early stage and small device companies, along with some top 25 devicemakers. The big companies generally recognize that they are more likely to be enforcement targets if they mess up risk analysis or management, Vogel said. “The FDA is not likely to focus on a small company and put them out of business” for flawed risk efforts, he said. Instead, the agency is more inclined to go after a bigger company with bigger fines – and bigger headlines.

But while the fines are relatively small for large companies that have deep pockets, getting risk analysis and management wrong can have “significant repercussions,” Vogel pointed out. For example, they can mean a product recall.

But lack of specifics from the FDA is making it tougher for regulated life sciences companies, said Brian Babineau, an analyst with The Enterprise Strategy Group. “Industry wants more specifics because no one knows what to expect” from the agency in terms of expectations and enforcement. “The more [the specifics of risk] is left open to interpretation, the more confusion” it generated for everyone, he said.

Waiting for granular risk specifics from the FDA may not be the best approach. Many close to and even inside the agency have said in recent months that drug and device companies should already know how to assess and manage their own risk situations without major agency input. Or, as an upper-level FDA compliance official told us recently, “We think there is plenty of guidance already on risk and Part 11-related compliance. Anyone who says there isn’t is stalling or selling someone something!”

Big pharmaceutical companies are having success tackling risk by approaching it like a process, said Kazeon CEO Sudhakar Muddu. His firm has worked closely with several major pharmaceutical players with their Data Security solution, the Kazeon IS1200-ECS, Muddu said. The product scours laptops, desktops and corporate networks for non-public personal data located anywhere on the network. It can then red-flag sensitive data that is at risk and/or in non-compliance with industry regulations like 21 CFR Part 11, he said.

“It’s a simple search concept like Google,” he said. But it allows users like regulated drug and device companies to create a special package where key FDA-related words are found, and it produces its own reports on findings to provide an early warning non-compliance or edata breach risk, Muddu said.

But FDA enforcement, or lack thereof, is not likely to change anyone’s habits anytime soon, Babineau said. “I don’t know that we’ll really see any enforcement until the final Part 11 rule is issued,” he said, noting that it has been delayed several times already. Current best guesses from sources close to the agency put its release at late first quarter or early second.

Vogel and others, however, stress that smart companies aren’t waiting for the FDA to clarify its own risk expectations. By constantly focusing on risk, you end up with a safer product and cut down on development time, Vogel noted. If you’ve done a good job early on your risk analysis it also helps shave time and costs off subsequent design and testing efforts. It also helps you to better budget where time and money should be allocated for testing and where you don’t need it so much, he said.

Vogel will lead an Edata Integrity Report audioconference “Risk Management: Lessons Learned from the Device Industry,” on March 14. For more information go to:

www.edataintegrityreport.com and click the Audio Resources link.

Comments Sought on Electronic Health Record Standards

There's still time to submit comments that could impact final recommendations on the best model standards to prevent claims errors and better detect fraud for use in electronic health record systems (EHRs).

"We've had tremendous participation already from a wide range of professionals," project manager and RTI International Senior Research Scientist Colleen McCue, told *EIR*. The six-month EHR project was awarded to RTI by the Office of the National Coordinator for Health Information Technology, a division of the Department of Health and Human Services.

Most of the comments have come from professional fraud investigators, physicians, healthcare providers, and emergency medical workers, she said. But drug and device company personnel are also weighing in and seem to be focusing on how provider payments for services can be made faster and more efficiently.

Comments are being reviewed as they come in by the Model Requirements Executive Team (see **M-RET Executive Team**, right). They'll issue their final recommendations in March.

"Currently, most billing errors or fraud is detected after payment is made, which makes dealing with the claims very inefficient for both the provider and the payer," McCue said. "EHR systems will allow for the opportunity to cor-

rectly bill from the very beginning, which will help physicians to receive accurate payments and ultimately reduce fraud." (See box, below, **The Value of EHRs for**

Clinical Practice).

To file a comment, register at <http://ehrantifrauddev.rti.org/>

M-RET Executive Team

Donald W. Simborg, MD, Chairman

Susan Hanson, MBA, RHIA, FAHIMA, Executive Coordinator

Preventive Workgroup

Reed Gelzer, MD, MPH, CCHC Advocates for Documentation, Workgroup Chairman Integrity and Compliance, Robert Burleigh, CHBME, Brandywine Healthcare Services, Rebecca S. Busch, RN, MBA, CCM, CBM Medical Business Associates, Jamie Ferguson, Kaiser Permanente, Lawrence Hughes, JD, American Hospital Association, Holly Louie, CHBME, BSN, Practice Management, Matthew McMullen, PhD, JD, Centers for Medicaid and Medicare Services, Blackford Middleton, MD, MPH, MSc., Partner's HealthCare Systems, Wes Rishel, Gartner Group, Susan Turney, MD, MS, FACP, CMPE Wisconsin Medical Society

Retrospective/Prospective Workgroup

A. John Blair, III, MD, Workgroup Chairman, Taconic IPA, Rebecca S. Busch, RN, MBA, CCM, CBM, Medical Business Associates, Bonnie Cassidy, MPA, RHIA, FAHIMA, Cherry, Bekaert & Holland, Christopher Dorn, United Health Group/Ingenix, Byron Hollis, Esq., CFE, AHFI, Blue Cross/Blue Shield of America, Richard Ingraha, SAS US Commercial, Holly Louie, CHBME, BSN, Practice Management, Matthew McMullen, PhD, JD, Centers for Medicaid and Medicare Services, Louis Saccocio, National Health Care Anti-Fraud Association, James Speros, JD Veterans Health Administration, Alan Yuspeh, JD, MBA, Hospital Corporation of America (HCA)

The Value of EHRs for Clinical Practice

Kazilonis Family Practice: Achieved \$9,000 savings annually on transcription costs, sees more patients, morale is higher.

Boise Kidney & Hypertension Institute: Streamlines patient's visits down to ten minutes, from 25.

Treat & Release Center University Physicians Group: Achieved \$57,000 in savings on paper and printing costs, office rental income for the space formerly used to store charts, and improved reimbursements thanks to more accurate coding.

Proctor Family Health: Increased gross revenues in six months that paid for system 1.5 times.

New York Heart Center: Eliminated transcription costs in 60 days, saving \$300,000 while improving care delivery.

Source: Nicholas Spanakis, National City Healthcare Business Banking, www.nationalcity.com

P&G EXPERT: DIGITAL SIGNATURES OFFER 'FIRST' EDATA INTEGRITY

Digital signatures offer “for the first time ever,” real edata integrity for FDA regulated life sciences companies to safely share information electronically, user and advocate Kay Bross, Senior PKI Specialist, Information Security & Solutions at Procter & Gamble, told *EIR* Jan. 10.

Signatures become much more important if the FDA decides to inspect a company, Bross pointed out. “The FDA will say point blank that when an esub is sent, they don’t care who signs it as long as it is signed. But at the point of the investigation, they begin to care a lot about the signatures.”

Bross, co-chair of DIA’s 20th Annual Conference for Electronic Document Management: Reconnecting the Process to the Delivery of Safe and Effective Medical Products in Philadelphia Feb. 6-9, will present a case study about implementing the SAFE Digital Signature using Adobe v7. SAFE BioPharma Association CEO Mollie Shields-Uehling will also present with Bross at a postconference workshop. Questions for the panel can be sent in advance of the event with the subject line “Questions for the Digital Signature Postconference Workshop,” to Joanne.wallace@diahome.org.

“It’s an important conference,” Bross said. With the entire industry going more electronic, attendance has climbed each of the past several years, she added. The conference also benefits from heavy FDA participation, and the candor of

vendors who participate on panels, Bross noted. “We really stress candor, some of the best feedback comes from learning why something didn’t quite work well, or why it failed.”

It is critical, however, to understand the difference between a digital and an esignature, Bross stressed. “All digital signatures are electronic, but not all esignatures are digital,” she said.

A digital signature requires specific infrastructures to support it, a private key to encrypt it and a public key to decrypt it, she noted. “It provides dual authenticity” allowing the sender and receiver to know that the edata was not tampered with and also was sent by the person purporting to send it, she said.

“That tells me as the recipient of a digitally signed document that if I try to validate it and the signature (of the sender) is not valid, then either the credential of the sender was not valid when used or the file has been tampered with...that is invaluable,” Bross said. Among other huge benefits, Bross said digital signatures provide real audit trail capability to prove you have edata integrity.

Esignatures typically use single-factor authentication. The most common approach is a password, something only you know. Digital signatures use two-factor authentication or strong authentication (“something you know and something you have”). The “something

you know” is usually a password, and “something you have” is a device such as a hardware token that protects the credential you use to sign electronic documents

Bross is also a big advocate of the SAFE BioPharma Association’s initiative. SAFE is a member-governed, not-for-profit enterprise that manages and promotes the SAFE standard, provides a single standard for digital identity and signatures across the industry. It provides a single process, signing experience and signature block for the end user and a single standard for vendors to SAFE-enable applications. Further, because of the contract basis, it provides a legal, technical, regulatory and risk framework for the industry.

When you sign a document with a SAFE digital signature, you need a SAFE credential and a passphrase. The credential is stored on either a USB token or a “SmartCard”, depending on how it was issued to you. (Some companies use tokens, and others use “SmartCard” identity badges and integrate the SAFE credential onto the badge.)

SAFE provides an online credentialing process called Registration and Certificate Configuration Authority (RACCA). RACCA includes a step where you prove your identity, either by visiting a notary public with appropriate forms of identification or through a RACCA Trusted Agent. RACCA requires this step before issuing your SAFE credential. Other credentialing processes have similar activities.

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NEW EDISCOVERY RULES CLOUD COMPLIANCE PICTURE

While the jury is still out, so to speak, on the impact of their actual content, the very issuance of new federal rules covering ediscovery should convince FDA regulated life sciences companies to devote more time and attention to their policies in this area.

“The new rules are not that big a deal” in what they contain, because they basically are codifying what was already common sense, said Elizabeth Charnock, CEO at Cataphora, a silicon valley software and services company that works closely with many drug and device firms.

The amendments to the Federal Rules of Civil Procedure went into effect December 1, 2006. Some of the rules had already been adopted in several states, including California, Texas and New Jersey. At their core, the new rules require corporations to be able to produce documents in legal cases or face serious financial and legal penalties.

“These rules place tighter time-frames on the production of electronic information, but they also provide a rationale to look more closely at how corporate data is archived,” said Jane Brandt, an attorney with Thompson & Knight.

Drug firms are generally further along in crafting comprehensive, proactive policies to deal with ediscovery issues, Charnock noted. That’s probably because they tend to be bigger companies and are more “popular” targets for law-

suits, she added. But generally speaking, companies of all stripes are not anywhere near as prepared for ediscovery issues as they should be, recent polls suggest (see box, below).

She’s heard of consumer plaintiff attorney’s that have giant whiteboards in their offices with the dates new drugs have or will reach the market. The goal: To be ready to organize and file class-action lawsuits against the companies that make those drugs on Day One.

The wise advice for drug and device companies is to address edata recovery and retrievability issues as early in the cycle as possible, she says. Her firm offers a service

where it can help drug and device companies rank their edata and determine how much of it can be stored offsite with her company, freeing up space. Often Cataphora can take 90% of the data it screens, she said.

“We have large customers with huge amounts of edata laying around,” she said. Some of that edata is clearly needed for regulatory compliance or other operations, but much of it is just sitting there because “storage is cheap,” Charnock says.

To look at the official rules, go to <http://www.uscourts.gov/rules/Reports/ST09-2006.pdf>.

SURVEY(S) SAYS...

AIIM heard back from 820 end users on records management issues and emerged with these discouraging findings:

- Barely one-third (36%) have a formal policy related to litigation readiness
- Less than half (47%) have “no spending planned” related to managing info related to ediscovery and litigation support
- Not quite half (48%) even have a statement in their employee manual related to employee responsibilities associated with records and information management

A recent report conducted in conjunction with the IT Compliance Institute and *Chief Executive* magazine, heard back from nearly 400 senior executives—including more than 250 CEOs—from corporate America. Coming from a wide range of industries, these executives span finance chiefs, business unit heads, legal counsel and compliance specialists, all of them with the authority to have a major impact within their enterprises. Their findings weren’t much more encouraging:

- Nearly one-third (29.5%) said IT compliance was a necessary function that “lacks adequate resources”
- Nearly 40% say their company’s IT execs don’t understand the current regulations well enough to effectively implement compliance technologies and policies
- More than 40% worried that the “failure to adequately archive and manage ALL electronic content represents a liability” for their company
- Not quite half (47.7%) said their company currently had a specific corporate policy covering record management covering federal regulations like Sarbanes-Oxley

CROs REMAIN WARY OF EDC...(from Page 1)

chance” to stick with paper if the sponsor shows any openness in that direction. In his view, many CROs still don’t see the “untapped opportunities” EDC presents for them.

“Half of CROs admit publicly they don’t like EDC, and maybe 80 percent feel that way privately,” one EDC vendor told us. “More are leery than confess it.”

“Everybody is wary of EDC,” says Bill Cooney, President and CEO of MedPoint Communications. His company helps Sponsors, CROs and others get trained on the nuts and bolts application of EDC. “It’s generally recognized that the healthcare industry is the last mega-industry to adopt informatics,” he noted.

Adopting EDC, though it has value, is obviously “a difficult adjustment that is painful,” for many in the industry, Cooney said.

For starters, it can be a way to leverage their operational expertise and perform the same number of trials in less time. Using EDC will allow some CROs to be able to have more flexible staffing, and even cut some positions and save money in the process, he said.

But he allows that many CROs still aren’t through the “learning curve” when it comes to EDC. “CRO sales people aren’t comfortable with pitching EDC yet,” he added.

But CRO’s wariness may go be-

yond that, others speculated.

“Some CROs are leery of it because they fear losing billable hours to EDC’s efficiency,” a VP at a firm that partners with CROs by offering them EDC services on trials, told us. “They are closing their eyes and hoping it goes away.” That’s a mistake, he adds, but an understandable attitude.

CROs need to “get on the EDC bus or get bypassed”
Scott Houton, President of Clinical Packaging and Logistics. (Formerly Vice President at Quintiles).

CROs may have also had bad technology-related experiences with EDC a few years back and remain stung by the experience, noted Rick Piazza, VP Product Strategy at eTrials. “People [at some CROs] still think those old obstacles exist, when EDC’s technology has improved a lot in the last several years,” he said. He agreed with Seguire that CROs leveraging EDC stand to do things less expensively and increase their margins.

Technology aside, EDC’s history of perhaps overpromising has left a bad taste in the mouths of some CROs, others speculated.

“CROs feel EDC is disruptive and doesn’t always meet its promises,”

Cooney said. He’s seen it from a training perspective when there is good effort at the study launch, but not enough training follow-up.

And some of those big promises began years ago when EDC vendors, proponents and others overstated how fast and how easily EDC would be adopted.

Piazza said he believes that about 30 percent of all trials use EDC today and that predictions of 50 percent in 2007 sound “about right.” That said, he notes he’s heard similar predictions for “about ten years, but I think it’s right now.”

Ultimately, CROs may not have much choice about incorporating EDC into their offerings. “If the market wasn’t pushing it, CROs wouldn’t adopt EDC...but the market *is* pushing it,” Rogers said.

Piazza said he’s a bit more encouraged by the recent rate of CRO adoption of EDC. “About two years ago [the attitude] really changed, it’s like a switch was flipped” and at least some CROs are now even seeking out EDC and EDC partners for trials, he said.

Next Issue: How are some CROs more effectively leveraging EDC? Is EDC being overhyped? A look at its true plusses and minuses.

Editor’s Note: CROs are invited to contact us with their EDC views (on or off the record) at 703-318-0147.

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Industry* with David Vogel, PhD, President, Intertech Engi-
neering Associates at 1:30 p.m. on March 14

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Forget FDA, Part 11 Business Case Clear, Expert Says

Sure the FDA may never inspect your facility, and maybe the FDA will never seriously enforce its 21 CFR Part 11 record integrity rules. But smart companies are nevertheless moving ahead with their own business-case driven compliance programs. Here are some reasons why:

- If you are a drug company, the immediate goal of drug discovery is a patent filing, notes Patrick Coffey with Coffey Analysis. "Compliance with Part 11 will ensure that you have full support for patents," he notes. That's because you'll be able to supply the exact records needed to support your filing and any patent dispute.
- Part 11's requirements, though much-maligned when they first came out in 1997, are based on "common sense and good workflow," Coffey notes. "Part 11 may be a regulatory process, but it is also a set of guidelines for improving the security and efficiency of your discovery-stage workflow."
- Another point: The "lines" between drug discovery and development are not that clear-cut, and drug candidates often float between the two stages, Coffey says. So, if your discovery process is Part 11-compliant, the transition to Part 11-compliant development will be much easier – faster and cheaper.

Coffey also advocates the use of biometrics to enhance esignature security. While the FDA does not require biometric signatures as part of Part 11 compliance, going that route makes compliance much easier, Coffey says. He suggests using low-cost (around \$150) fingerprint authentication devices that plug into a USB port or can be built into a computer mouse or keyboard.

For more info, go to www.coffeyanalysis.com.

EDATA MATTERS

IT Adoption Lags at Small Physician Practices

Larger physician practices have been the earliest adopters of IT while overall industry adoption has remained slow, says a new survey from the Center for Studying Health System Change. The bad news continues because more than half of all physicians surveyed in 2005-6 worked in smaller practices where the rate of IT adoption is worse, the survey says. “Small and safety net practices may be left behind even as adoption accelerates among larger practices, widening the adoption gaps and, potentially, disparities in the quality of care among patients,” warns the survey’s accompanying Issue Brief. To see the entire brief, go to www.hschange.org

Thin-Client Applications Face Higher SOX Compliance Hurdles

Despite some signs that its demands will be lowered, Sarbanes-Oxley remains a formidable law that demands serious compliance attention, says a new white paper from Interwoven. Compliance is especially difficult in the case of thin-client applications, because those are managed in a complex and dynamic browser environment spanning multiple systems, servers, and workgroups, Interwoven says. The company advocates content provisioning as the silver bullet for compliance. To view the full white paper, go [here](#).

Ignoring Risk too Risky, Deloitte Says

It takes intelligence to navigate risk, says a new white paper from Deloitte Consulting. Specifically, “risk intelligence.” Deloitte’s white paper outlines risks in the life sciences industry that arise around definable initiatives and occurrences, dubbed “life events.” The report also includes a hypothetical case study highlighting how a risk intelligent approach can mitigate risk for life sciences companies. Key to success: Making sure risk management is an organizational-wide responsibility and competency. To get a free copy of the report, go to www.deloitte.com/riskintelligence.

Frost & Sullivan: Drug Makers Need More Automation

Drug makers fighting tighter margins and increasing regulatory and edata validation demands are likely to lean more and more on good software vendors and smart automation, says a new analysis from Frost & Sullivan. Strict regulatory approvals are making it tougher to introduce new drugs into the marketplace, the analysis says. It notes that Process Analytical Technology (PAT) is “encouraging pharmaceutical manufacturers to adopt innovative technologies without fearing validation risks and production delays, thereby fueling demand for automation and software solutions.” To get more information about the full report, email tori.foster@frost.com with your full name, company name, title, phone and fax numbers and email address.

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