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FDA Updates Recommendations For Cleaning Duodenoscopes

Following the outbreak of infections related to a deadly super-bug, the FDA has provided new guidelines to help healthcare facilities ensure their duodenoscopes are cleaned adequately.

Duodenoscopes gained intense media scrutiny after reports of antibiotic-resistant infections in Chicago, Pittsburgh, Seattle and Los Angeles. Earlier this year, the FDA revealed that between January 2013 and December 2014, it had received 75 reports involving about 135 patients suffering from carbapenem-resistant Enterobacteriaceae transmissions linked to these devices.

The FDA acknowledges that the duodenoscope's unique design is useful for performing endoscopic retrograde cholangiopancreatography procedures. This utility has its drawbacks, however, as the device has small working parts, including a moveable elevator

*(See **Duodenoscopes**, Page 2)*

FDA Updates Checklists For Accepting 510(k)s

With an eye toward encouraging quality applications for review, the FDA has provided an update on what information it needs from sponsors to determine whether a 510(k) submission meets a minimum threshold and thus may be accepted for substantive review.

Issued Aug. 4, the new FDA guidance updates a 2012 document and is intended to explain the refuse-to-accept policy for 510(k)s. As part this policy, the FDA reviews an application and within 15 calendar days should inform the company whether the submission is administratively complete or if additional elements are needed.

“In order to enhance the consistency of our acceptance decisions and to help submitters better understand the types of information FDA needs to conduct a substantive review, this guidance, including the checklists included in the appendices, clarify the necessary elements and contents of a complete 510(k) submission,” according to the document.

*(See **Refusal**, Page 2)*

Duodenoscopes, from Page 1

mechanism with tiny crevices. This elevator is particularly difficult to clean and disinfect properly, even if a healthcare professional adheres to a manufacturer's instructions for use.

"Meticulous adherence to the manufacturer's reprocessing instructions is labor-intensive and prone to human error," according to the agency, meaning there is a high possibility contaminants remain despite best efforts on the part of staff.

To combat the threat of infection transmission, the FDA is recommending facilities adopt the following supplemental measures: microbiological culturing, ethylene oxide sterilization, use of a liquid chemical sterilant processing system and repeat high-level disinfection.

"We recognize that not all healthcare facilities can implement one or more of these measures, which require specific resources, training, and expertise," according to the FDA. While this may be the case, it is still critical that those professionals in charge of reprocessing the devices have instructions for use at hand and remain proficient in performing all reprocessing steps.

In addition to the supplemental measures, the agency is urging healthcare facilities to adopt the following best practices:

- Meticulously clean the elevator mechanism and recesses surrounding it by hand;
- Implement a comprehensive quality control program for reprocessing duodenoscopes; and
- Review reprocessing recommendations from a consensus document from the American Society for Gastrointestinal Endoscopy and the Society for Healthcare Epidemiology of America.

The FDA notes that it is monitoring the situation and evaluating information from the healthcare community, adverse events reports and other sources. It also is partnering with The Joint Commission, the nation's largest hospital accreditation

body, and the Centers for Medicare & Medicaid Services to bolster hospitals' adherence to duodenoscope cleaning instructions. In addition, the agency says it is working with industry as it modifies and validates instructions for cleaning duodenoscopes.

The new guidelines were developed as a result of lessons learned at a May meeting of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee. At the conclusion of the two-day meeting, panelists determined that current methods of cleaning duodenoscopes do not provide a reasonable level of safety and effectiveness (*IDDM*, May 15).

To read the FDA's safety communication, visit www.fdanews.com/081015-duodenoscopes-fda.pdf. — Elizabeth Hollis

Refusal, from Page 1

As part of the update, the agency has added guidance documents and other resources that industry may use when preparing regulatory submissions. It also has streamlined the checklists in the appendices covering traditional, abbreviated and special 510(k)s.

Some sections have been either eliminated or incorporated in other parts of the list. One change is the elimination of a section requesting companies include a form for each national or international standard referred to in the application to demonstrate substantial equivalence for traditional 510(k)s. That checklist adds to the section on sterilization, which now includes options for devices not requiring a sterility status, such as, software-only devices, and for those products whose sterility status is unclear.

The guidance, which goes into effect Oct. 1, will supersede three previous documents: 2012's "Food and Drug Administration's Refuse to Accept Policy for 510(k)s," 1993's "Premarket Notification (510(k)) Refuse to Accept Policy" and 1994's "510(k) Refuse to Accept Procedures (K94-1) blue book memo."

To read the guidance document, visit www.fdanews.com/081015-refuse-to-accept.pdf. — Elizabeth Hollis

Promoting Interoperability Between In Vitro Devices, Database Systems

How can U.S. healthcare regulators encourage stakeholders to adopt standards related to the reporting of laboratory data? That question will be the focus of a fall workshop led by the FDA, Centers for Disease Control and Prevention and the National Library of Medicine.

Scheduled for Sept. 28 at the FDA's White Oak campus in Silver Spring, Md., the workshop will focus on ways to promote the semantic interoperability of laboratory data between *in vitro* diagnostic devices and database systems, including laboratory information systems and electronic health records.

Semantic interoperability refers to the ability of two or more systems to exchange and use information. It represents the highest level of interoperability, according to the Healthcare Information and Management Systems Society, a nonprofit focused on improving care through information technology.

Tracking Challenges

"Much of laboratory information is directly generated by medical devices and, as such, should be readily amenable to standardization that would enable semantic interoperability; however, significant challenges exist both in the adoption of standards by device manufacturers and implementation by clinical and public health laboratories," according to an Aug. 3 *Federal Register* notice announcing the meeting.

The federal bodies are particularly interested in obtaining feedback from individuals representing laboratories, industry, government, academia and healthcare, as well as others involved in developing interoperability standards. Participants will discuss specific models for semantic interoperability, such as Logical Observation Identifiers Names and Codes for identifying laboratory tests, Systemized Nomenclature of Medicine-Clinical Terms coding sets for describing qualitative test results and Unified

Code for Units of Measure for quantitative results. The use of unique device identifier codes, as well as mechanisms for distributing device coding information, such as Structured Product Labeling or Electronically Exchanging Directory of Services, also will be covered.

The FDA, CDC and NLM plan to develop a summary of issues to be discussed at the meeting to be posted online. Interested parties may submit comments for presentation through Sept. 18. Comments will be accepted for the *Federal Register* announcement through Sept. 28.

To view the notice, visit www.fdanews.com/081015-fda-workshop.pdf. — Elizabeth Hollis

New ANVISA Head Reveals Priorities

Ensuring that agency staff is adequately trained, promoting the use of best scientific practices and improving communications with the public are three of the goals the new head of Brazil's healthcare regulator is promising to tackle during his tenure.

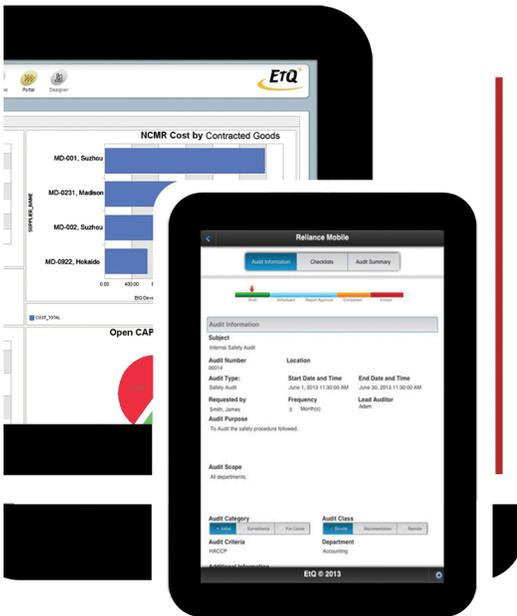
Jarbas Barbosa da Silva Jr. took the helm at Brazil's Agência Nacional de Vigilância Sanitária late last month. Before assuming the role, he served as secretary of science, technology and strategic products at the Brazilian Ministry of Health, a position he assumed at the beginning of the year, previously holding the position of secretary of health surveillance.

During his inauguration ceremony, da Silva praised ANVISA for strides in terms of improving health over the past 15 years. He highlighted a recent update of clinical research rules as one of the ways the agency should approach its work moving forward.

Arthur Chioro, Brazil's minister of health, spoke highly of da Silva, adding that he is taking the reins as the agency works to enhance transparency with stakeholders and improve its technical and scientific innovation. — Elizabeth Hollis

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FDA Alerts Providers About Adverse Events with LVADs

The FDA is reminding healthcare providers that pump thrombosis, strokes and bleeding events are complications that can result from using implantable left ventricular assist devices on certain heart failure patients. Currently, Thoratec and HeartWare are the only companies marketing such devices in the U.S.

While acknowledging that LVADs are life-sustaining devices whose benefits can outweigh their risks, the agency says in a safety communication that providers should conduct a thorough clinical evaluation when considering these devices for patients. It encourages them to return explanted devices to help manufacturers determine why adverse events occur.

Adverse Events

Specifically, the FDA highlights an increased rate of thrombosis events in patients implanted with Thoratec's HeartMate II LVAD, which is approved as a bridge-to-transplant therapy for those at risk of imminent death from nonreversible left ventricular heart failure and awaiting a transplant. It also is approved as a destination therapy for end-stage patients who are ineligible for a transplant.

The agency cites the analysis of scientific literature showing that the HeartMate II's thrombosis rate was as high as 8.4 percent of implanted devices at three months and 6 percent at six months. Those numbers are higher than those seen in clinical studies — 1.6 percent in the BTT trial, and 3.8 percent in the DT trial.

With HeartWare's HVAD, which only has the BTT indication, the FDA says there is an increased stroke risk in patients implanted with the device for the DT. "Investigators reported 28.7 percent of HVAD patients experienced one or more strokes over two years, compared to 12.1 percent among patients implanted with the control device (HeartMate II)."

That information comes from clinical trial results intended to demonstrate the safety and effectiveness of the device in the DT indication.

In addition, there have been reports of patients experiencing bleeding complications after being implanted with both the HeartWare and Thoratec devices. The agency says it the cause of the bleeding isn't understood, adding that modification to the blood thinning therapy to lower the risks of thrombosis and stroke could be a factor.

Last month, St. Jude Medical offered to buy Thoratec in an all-cash transaction valued at about \$3.4 billion (*IDDM*, July 24). The HeartMate II was touted as making Thoratec as an attractive acquisition target. Medtronic, Abbott and Johnson & Johnson were mentioned as potential suitors that could woo Thoratec away from St. Jude during a 30-day "go-shop" period.

At least one analyst group doesn't think the FDA's announcement will have an impact on the deal. The information isn't new, according to a Wells Fargo communication. "We do, however, believe that it highlights the need for new and better devices with improved adverse event profiles like [Thoratec's] HeartMate 3 and [HeartWare's] MVAD," according to the group.

Neither company responded for a request for comment by press time. — Elizabeth Hollis

Wanted: Medical Device Volunteers for IMDRF Pilot

Medical device companies looking to get their products approved in more than one jurisdiction are being sought by the International Medical Device Regulators Forum.

IMDRF, a multinational group of device regulators working to harmonize global standards and regulations, is seeking volunteers for a pilot project to evaluate table of contents structures for premarket applications. The ToC documents are expected to be used by companies when filing medical device submissions to multiple regulators. They define the location for both IMDRF and regional content for all submission types.

Slated to begin this September, the pilot is expected to remain open for 12 months, with an eye on finalizing findings by November 2016.

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IMDRF, from Page 5

The pilot's objectives, according to an IMDRF document, are the following:

- Develop and validate documentation supporting the use of the IMDRF ToCs, based on industry feedback;
- Identify possible industry challenges and develop ways to address them;
- Provide industry and regulators with the opportunity to use ToCs with real submissions in a controlled setting;
- Evaluate the proper usage of the ToC headings, including the appropriate placement of documents within the headings and submission of complete and relevant content;
- Identify additional ToC harmonization opportunities; and
- Establish and ensure ToC pilot technical guidelines are fit for purpose, and to the extent possible, are harmonized among all of the players.

Australia, Brazil, Canada, China, the EU and the U.S. are participating in the current pilot. A previous ToC pilot used historical submissions for products, but, at the time, there were no guidelines for building a regulated product submission. IMDRF is looking to develop a Health Level Seven Regulated Product Submission exchange standard to serve as the international standard for medical device and human pharmaceutical submissions.

Parties may send an e-mail in English by Aug. 21 to imdrftoc@gmail.com indicating their interest in the program.

Several IMDRF countries are conducting corresponding regional pilots. Brazil's Agência Nacional de Vigilância Sanitária, for example, is encouraging parties to indicate their interest by copying toc.pilot@anvisa.gov.br in their request to IMDRF.

To view the IMDRF document explaining the pilot, visit www.fdanews.com/081015-imdrf.pdf.
— Elizabeth Hollis

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DIA

FDA Warns of Cybersecurity Vulnerabilities with Hospira's Symbiq

The FDA is cautioning healthcare facilities on the use of the discontinued Symbiq infusion system after the manufacturer and an independent investigator determined that unauthorized users could gain access to the pump through a hospital network.

In a notice posted to its website, the FDA says Hospira and the researcher have found that a cyber intruder could change the dosage of the pump delivers, causing an over- or underinfusion of patient therapies. While there have been no reports of adverse events related to the use of the pump, which can communicate with a hospital's information system through a wired or wireless connection, the FDA is encouraging facilities to transition to an alternative as soon as possible.

For those facilities still using the systems, the FDA is advising that they disconnect the devices from the network. It warns of potential issues associated with this task, such as having

to update drug libraries manually — a time-intensive process that could lead to errors.

Hospira no longer manufactures or distributes these systems, due to factors unrelated to cybersecurity. However, third parties still may be selling Symbiq, and the FDA is strongly discouraging hospitals from buying these systems from them.

This is not the first time federal officials have warned of cyberthreat posed by a Hospira device. This past spring, the Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team issued an advisory warning to users of the LifeCare PCA infusion system that the device may be vulnerable to a cyberattack.

In a case similar to the Symbiq vulnerability, the LifeCare weaknesses involve user authorization and verification of data authenticity, which could allow hackers to access the pump's controls and alter the type or amount of drug dispensed (*IDDM*, May 6). — Elizabeth Hollis

Expert Advises Device Industry To Pick Up Social Media Pace

Medical device companies and big pharma need to be more proactive in terms of utilizing social media. That's according to one expert who spoke at a recent FDAnews webinar.

Peter Pitts, a former FDA official and an executive partner at YourEncore, says that over the years, both industries have displayed reluctance in adopting social media. They point to reprimands, including an April 2009 warning letter to 14 pharmaceutical companies over sponsored links seen in Internet searches and a 2008 caution on a YouTube promotion. He says that there was a "secret sigh of relief" by members of industry who thought they could avoid social media as a result of the FDA's actions.

Not so fast, says Pitts. He tells *IDDM* that many companies think tending to social media

sites is just too hard. They believe it requires an additional full-time employee, and there are many legal and regulatory implications that can affect what they post. "Social media is 24-7," he says, and that intimidates companies.

But whether it's a tweet or a Facebook posting, pharmaceutical and medical device industries need to get with the times. And it's pretty simple, says Pitts — companies need to make sure that they tell the truth. "Truthful, accurate and transparent—those are three good rules of thumb," Pitts adds.

In terms of third-party posts, Pitts cautions companies against liking a statement that exaggerates the effectiveness of a device. "Liking a violative statement on your platform is violative behavior," he explains.

For incorrect statements on third-party sites, sometimes it's in the best interest of public health

(See **Pitts**, Page 8)

Pitts, from Page 7

to clear up a wrong assumption or misinformation — especially if a post overstates a product's effectiveness. In 2014, the FDA issued draft guidance on this topic, in which it says companies generally aren't responsible for third-party communications posted on outside websites or platforms. It says that firms may voluntarily correct misinformation — an action Pitts backs.

He adds that companies don't have to be vigilant all of the time, even when it comes to previously corrected pages. If companies act appropriately and work on addressing the misinformation, they will not be held responsible in the future.

That said, it's in a company's best interest to keep records on any corrective actions it has undertaken.

FDA Actions

The FDA's attention to social media posts is unique, Pitts tells *IDDM*, adding that the situation in other countries isn't the same.

The FDA has released guidance documents intended to help industry. For example, in 2011, it unveiled draft guidance on addressing unsolicited requests for off-label information related to both drugs and medical devices. It came in the wake of a citizen petition filed by seven drugmakers seeking clarification on the topic. That document has yet to be finalized.

It also has released guidance on fulfilling requirements for postmarketing submissions of interactive promotional media. Pitts says FDA draft guidance issued last year on Internet or social media platforms with character space limitations has brought a lot of comments. For example, the 510(k) Coalition urged the FDA to develop a strategy for space-restrictive platforms for medtech that is distinct from pharmaceuticals.

"[T]he majority of medical devices are used as 'tools' to assist healthcare professionals and patients in treating or diagnosing disease but do not, themselves, provide therapy," the group says

in its comments. "These products do not fit into the 'drug model' that forms the basis for the draft guidance."

The comments also question the assumption that users will make clinical decisions based on a tweet or a banner ad.

In separate comments, industry trade group AdvaMed agreed that devicemakers need to provide appropriate risk information within social media platforms. That said, "care must be taken with a one-size-fits-all approach," the group adds.

"We are concerned that device firms will also be in a position of subjectively picking and choosing a specific relevant risk at the expense of others rather than linking more appropriately to a page with fuller information," according to the comments. It suggested that the FDA consider a fair balance of a combination of links with appropriate introductory language, particularly since consumers are used to clicking on links to obtain additional information. — Elizabeth Hollis

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Report Sees Big Growth In Medical Device Staffing

The megamerger trend has had a tremendous — and positive — impact on jobs, according to a new report that found increased headcounts in 2014 for the top medical device companies.

That news come from Evaluate, which analyzes the life sciences industries, through its EP Vantage report titled *Fewer, but bigger: medtech jobs jump thanks to mergers*.

“Not one of the top 15 medtech companies by market capitalization saw a net decrease in staff numbers over the last year,” according to Elizabeth Cairns, one of the report’s authors. “It could be that the economic upturn in the U.S. is making medtech companies more confident of growing sales, and they are hiring accordingly.”

The analysis only looked at companies that received at least 40 percent of their sales from medical technologies. As a result of its divestiture of its Ortho-Clinical Diagnostics business, titan Johnson & Johnson failed to meet the criteria.

Leading the Pack

So, who came out on top? Thanks to its takeover of Covidien, Medtronic is the biggest company in terms of headcount, with more than 90,000 employees at the end of fiscal year 2014. That’s an 88 percent growth over 2013, when the company had 49,000 employees.

When taking out the employees added as a result of the Covidien acquisition, Medtronic’s headcount grew by 3,500, or 7 percent.

Prior to 2014, Medtronic’s staffing was relatively stable over the previous four years, starting at 43,000 in 2009.

Coming in second in terms of year over year growth is Smith & Nephew at 22 percent. Its \$1.5 billion purchase of ArthroCare added about 1,800 jobs last year. Abbott Laboratories, whose staffing has ebbed and flowed, particularly in the wake its 2012 split with AbbVie. Between 2012

and 2013, Abbott saw the number of employees drop from 91,000 to 69,000. It has since rebounded to 77,000, a 12 percent increase.

The rest of the companies in the top 5 are Baxter International, adding 5,000, B. Braun, 4,128, and Essilor International, 2,903.

While St. Jude Medical was the only company whose numbers remained stagnant, that may change if its \$3.4 billion proposed acquisition of Thoratec goes through (*IDDM*, July 24). Zimmer’s acquisition of Biomet, and Becton, Dickinson’s pick up of CareFusion also should continue the trend.

In terms of percentage of staff added, Exact Sciences increased 131 percent, driven by the launch of its colorectal cancer stool test. While not in the top 15 companies in terms of size, Exact’s current headcount stands at 236. Other small companies that saw a big rise are Cogentix Medical, which saw its ranks grow 81 percent to 214.

Tax’s Limited Impact

The increase in staff comes even as Congress works to repeal the medical device excise tax, which many companies say will eliminate jobs. The authors say the tax hasn’t had much of an impact on employment in the device sector.

“It is true that companies had warned that they would have to cut staff in order to meet the tax’s demands, but employment in the medtech sector has remained roughly steady for the last three years,” Cairns tells *IDDM*.

That is particularly true among the larger players, she says, although some companies have had to restructure, blaming the tax.

Earlier this year, industry trade group AdvaMed claimed the 2.3 percent tax is costing the U.S. economy roughly 195,000 jobs since it took effect in January 2013. However, an economic analysis by the Congressional Research Service played down the tax’s impact, putting industrywide job losses at 1,200 or fewer employees (*IDDM*, Jan 30). — Elizabeth Hollis

BRIEFS

NuVasive to Pay \$13.5M over FCA Allegations

San Diego-based NuVasive has settled with the federal officials over alleged violations of the False Claims Act for promoting its CoRoent system for unapproved uses, including severe scoliosis. It will pay \$13.5 million as a result. The government had accused the company of causing healthcare professionals to submit false claims to federal healthcare programs and of paying kickbacks to doctors to use the system. Whistleblower Kevin Ryan, a former employee who helped bring NuVasive's alleged malfeasance to light, will receive \$2.2 million. In a statement, the company says it admits no wrongdoing, adding that resolution of this matter "avoids the time and expense of a potentially lengthy litigation process."

EU Signs Off on Pfizer/Hospira Deal

Pfizer has agreed to divest certain sterile injectable drugs and the biosimilar infliximab program as it seeks to wrap up its \$17 billion buyout of Hospira by the end of the year. The divestitures were established by EU competition authorities to approve the deal. In a statement, Commissioner Margrethe Vestager says these requirements aren't just about keeping prices low, but also about not impeding research and development. Known for its injectable drugs, Hospira also makes infusion pumps, clinical software and intravenous sets. In February, Morningstar analysts Damien Conover and Michael Waterhouse wrote in a commentary that they expected Pfizer would likely sell Hospira's device business. The Federal Trade Commission has yet to grant its final approval of the deal.

Infusion Sets Recalled in Australia

Australasian Medical and Scientific has initiated a recall for product correction for its Contact Detach infusion sets used to deliver insulin. The move comes after a growing number of reports of needles breaking during use. The affected lots were manufactured before May 2014. If a needle breaks during use, it can disrupt the delivery of insulin, leading to hyperglycemia. There is no alarm on the pump to alert the patient and caregiver that the flow of insulin has been disrupted. While the products are not being removed from the market, consumers may have the affected devices replaced for free or using them in conjunction with additional instructions.

Boston Scientific Closes AMS Buy

Boston Scientific has finalized its purchase of Endo International's American Medical Systems men's health and prostate health businesses for \$1.6 billion up-front. That figure could grow with a potential \$50 million milestone payment based on 2016 sales. The AMS businesses will be added to the urology and women's health product portfolios to form Boston Scientific's urology and pelvic health business. Dublin, Ireland-based Endo has said that it wants to concentrate on pharmaceuticals and last week announced a plan to divest a portfolio of device, vaccine and other noncore products from its international subsidiary in South Africa, Litha Healthcare Group. A consortium comprised of Westrate Trade and Invest Proprietary and Immunotek agreed to the deal, which is expected to close in the fourth quarter.

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DAY ONE

8:00 a.m. – 8:30 a.m. | **REGISTRATION AND CONTINENTAL BREAKFAST**

8:30 A.M. – 9:00 A.M. | **WELCOME AND INTRODUCTIONS**

9:00 a.m. – 10:00 a.m.

I. Software Characteristics Comparing to Hardware

- Understanding the difference between software and hardware
- Understanding software quality and reliability engineering
- Challenges of software risk management and cybersecurity

II. FDA's Analysis of Software Recalls

- What kinds of software issues causing recalls
- What kinds of devices have more software issues
- What are the common types of causes for software calls

10:00 a.m. – 10:15a.m. | **REFRESHMENT BREAK**

10:15 a.m. – 11:00 a.m.

III. Overview of FDA Software & Cybersecurity Related Guidance

- Mobile Medical Applications (Feb 2015)
- Medical Devices Data Systems, Medical Image Storage Devices and Medical Image Communications Devices (Feb 2015)
- Total Product Life Cycle: Infusion Pump (Dec 2014)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Oct 2014)
- FDASIA Health IT Report – Proposed Strategy and Recommendations (April 2014)
- NIST Framework for Improving Critical Infrastructure Cybersecurity (January 2014)
- Radio Frequency Wireless Technology in Medical Devices (Aug 2013)
- General Principles of Software Validation
- Content of Premarket Submissions for Software Contained in Medical Devices
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software

11:00 p.m. – 12:15 p.m.

IV. Overview of Software & Cybersecurity Related Standards

- ISO 14971:2007, EN ISO 14971:2012,
- IEC TR 80002-1 Application of ISO 14971 for Software
- IEC 62304 Medical Device Software Life Cycle Process, IEC 82304 Healthcare Software
- NIST Framework for Improving Critical Infrastructure Cybersecurity, 2014
- ISO/IEC 27001:20013 – Information Security Management
- AAMI/ISO 14971 TIR in Process – AAMI Device Security Group
- Medical IT Networks Safety, Security and Interoperability
- IEC 80001-1 Managing Medical IT Networks and Relevant Technical Reports
- TIR 80001-2-2:2012 – Application of Risk Management for IT Networks Incorporating Medical Devices

12:15 p.m. – 1:15 p.m. | **LUNCH**

1:15 p.m. – 2:15 p.m.

V. Risk Analysis for Medical Device Software

- Preliminary hazard analysis
- Top down analysis, Fault Tree Analysis
- Bottom up analysis – design FMEA, function FMEA, process FMEA, use FMEA, common causes of software failures
- Connectivity analysis between top down and bottom up

2:15 p.m. – 3:15 p.m.

VI. Group Exercise and Review With Instructors – Risk Analysis for Medical Device Mobile Apps

3:15 p.m. – 3:30 p.m. | **REFRESHMENT BREAK**

3:30 p.m. – 4:30 p.m.

VII. Risk Assessments and Risk Controls for Medical Device Software

- Software related risk assessment
- Risk control basics
- Software lifecycle process control measures
- Risk control identification
- Control measures implementation and effectiveness

4:30 p.m. – 5:30 p.m.

VIII. Group Exercise and Review With Instructors – Risk Controls for Software Hazards

DAY TWO

8:00 a.m. – 8:30 a.m. | **CONTINENTAL BREAKFAST**

8:30 a.m. – 9:00 a.m.

IX. Latest Updates from FDA on Cybersecurity

- Understanding the difference between software and hardware
- Understanding software quality and reliability engineering
- Challenges of software risk management and cybersecurity

9:00 a.m. – 10:00 a.m.

X. Cybersecurity Risk Analysis (Assets, Threats, Vulnerabilities)

- Medical device cybersecurity basics
- Asset profiling
- Threat identification
- Vulnerability identification
- Software vulnerabilities
- Attack Tree – top down and bottom up cybersecurity analysis
- Connectivity between cybersecurity risk and safety risk

10:00 a.m. – 10:15 a.m. | **REFRESHMENT BREAK**

10:15 a.m. – 11:15 a.m.

XI. Group Exercise and Discussion With Instructors – Cybersecurity Risk Analysis

11:15 a.m. – 12:15 p.m.

XII. Cybersecurity Risk Assessments and Risk Controls

- Cybersecurity risk assessment
- Cybersecurity risk control basics
- Software lifecycle process control measures
- Cybersecurity capability and requirements identification
- Special considerations for cybersecurity risk controls
- Control measures implementation and effectiveness

12:15 p.m. – 1:15 p.m. | **LUNCH**

1:15 p.m. – 2:15 p.m.

XIII. Group Exercise and Discussion With Instructors – Cybersecurity Risk Assessments and Risk Controls

QUALITY RISK MANAGEMENT FOR MEDICAL DEVICES

ON AND BEST PRACTICES FOR COMPLIANCE

2:15 p.m. – 2:45 p.m.

XIV. Safety and Cybersecurity Risk Analysis Documentation for Stakeholders (FDA Reviewers, Hospitals, etc.)

- Documentation for pre-market submission
- Documentation for FDA inspection
- Documentation for healthcare provider (e.g. hospitals)

2:45 p.m. – 3:15 p.m.

XV. Risk Management Completeness and Effectiveness – Introduction of Assurance Case Method

- Limitations of current risk analysis methods
- Assurance case concept
- How assurance case method can help

3:15 a.m. – 3:30 a.m. | **REFRESHMENT BREAK**

3:30 p.m. – 4:00 p.m.

XVI. Safety and Cybersecurity Assurance Case Examples

- Safety assurance case example for medical device
- Security assurance case example

4:00 p.m. – 5:00 p.m.

XVII. Post-Market Safety and Cybersecurity Risk Management

- Post market risk assessment and evaluation
- MDR assessment
- FDA recall classification — HHE
- Legacy device cybersecurity risk management

5:00 p.m.

Workshop Adjournment

"All instructors were very knowledgeable and had expertise in the industry. Well done."

—May 2014 Workshop Participant

"The class had a good pace. It covered standard risk management well."

—May 2014 Workshop Participant

"[I liked the] small discussion groups and intimate setting"

—May 2014 Workshop Participant

WHO WILL BENEFIT

- Software systems design engineers and managers
- Quality, reliability and risk management engineers and managers
- Project managers involved in design and development
- Medical staff evaluating risk, safety or effectiveness
- Quality managers
- Regulatory affairs specialists and managers
- Medical device app developers
- IT systems development managers
- Contract manufacturers
- General/corporate counsel

MEET YOUR INSTRUCTORS

Fubin Wu is the Co-Founder of GessNet. GessNet is a software and consulting company specializing in medical device risk management (www.GessNet.com). He designed and led the development of TurboAC™ risk management and assurance case software, in concert with the FDA, Association for the Advancement of Medical Instrumentation (AAMI), medical device manufacturers, hospitals and industry experts. Mr. Wu has spent more than 16 years in medical device quality management systems, hardware/software reliability engineering and risk management, serving various roles from quality engineer to quality director.

Lisa Simone, PH. D., works for the FDA as Software Engineering Team Lead and Policy Advisor in the Office of Blood and Research and Review in the Center for Biologics Evaluation and Research (CBER). In this role she leads the software group in review of devices including blood donor screening tests, retroviral diagnostic tests, and software used to test, collect, process, or store donated blood. Dr. Simone also leads the development and review of policy for software in regulated devices.

COURSE BINDER MATERIALS

Each participant will receive a folder and flash drive packed with tools and reference materials in a combination of both electronic and hard copy format you can put to use right away, including:

- Copies of slides from PowerPoint presentations
- Preliminary hazard analysis example
- Fault Tree Analysis example, FMEA examples
- Example of connectivity between FMEAs and hazard analysis
- Risk Summary Traceability matrix example
- Cybersecurity risk analysis example – assets, threats, vulnerabilities analysis
- Safety assurance case example
- Cybersecurity assurance case example
- ISO 14971:2007 and EN ISO 14971:2012, IEC TR 80002-1 Application of ISO 14971 for Software
- IEC 62304 Medical Device Software Life Cycle Process - Risk Management Section
- Cybersecurity in Medical Devices (FDA Guidance, Oct 2014)
- NIST Framework for Improving Critical Infrastructure Cybersecurity (Version 1.0, 2014)
- Software-Related Recalls: An Analysis of Records (by Lisa K. Simone of FDA, AAMI BI&T Nov/Dec 2013 Issue)
- Best Practices in Applying Risk Management Terminology (by Fubin Wu and Alan Kusnitz, AAMI Horizons Spring 2015 Issue)
- Documenting Medical Device Risk Management through the Risk Traceability Summary (by Edwin Bills, Stan Mastrangelo, and Fubin Wu, AAMI Horizons Spring 2015 Issue)
- Reducing Risks and Recalls: Safety Assurance Cases for Medical Devices (by Sherman Eagles and Fubin Wu, AAMI BI&T Jan/Feb 2014 Issue)
- Hazard Analysis for a Generic Insulin Infusion Pump (by Yi Zhang, Paul Jones, and Raoul Jetley of FDA, J Diabetes Sci Technol. Mar 2010)
- Total Product Life Cycle: Infusion Pump (FDA Guidance, Dec 2014)
- IEC 80001-1 Managing Medical IT-Networks and relevant Technical Reports
- Radio Frequency Wireless Technology in Medical Devices (FDA guidance, August 2013)
- Mobile Medical Applications (FDA guidance, September 2013)
- Risk Management In the Design of Medical Device Software Systems (by Paul Jones PL, Biomed Instrum Technol 2002 Jul-Aug; 36(4):237-66)

SOFTWARE AND CYBERSECURITY RISK MANAGEMENT FOR MEDICAL DEVICES

UNDERSTANDING THE FDA'S POSITION AND BEST PRACTICES FOR COMPLIANCE

LOCATIONS AND HOTEL ACCOMODATIONS

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the FDAnews workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. The hotel may require the 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.

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