INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE



## Abbott to Buy St. Jude; Provides Update on Alere Buy

The megamerger trend in the medical device industry is showing no signs of slowing down, with Abbott inking a $25 billion deal to buy St. Jude Medical.

The deal is intended to make the company the number one or two in certain high-growth cardiovascular device markets. The merged company would have projected annual cardiovascular sales of $8.7 billion.

Although both boards have approved the transaction, approval from shareholders and regulatory clearances are still required. The companies expect the deal to close in the fourth quarter.

In related news, Abbott also provided an update on its $5.8 billion acquisition of diagnostics maker Alere. The deal would make Abbott the leading diagnostics provider of point-of-care testing, with total diagnostics sales exceeding $7 billion (*IDDM*, Feb. 5).

*(See* **Abbott***, Page 2)*

## After Nearly A Two Decade Wait, Health Canada Finalizes IVD Regs

Health Canada has finalized its regulations on in vitro diagnostic labeling 18 years after issuing draft guidance.

The final guidance — which took effect April 22 — offers an overview on requirements for the label, package insert, outer container label and immediate container label requirements.

An identifier that distinguishes the device and enables postmarket traceability also is required, and it can be a unique series of letters and numbers or a bar code.

The "intended use" section requirements appear fairly standard. In addition, Health Canada writes that "the package insert should indicate a brief summary and explanation of the [IVD] test and how it works, including the clinical benefits and limitations of the test with respect to the intended use."

*(See* **Canada***, Page 4)*

## Boston Scientific to EU Docs: Get Trained Before Using Lotus

Boston Scientific is reminding European healthcare providers that a company field clinical specialist must be present during procedures involving the Lotus Valve System unless the establishment has been classified as independent.

The company issued this reminder in the form of a letter that is posted on Germany's Federal Institute for Drugs and Medical Devices' website. The Lotus valve is used for transcatheter aortic valve implantation and is not available in the U.S.

To be deemed independent, a facility must have two doctors who have received live classroom training. These physicians must have participated in two procedures involving the device in the presence of a training physician and a Boston Scientific field clinical specialist. Further, they must perform an additional four procedures in the presence of a field clinical specialist.

The company emphasizes that the product is not being recalled and there is no effect on already implanted devices. That said, the company did advise that part of the system could be damaged during the preparation phase prior to the procedure, but the problem may not be visible.

Physicians may remove a damaged device; however, a longer procedure time will result.

To help avoid damage during the preparation phase, the company is advising that catheter lab staff receive training from a field clinical specialist.

Read the letter here (*in German*): www.fdanews.com/05-02-16-lotus-letter.pdf.

**Lawsuits**

Separately, Boston Scientific has filed a lawsuit in the U.S. District Court for the District of Delaware against Edward Lifesciences, alleging infringement of the '608 patent related to adaptive sealing technology, a key feature of Lotus.

It alleges that the sale of Edwards' Sapien 3 transcatheter heart valve constitutes willful infringement.

It filed *Boston Scientific Corporation and Boston Scientific Scimed, Inc., v. Edwards Lifesciences Corporation* April 19.

The devicemaker filed a separate suit against Edwards in the U.S. District Court for the Central District of California the same day, alleging infringement of a number of patents.

Last October, a Boston Scientific unit filed suit in the Düsseldorf District Court in Germany against Edwards that also alleged the SAPIEN 3 infringes the company's patent related to adaptive sealing technology. — Elizabeth Hollis

## Stryker Strikes Big With Stanmore Purchase

Devicemaker Stryker has acquired Stanmore Implants in an all-cash transaction for $52 million.

Stanmore focuses on providing supplies for surgeons who treat orthopedic oncology.

With the acquisition, Stryker has added to its extensive portfolio of patient-specific and off-the-shelf implant systems aimed at limb salvage. The move also expands its presence in the global orthopedic oncology market. — Joya Patel

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**Abbott,** *from Page 1*

In a recent meeting, Abbott representatives told Alere that they had grave concerns about the deal after the diagnostics maker was subpoenaed for alleged FCPA violations for sales practices in Africa, Asia, and Latin America.

In an SEC filing, Alere said Abbott offered to terminate the deal and pay between $30 million to $50 million. Alere said its board rejected this request and that Abbott agreed to go through with the deal.

Larry Biegelsen, a senior analyst at Wells Fargo Securities, says his group thought Abbott and St. Jude should join, given that there is very little overlap and they can compete with rivals Medtronic and Boston Scientific. — Joya Patel

## Complaint Handling, Quality Problems Lands Greek Firm in Hot Water at FDA

A Greek dental resin maker has been hit with an FDA warning letter for failing to properly investigate complaints.

In a warning letter dated March 4, the FDA takes DMP to task for not documenting oral complaints upon receipt and not evaluating complaints for MDR reportability. Investigators made these determinations after an Oct. 5 to 8, 2015 inspection of the firm's Markopoulo, Greece plant.

In a response to a Form 483 resulting from the inspection, the company contended that it had established an MDR standard operating procedure and trained a management representative on the SOP. However, the FDA deemed the response inadequate, saying it neither provided an overview of how oral complaints will be documented upon receipt, nor explained how staff will be identified and trained on the SOP.

DMP also was hit for failing to establish and maintain procedures for quality audits. The letter cites an internal audit procedure through which the quality manager is supposed to designate auditors who are not involved in the section or process being evaluated.

"However, the individual who conducted the quality audits for 2014 and 2015 had direct responsibility for the document control and complaint handling activities being audited," according to the letter.

Although the company created an organizational chart identifying parties responsible for audits and provided a timetable on the next audit, the FDA was not impressed with the response.

The company also fell short with device history records (DHR) by failing to document the following for each batch, lot or unit:

- Dates of manufacture;
- Quantity manufactured;
- Quantity released for distribution;
- Acceptance records which demonstrate the device was manufactured in accordance with the device master record;
- The primary identification label and labeling used for each unit; and
- Any device identification and control number used.

Despite the company's contention that it had instituted a new DHR procedure, the FDA again found fault with its response. It chided the company for not indicating what documentation was used to generate updated records. "Additionally, there is no information on how situations [in which] DHRs are not sufficient will be handled," the letter states.

Other areas the FDA found wanting include failing to establish and maintain procedures for implementing corrective and preventive actions; not verifying the results of a process in a subsequent test; not having procedures to ensure that equipment is suitable for its intended purpose; and failing to have procedures for verifying device design.

The company did not respond to a request for comment by press time.

The warning letter is available here: www.fdanews.com/05-02-16-warning.pdf. — Varun Saxena

## Invibio Settles With FTC Over Alleged Anticompetitive Practices

Invibio — which makes a polymer for medical implants — has settled with the FTC for allegedly using anticompetitive tactics to keep potential rivals from gaining customers.

The Conshohocken, Pa.-based company was the first to market implant-quality polyetheretherketone, or PEEK, to medical device manufacturers. The FTC's complaint alleges that Invibio's noncompetitive tactics impeded two rivals — Solvay Specialty Polymers and Evonik — from entering the market, allowing the company to retain 90 percent of PEEK sales.

*(See* **Invibio**, *Page 4)*

## FDA Extends Comment Period for Refurbishing Medical Devices

The FDA is extending a comment period to June 3 for its proposal to redefine third-party servicing for medical devices.

The FDA had asked industry for feedback in March on the challenges third-party entities face in maintaining or restoring devices to their original or current specifications. The input will be used to redefine terms related to refurbishing devices.

The March 4 notice came after FDA heard stakeholders' concerns that third-party entities may not have expertise to maintain or restore devices to original specifications and that the work may not be adequately documented. The document singled out endoscopes as a particular area of concern (*IDDM*, March 4).

The FDA will hold a public meeting in 2016 to discuss comments submitted to the docket. — Joya Patel

**Invibio**, *from Page 3*

The FTC alleges that Invibio seized an all-or-nothing negotiation strategy for its supply contracts, through which companies had to agree to use Invibio's PEEK exclusively for nearly all of their implantable devices. As a result, Invibio was able to maintain high prices for PEEK and exclusively control supply source. Consequentially, Invibio stifled incentives to develop improved forms of PEEK.

The devicemakers directly affected by the monopolization are not named or the estimated amount of extra money paid because of Invibio's actions. Under the proposed consent, Invibio is prohibited from:

- Entering into exclusive supply contracts;
- Preventing customers from using an alternate source of PEEK;
- Requiring customers to purchase PEEK products exclusively from Invibio;
- Utilizing pricing terms that result in exclusive arrangements; and
- Setting minimum purchase requirements or providing volume discounts.

"This settlement is designed to provide buyers a meaningful choice among suppliers, to open the door to price competition, and to enhance innovation," said Debbie Feinstein, director of FTC's Bureau of Competition.

The public comment period closes on May 27. — Joya Patel

**Canada**, *from Page 1*

The directions for use should describe all of the parts or components supplied in an IVD package, and they should include appropriate warnings and precautionary statements.

Directions for use should also explain how to interpret the results, as well as storage instructions. The IVD's expiration data does not need to appear on the package insert.

The final guidance also contains a new section on electronic labeling. Health Canada permits electronic labeling of information that would normally be found in an IVD's instructions for use information, as long as the information is identical.

For devices that are not sold to the general public, electronic information may be provided as downloadable from the Internet and/or on electronic data storage devices such as a USB flash drive. "The electronic label or internet web address must accompany the device at the time of sale and/or delivery and be displayed in a manner that alerts the user to its purpose," the guidance says.

Also new are the guidance's special considerations for blood glucose monitoring systems. The devices' intended use section should include specific information, such as whether the meter is intended for single or multiple use and whether it is intended for testing neonate samples. It also should include a statement that says the test is "not for the diagnosis of diabetes."

The guidance is available here: www.fdanews.com/05-02-16-canada.pdf.— Varun Saxena

## Quest Diagnostics First Commercial Lab with EUA for Zika Test

Quest Diagnostics is the first commercial laboratory to be granted an emergency use authorization (EUA) for testing patients for Zika virus with its Zika Virus RNA Qualitative Real-Time RT-PCR test.

Developed by Quest's Focus Diagnostics Lab, the new test is expected to be available in the U.S. beginning May 2.

Under the EUA, Focus has authority to designate laboratories within Quest Diagnostics networks to perform testing.

This is the second EUA Focus Diagnostics has received for an emerging infectious disease diagnostic test. It was awarded an EUA in 2009 for the H1N1 influenza pandemic virus. — Joya Patel

## MHRA Outlines 2016-2017 Business Plans

The UK's Medicines and Healthcare products Regulatory Agency plans on taking a global leadership role in surveillance and regulation of devices, focusing on:

- Extending the yellow card reporting application to medical devices, defective medicines, and counterfeit products;
- Developing incident and safety reporting systems;
- Supporting DH in GS1— which includes the Unique Device Identifier — and PEPPOL standards for medical devices;
- Securing EU agreement on new medical devices and in-vitro diagnostic devices regulations to align with UK priorities and European Affairs Committee clearance;
- By March 2017, introduce fees for medical devices, subject to HM Treasury agreement;
- Providing leadership IMDRF initiatives such as Medical Devices Single Audit Program and Medical Device Nomenclature Working Group; and
- Continue to develop its collaboration through the Medicines Industry and Medical Devices Liaison Groups (MLG and MDLG), emphasizing regulation and burden reduction throughout Parliament.

To read the report, visit: www.fdanews.com/05-02-16-MHRA-report.pdf. — Joya Patel

## FDA Takes Action on Electrical Stimulation Devices

The FDA is looking to ban electrical stimulation devices used to prevent self-injury and aggressive behavior.

"ESDs pose an unreasonable and substantial risk to public health that cannot be controlled or corrected from changes to labeling," the FDA says in a proposed rule.

The device works by applying an electrical stimulus to a person's skin to help deter a certain behavior.

According to the FDA, there is evidence of a number of risks associated with these devices, including depression, anxiety, worsening of self-injury behaviors, symptoms of posttraumatic stress disorder, pain, burns, tissue damage and errant shocks from a device malfunction.

Only one U.S. facility — the Judge Rotenberg Educational Center in Canton, Mass. — uses the device, with roughly 45 to 50 individuals are receiving treatment with it.

The FDA drew its conclusion by considering all available evidence, including: clinical and scientific data, input from experts in the field and state agencies, comments from JRC, individuals and parents of individuals on whom ESDs have been used, and disability rights groups, as well as insights from an April 2014 FDA advisory panel.

The FDA rarely proposes banning a device only when seen as necessary to protect public health. The proposal is open for public viewing and comment for 30 days. — Joya Patel

# BRIEFS

## 3M Launches Intelligent Inhaler

3M Drug Delivery Systems has introduced its 3M Intelligent Control inhaler, which delivers on-screen guidelines and feedback to patients via a mobile application. The device also features a data management system to record usage and patient profiles. As a fully integrated device, the dose gets registered when the patient correctly inhales medication, reducing errors. The inhaler will be developed in partnership with an undisclosed pharmaceutical company.

## Stryker Picks Up BD's VCF Portfolio

Stryker has finalized its acquisition of Becton, Dickinson and Company's CareFusion vertebral compression fracture portfolio. The BD subsidiary's portfolio of minimally invasive vertebroplasty and vertebral augmentation solutions will strengthen Stryker's position in neurotechnology, according to the company. The acquisition is an all-cash transaction.

## Zimmer Biomet to Acquire Cayenne Medical

Zimmer Biomet has entered an agreement to acquire Cayenne Medical for an undisclosed sum. The acquisition will expand Zimmer's existing sports medicine portfolio of soft tissue reconstruction products for the knee, shoulder and extremities. The transaction is expected to be finalized during the second quarter and is subject to customary conditions.

## FDA Approves Boston Scientific's MRI System

Boston Scientific has scored FDA approval for its ImageReady MR-Conditional pacing system for treating bradycardia. The approval — which was based on two global clinical trials — covers the ACCOLADE MRI and ESSENTIO MRI pacemakers and INGEVITY MRI pacing leads. This marks the first time a passive fixation pacing lead has been approved in the U.S. for patients undergoing MR scans, according to the company.

## Pinnacle's InFill Technology Wins Chinese Patent

The Chinese Patent Office has issued a patent that covers Pinnacle Spine Group's InFill fusion technology. The InFill fusion systems include a number of interbody fusion devices the company says allow for easier insertion. Pinnacle is a Dallas, Texas-based devicemaker focused on technologies for spinal fusion surgeries.

## Medtronic Releases Data for VenaSeal

Medtronic has revealed positive data for its VenaSeal closure system, which is designed for the treatment of symptomatic venous reflux. Results show complete closure of the great saphenous vein in 94.3 percent of patients receiving treatment with the VenaSeal system. The system minimizes the risk of nerve damage often related to thermal-based procedures and reduces the need for multiple needle sticks, the company says.

## AtriCure Secures FDA Clearance for AtriClip

The FDA has granted 510(k) clearance to AtriCure's AtriClip PRO2 left atrial appendage exclusion system for the occlusion of the LAA during minimally invasive procedures. The device features an "ambidextrous locking and trigger-style clip" designed to allow surgeons to focus on the LAA while steering the device. AtriCure is based in Mason, Ohio and specializes in atrial fibrillation products.

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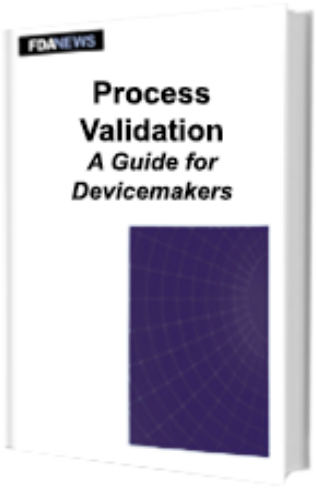


# Process Validation
## *A Guide for Devicemakers*

When must a process be validated? That is the first crucial question devicemakers must answer. But with no clear guidance from the CDRH, finding the answer can be difficult.

The new FDAnews management report — **Process Validation: *A Guide for Devicemakers*** provides you with the answers. This report will walk you through each point in the decision-making process, including how to determine if a product can be "fully verified," and how FDA inspectors define that term.

In it, you'll also find a valuable in-depth overview of all of the currently applicable regulatory guidelines that have an impact on process validation for devices, including those from three key sources: the FDA, the International Organization for Standardization (ISO) and the Global Harmonization Task Force (GHTF).

**Process Validation: *A Guide for Devicemakers*** teaches the proper application of the regulatory requirements that lead to successful process validation, and also offers advice on the practical issues confronting validation compliance by using real-life anecdotes and scenarios.

You also get invaluable extras, such as checklists for IQ, OQ and PQ — and hundreds of pages of appendices, including the invaluable *Medical Device Quality Systems Manual: A Small Entity Compliance Guide*, which is no longer available from the FDA.

But, most importantly, throughout the report, you'll find real-life examples that illustrate relevant concepts … show when processes need to be validated … identify the kinds of evidence you need to collect and maintain to demonstrate proper validation … and actual FDA warning letters to help you learn from others' mistakes.

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# HOW TO REDUCE HUMAN ERROR ON THE MANUFACTURING FLOOR

AN INTERACTIVE WORKSHOP PRESENTED BY GINETTE COLLAZO, PH.D. AND FDANEWS

## YOUR EXPERT SPEAKER:

### GINETTE COLLAZO, PH.D.

A 15 year veteran of helping drug, biologic and device firms reduce manufacturing errors by 50 percent or more — will conduct a one-of-a-kind workshop that teaches quality managers and manufacturing excellence professionals how to reduce errors and improve quality metrics

*"[Ginette is] very knowledgeable with great industry examples. Very spunky! Great delivery."*

**— Irene Rockwell, Manufacturing Compliance, Biogen Idec**

**MAY 23-24, 2016** | EMBASSY SUITES RALEIGH-DURHAM AIRPORT/BRIER CREEK

**This workshop will provide a thorough overview of the basis for human error as well as the factors that drive them.**

As technology advances, human errors in manufacturing become more and more visible every day: they account for more than 80 percent of process deviations in pharmaceutical manufacturing. This workshop explains how small improvements in manufacturing systems and employee training can deliver big results. In addition to an analysis of how and why errors occur, this workshop features multiple interactive exercises allowing you to work in small groups with your colleagues to tackle common manufacturing problems. Attendees will learn:

- **The basics of human error.** Participants will learn how human errors intersect with manufacturing regulations. Participants will also be provided with an overview of the most commonly found errors on the manufacturing floor and what investigators look for during an inspection. Participants will be break into groups and describe the most common human errors in their facilities. The workshop will then reconvene and break-out group leaders will describe what they uncovered. A list of the most common problems will be tallied to help focus the discussion.
- **The factors that drive human error.** Participants will learn why administrative and management systems factor so prominently into deviations and non-conformances. Attendees will also learn how common day-to-day communication gaps contribute to human error. Participants will also be given a list of the various internal and external factors that lead to human error.
- **CAPA.** Attendees will be taught how to determine when human error reduction is the key to a successful solution and FDA compliance. Broken into small groups, each group will be asked to determine if a CAPA solution is effective and if human error prevention related provisions will satisfy the FDA.

Attendees will finish up the workshop brainstorming with other attendees the root causes for real cases. Getting to the true root cause of an error is commonly described as the hardest part of reducing errors. We'll take your toughest problems and send you home with detailed, written solutions.

## DAY ONE

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

**8:30 a.m. – 10:00 a.m.**

### Understanding The Basics of Human Error On The Manufacturing Floor

- How human errors intersect with manufacturing regulations
- Examples of applicable FDA requirements and what the FDA expects companies to be complying with
- A review of other industry standards that apply to drug and device manufacturing
- What FDA investigators look for during inspections and the most common violations found in Form 483s and Warning Letters
- Which violations tied to human errors and manufacturing are trending up
- The various types of human errors are commonly found on manufacturing floors
- How we got here — why is human error reduction such an important topic

**Interactive Exercise:** Do we also err? Attendees will be broken into groups and asked to describe the most common human errors within their facilities. The workshop will then reconvene and break-out group leaders will describe what they uncovered. A list of the most common problems will be tallied to help focus the future discussion.

**10:00 a.m. – 10:15 a.m. | BREAK**

**10:15 a.m. – 12:00 p.m.**

### Human Error In Context — What Are the Factors That Drive Human Errors?

- The taxonomy of human error; how and why drug and device companies need to focus on this in their investigation processes
- Why administrative and management systems factor so prominently into deviations and non-conformances
- The role of innovative operational controls and their role in reducing human errors
- Simple procedures that prevent human error -- how they should be described and presented to maximize human error reduction
- Common examples of poor human factors engineering and workplace conditions that contribute to human error
- When training is appropriate and when we should stop
- Learn how common day-to-day communication gaps contribute to human error
- How supervision can be one of the best human error reduction strategies at your site
- When is individual performance responsible for human error and when does it become a root cause
- How to address cognition, attention, and memory failures at your site

**12:00 p.m. – 1:00 p.m. | LUNCH**

**1:00 p.m. – 2:30 p.m.**

### Internal vs. External Factors

- How our biology affects our thinking process and individual performance
- Understanding the latest on cognitive load and attention, memory, and decision making errors — how they commonly occur on the manufacturing floor
- How our senses control how we react — it's more important that you think
- Best practices for controlling human factors for optimum people performance
- How to create an organizational environment that supports human error reduction initiatives — from senior management to floor level staff
- Why our culture with regards to human error has to change; it's not an easy process but vitally necessary for drug and device companies

**2:30 p.m. – 4:30 p.m.**

### Corrective and Preventive Action (CAPA) — FDA's #1 Manufacturing Compliance Problem

- How to develop corrective actions that make sense —what's working and not working
- Creating preventive actions that truly prevent; how to stop errors that have not yet happened
- Understanding the human error prediction process and tools
- Prevention and human error control: proven ways to measure improvement and on-going trend analysis
- When to use detection mechanisms instead of preventive mechanisms — the pros and cons of each
- Human error detection and recovery rate — are you really uncovering all the errors within your facilities?
- Assuring for the FDA your CAPA program is effective and you've adequately focused on human error

**Interactive Exercise:** When to do what?

## DAY TWO

**8:30 a.m. – 10:00 a.m.**

### Human Error Reduction Techniques

- Discussion of insights from day 1
- When is human error a human resources issue?
- How and when to apply engineering controls to correct and prevent human error deviations
- What to do when individual performance is the major contributor
- Human error and documentation: from design, construction, change management and implementation.
- Additional contributors for human errors will be discussed.

**Interactive Exercise:** Practice identifying techniques to be applied.

**10:00 a.m. – 10:15 a.m. | BREAK**

**10:15 a.m. – 12:00 p.m.**

### Human Error Investigation

- Human Error investigation process defined from beginning to end
- How to gather data in the human error investigation process
- How to perform an effective interview.
- Important steps foe effective human error investigations
- How to report issues to make sure management listens.

**12:00 p.m. – 1:00 p.m. | LUNCH**

# R ON THE MANUFACTURING FLOOR

**1:00 p.m. – 2:30 p.m.**

**Root Cause Analysis Tools**

- A brief review of common tools used in determining root cause
- Hierarchy and use of the root cause determination tool for human error investigations.
- How to perform a cognitive load assessment
- The interview process and interview techniques for human error root cause analysis.
- When and how to use the human error prediction tool.
- When to perform a Process vs. procedure analysis and why it is so important to do so before establishing procedure revision as a CAPA for human error

**Interactive Exercise:** Brainstorm root causes for real cases with peers. Using the situations identified in the first exercise we will try and apply the applicable tool.

**2:30 p.m. – 2:45 p.m. | BREAK**

**2:45 p.m. – 4:45 p.m.**

**Metrics and Human Error**

- KPI's
- Human Error rate
- 1st time pass rate
- Overall equipment effectiveness (OEE)
- Trending
- Tracking

**Interactive Exercise:** Discuss group discussion.

**4:45 p.m. – 5:00 p.m.**

**Review and Key Insights Materials**

- Copies of the presentations
- Current FDA regulations
- Pertinent guidance documents
- Articles on Human Error
- Manual Tools
- Interviewing guide
- Report Example
- Root Cause Determination Tool

**5:00 p.m. | ADJOURN WORKSHOP**

## WHO SHOULD ATTEND

- QA/QC directors and managers
- Process improvement/excellence professionals
- Training directors and managers
- Manufacturing operations directors
- Human factors professionals
- Device engineering
- Compliance officers
- Regulatory professionals
- Executive management

## COURSE BINDER MATERIALS

- Root cause determination tool
- Interviewing guide – you can take back and use immediately
- Example of well-documented HE report
- Complete copy of slide deck materials
- Copies of applicable FDA regulations referenced in the course
- Copies of pertinent FDA guidance documents
- Articles focused on human error reductions

*"The topic is very relevant to the needs of our business at the moment. I learned several things associated with how to train and use lean techniques to reduce the opportunity for human error. It also reaffirmed the things we are doing well that are working."*

**— Richard Leach, Director of Quality, Nosco**

*"[Ginette is] very passionate [and] high energy. A lot of take aways. Reduction of human error has been a challenge and the tools provided will be put to the test."*

**— Alex Masso, QA In-Process Supervisor, Mylan Institutional Inc.**

## YOUR EXPERT INSTRUCTOR

**GINETTE COLLAZO, PH.D.,** has spent more than 15 years in technical training, organizational development and human reliability. She has worked with Bristol-Myers Squibb, Johnson & Johnson, Schering-Plough, Wyeth and Medtronic, many more small and mid-sized drug and device companies. An active researcher in specialized studies related to human reliability, she is the author of numerous publications on these topics.

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# HOW TO REDUCE HUMAN ERROR ON THE MANUFACTURING FLOOR

☐ **Yes!**
**Sign me up for How to Reduce Human Error on the Manufacturing Floor**

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## TUITION:

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

## TEAM DISCOUNTS:

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Multi-attendee discounts are available and will be calculated at check out.

## CANCELLATION AND SUBSTITUTION:

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