An Interactive Workshop presented by LearningPlus LLC and FDAnews

The FDA wants you to move beyond simple training — and continuous retraining. Breakthrough workshop teaches you how!

Beyond GMP Training:

Improving Human Performance and Reducing Errors

March 19–20, 2014 • Doubletree Bethesda Hotel • Bethesda, MD

The FDA wants the industry to move beyond simple training — and continuous re-training that doesn't add value. They want training to be part of a holistic system/process that contributes to performance and helps to assure that errors are reduced and quality is improved.

Take your GMP training system to the next level by focusing on performance.

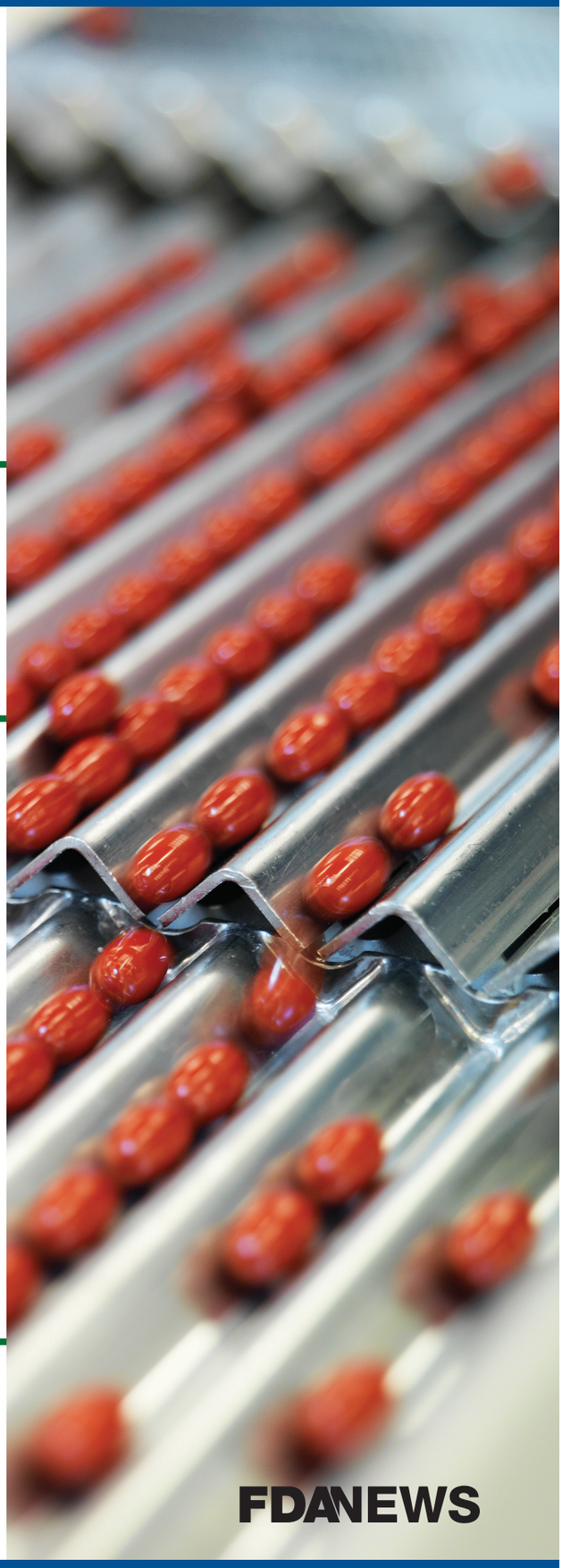
Attend this invaluable workshop to:

- Examine learning systems and programs at use in the pharma, medical device and other industries
- Identify current expectations that regulatory agencies and quality auditors have of learning systems and error reduction
- Use a systematic approach to decide when training is — and isn't — a useful solution to deviations and problems
- Examine how after-action reviews contribute to improved performance
- Identify models used to determine contributors to "human error"
- Given a case study, identify factors that contributed to an accident
- Discover how the way procedures are written can help — or hurt — training efforts
- Discuss ways to evaluate the effectiveness of a learning system and error reduction program

JIM VESPER, LearningPlus, Inc.

"Jim did an excellent job balancing a highly diverse group of participants from widely varying backgrounds. I picked up some good ideas for continuous improvement of our training process."

Stephen Miller, Manager, Learning & Development, Novo Nordisk



Visit www.BeyondGMPTraining.com or call (888) 838-5578

Beyond GMP

Improving Human Performa

March 19-20, 2014 • Doubletree Be

WORKSHOP AGENDA

DAY ONE

8:00 A.M. – 9:00 A.M.
REGISTRATION/CONTINENTAL BREAKFAST/NETWORKING

9:00 a.m. – 12:00 p.m.

- **Training — a cost or an investment?**
  - The state of training in our industry and beyond
  - The connections between training, quality and other benefits
  - Is yours a learning or a training organization?
  - ☑ **INTERACTIVE EXERCISE! Issues affecting training programs today — Identifying deficiencies that can reduce the effectiveness of training.**
- **Regulatory expectations for training and deviation investigations related to human errors**
  - Expectations — what they are and where they come from
  - Examples of training and investigation-related expectations from US, Canada, EU and WHO for the pharma and device industry
- **Compliance failures — identifying the causes**
  - Where firms have fallen short of the expectations
  - Recent citations for inadequate training
  - Recent citations for inadequate investigation into "human errors"
  - Root and contributing causes: Why?
- **Training is not the answer to all your problems**
  - ☑ **INTERACTIVE EXERCISE! Ways to waste time, money and opportunity through training — Finding real-life examples of where training hasn't had the impact that it was supposed to have.**
  - Thinking about performance solutions in your CAPAs, not just training
  - Knowledge in the head, knowledge in the world, or both?

12:00 P.M. – 1:00 P.M.
LUNCH

1:00 p.m. – 4:00 p.m.

- **Models for investigating accidents and incidents**
- **Case study: The case of Flight 5191**
  - Going beyond the category of "human error"
  - ☑ **INTERACTIVE ACTIVITY! Where were the errors? — With a model to further define human error, identify potential causes of the crash of Flight 5191.**
- **How we (unintentionally) contribute to mistakes**
  - Why we make mistakes
  - "Error traps" that can ensnare even the best
  - Hazards of "black box" technology
  - Hierarchies and silos as barriers
  - Why even experts make mistakes
- **Why not? Simple, effective ways to increase learning, share knowledge and reduce mistakes**
  - Risk assessment and risk management
  - After-action reviews
  - Don't defy gravity
  - Pre-action visualizations
  - Technological tools
  - Job and performance supports
- **What can we learn from other industries?**
  - Aviation
  - Healthcare delivery
  - Nuclear power

DAY TWO

8:00 A.M. – 8:30 A.M.
CONTINENTAL BREAKFAST/ NETWORKING

8:30 a.m. – 12:00 p.m.

- ☑ **INTERACTIVE EXERCISE! A quick review — Discuss what you and your team-mates found useful from the previous day and ways you can apply the ideas.**
- **Procedures as tools to support performance**
  - ☑ **INTERACTIVE EXERCISE! The amount of detail in a procedure**
    - Ways to promote consistent performance using an SOP
- **Case studies: What could we do?**
- ☑ **INTERACTIVE EXERCISE! Identifying integrated approaches to solve problems using supplied cases or "bring-your-own" — A chance to apply the models and find could have caused or contributed to the problem. (If you have a problem you are working on, bring a "disguised" version of it as a case your team can consider.)**

12:00 P.M. – 1:00 P.M.
LUNCH

1:00 p.m. – 3:30 p.m.

- **Assessment and evaluation — how can you measure success?**
  - What can your quality system tell you about the effectiveness of your learning program?
  - ☑ **INTERACTIVE EXERCISE! What would evaluation and assessment look like for this course? — Come up with ways to evaluate the course and assess individual learning – models that you can take back and use**
- **Alignment: Making sure all the pieces fit**
  - What is "alignment?" Why is it so important?
- **Evaluating and enhancing YOUR learning program and investigation program**
  - What metrics are you using?
  - ☑ **INTERACTIVE EXERCISE! What are some ways they can be improved? — Create an action plan that you can use to improve your learning and performance program.**
  - Making the case to management to support and enhance training, improve investigations and drive down human errors

3:30 P.M. – 4:00 P.M.
SUMMARY/CLOSING

MP Training:
mance and Reducing Errors
ee Bethesda Hotel • Bethesda, MD

WHO SHOULD ATTEND

- Compliance officers
- Consultants/service providers
- Engineering and design control teams
- Executive management
- Managers
- Manufacturing directors and supervisors
- Procedure writers
- Pharmaceutical and cGMP auditors
- QA/QC personnel
- R&D staff
- CAPA specialists
- Training personnel
- Instructional designers and technologists

COURSE MATERIALS BOOK

- Examples of training and investigation-related 483 citations and Warning Letters
- Models used to determine contributors to "human error"
- Sample evaluations and assessments
- Checklist for evaluating eLearning courses
- Recommended resources

WHAT YOUR COLLEAGUES HAVE TO SAY

"It's obvious James has a lot of experience and knowledge on the subject. His approach makes it easy to respond and share information. Great job, James!"
Christine Koenig, Manager, QA Compliance, Alcon Surgical

"I really enjoyed and feel that I Learned a great deal from the instructor, Jim Vesper, he has an engaging quality especially when describing real-life stories when reinforcing a training concept."
Monica MacInnis, Senior Quality Systems Trainer/Auditor, Fresenius Medical Care North America

"A fantastic conference! The tools Jim taught is will be incredibly valuable to my training department."
Ivan Odegard, GMP Training Specialist, Paddock Laboratories

YOUR EXPERT INSTRUCTOR

JAMES VESPER designs and develops instructional courses and workshops for pharmaceutical and medical device companies. He established and is president of the firm LearningPlus, Inc., and has had more than 30 years' experience in the pharmaceutical industry.

Mr. Vesper worked eleven years at Eli Lilly and Co. His first assignment was as corporate industrial hygienist, followed by three years in corporate quality assurance. He was responsible for issues concerning the manufacturing and testing of parenteral products made at Eli Lilly facilities and third parties worldwide. His last assignment at Lilly was project leader of GMP education and instruction, establishing the department and its mission.

Since 1991, Mr. Vesper has been creating innovative instructional training products for the pharmaceutical and healthcare industries using video and computer technologies as more effective and efficient delivery media. Working as a consultant with a wide variety of clients, his firm creates integrated curricula for personnel and customized training courses targeted to specific needs. He presents papers and workshops at various international technical and professional meetings, including those of the International Society for Pharmaceutical Engineering, GMP TEA, PDA, Pharmaceutical Sciences Group and PharmTech. In 2001, he was awarded the PDA's Agallaco Award for Excellence in Training. He is also an advisor to the World Health Organization's Global Learning Opportunities/ Vaccine Quality group, and has mentored, designed and developed learning programs that are in use worldwide.

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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.

LODGING AND CONFERENCE VENUE:

March 19-20, 2014
Doubletree Bethesda Hotel
8120 Wisconsin Avenue
Bethesda, MD 20814
Toll free: (800) 560-7753 • Tel: +1 (301) 652-2000
www.doubletreebethesda.com
Room rate: $224 plus 13% tax
Reservation cut-off: Feb. 25, 2014

TUITION

Tuition of $1,797 includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

CANCELLATIONS AND SUBSTITUTIONS

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days of the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

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. Call (888) 838-5578 for details.

FOUR EASY WAYS TO REGISTER

Online: www.BeyondGMPTraining.com
Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.)
or +1 (703) 538-7600
Mail: FDAnews, 300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA

☑ **YES!** I want to attend *Beyond GMP Training: Improving Human Performance and Reducing Errors* on March 19-20, 2014. I understand the fee of $1,797 includes all workshop sessions, workshop written materials, two breakfasts, two luncheons and daily refreshments.

FDANEWS
300 N. Washington St., Suite 200
Falls Church, VA 22046-3431

Attendee 1: Name _____ Title _____ Email _____

Attendee 2: Name _____ Title _____ Email _____

Attendee 3: Name _____ Title _____ Email _____

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Print name _____

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Purchase order # _____

(Payment is required by the date of the conference.)