NEW ENGLAND PDA NEWSLETTER

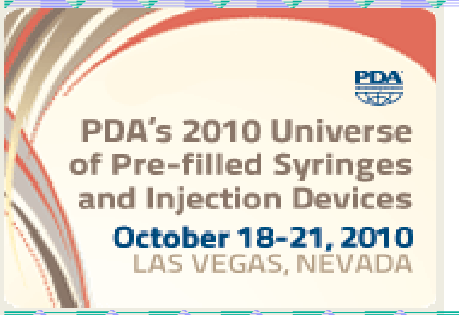
23 Sept 10 | Volume 5, Number 3 | Page 1 of 6

Connecting People, Science and Regulation

Upcoming Events

PDA New England Chapter Dinner Meeting:
Inspection Trends and the New inspection Paradigm
Featuring Amber Wardwell, Compliance Officer
U.S. FDA New England District
Presentation to be followed by an expert panel discussion.

November 10, 2010
5:30 – 9:00PM
Hilton Garden Inn
Burlington, MA
(registration opens 10/4/10)



PDA's 5th Annual Global Conference on Pharmaceutical Microbiology
Advances in Microbial Control and Product Quality
October 25-28, 2010
| Capital Hilton | Washington, D.C

Rx-360 Making Great Progress to Secure the Supply Chain by Working Together

By Martin Van Trieste
Senior Vice President Quality, Amgen

In January 2009, five pharmaceutical quality professionals held a teleconference to launch Rx-360, an international pharmaceutical supply chain consortium with a vision to help assure patient safety by enhancing product quality and authenticity throughout the supply chain-- responds to one of the most significant crises the industry has ever faced.

Consumer safety and effective management of the pharmaceutical supply chain are top public health concerns. The globalization of distribution of drug components and finished products has introduced complexities and complications that need to be addressed. Unethical players and noncompliant companies along the supply chain can introduce counterfeited, adulterated and contaminated materials, often with tragic consequences. Naturally, such incidents lead to a loud and swift reaction from the public, health authorities and policy makers.

As pharmaceutical executives, supplier executives and members of professional organizations, consortium members share a common mission: to serve patients. Millions of people around the world are treated everyday with medicines that members collectively provide. However, the threats to the supply chain prevent effective treatment of patients and in some cases have caused harm, including the deaths of hundreds, if not thousands, of the individuals we are trying to serve

Legislators, regulators, and other organizations around the world are developing and implementing local measures to curtail or mitigate illegal and unethical activities that undermine supply chain integrity. Rx-360 complements these efforts worldwide by seeking to enhance global consistency that local measures cannot achieve.

Unethical individuals and criminals have entered into the pharmaceutical supply chain to adulterate pharmaceutical ingredients for profit. But why have they targeted the pharmaceutical supply chain? The documentary "Illicit: The Dark Trade" details organized crime's sophisticated operations connecting the entire world. The documentary shows how criminals leverage their global supply chain to move all kinds of illicit goods, from counterfeit watches, to counterfeit airplane parts, to sex slaves, to counterfeit pharmaceutical ingredients, into markets around the world. What is sold in this illegal marketplace does not really matter—those involved seek only to make a quick profit.

Surprisingly, the criminal penalties for counterfeiting a purse are often significantly more severe than penalties for counterfeiting life-saving medications. The lack of penalties and the potential for big profits make the illegal enterprise of counterfeiting pharmaceutical products a daunting and dangerous public health problem. **(continued on page 3)**

AUDIT SHARING WILL IMPROVE SUPPLY CHAIN EFFICIENCY AND SAFETY

By Tom Beil, Vice President, Quality & Regulatory Affairs, Sigma-Aldrich / SAFC

Sigma-Aldrich / SAFC is a global organization with 31 manufacturing sites in 11 countries. As both a leading industry supplier and customer we see multiple benefits in the Rx-360 consortium and are pleased to participate in its Audit Sharing Program, which has been designed to create greater supply chain transparency and improve efficiency.

As a complete pipeline partner for pharmaceutical and biopharmaceutical companies, we currently undertake in excess of 200 customer audits each year, in addition to our standard FDA and EMEA audits, and see standardization of the audit process and the sharing of audit information as ways to significantly reduce both the time and cost burden, while maintaining audit standards. As a customer, we carry out audits of our suppliers and, like all companies, want to utilize our internal resources more efficiently and maximize our return on investment, while enhancing the integrity of our supply chain. While we consider each of our customers to be special and unique, our vast experience has told us that their audit requirements are often very similar.

What we hope to achieve through our participation in Rx-360 is to implement a degree of standardization so that the audit process becomes more cost effective, while maintaining or improving quality in a logical fashion. Throughout SAFC we receive thousands of requests for information and, while the lists of questions that customers send for audits aren't always the same, there is a basis of consistency among them. There is currently no structure that lets us efficiently disseminate our information back to the customers so one of our goals is standardize and harmonize procedures, to make that process much more transparent and efficient.

(Continued on page 4)

NEPDA PRESIDENT'S MESSAGE

By Jerry Boudreault
President, Drug Development Resources, Inc.

Greetings NEPDA Members,

I hope everyone had a wonderful summer. I would like to take this opportunity to welcome you back!

Our Fall program kicked off with a tour of the new Genzyme Framingham manufacturing facility and a packed house at the Framingham Sheraton for an evening of outstanding presentations on compliant training systems. The meeting topic and the introduction to RX-360 provided by this newsletter were suggested by members in meeting surveys, as are most topics our chapter focuses on. If you have ideas, please send them by email or complete the survey provided at the meetings. It's your chapter. Make it work for you!

Our next meeting will be held on November 10th at the Hilton Garden Inn, Burlington and will feature an FDA speaker. If you are interested, do not hesitate to register once you receive the open registration notice. This meeting will sell out quickly and you won't want to miss it!

Lastly, I urge you to get involved in your local chapter. We have one of the most active chapters in PDA and that is due to the large number of members who participate and share their talents. If you want to write an article, give a presentation, hear a presentation, or assume a leadership position, or any or all of the above, let us know! At the November meeting, elections for the Chapter Officers will be held. We need good people to carry the torch. If you would like to nominate yourself or someone else for a leadership position, contact Myron Dittmer at mdittmer@mfdassociates.com prior October 1st and come cast your vote.

See you in November!

Best Regards,

Jerry

boudreault@ddres.com

Rx-360 (Continued from Page 1)

Rx-360 plans to 1) develop voluntary standards and best practices to promote supply chain integrity; 2) encourage further development of new technologies for securing the supply chain; 3) Monitor and share information on relevant global legislation, regulation and suspicious events around the world; and 4) share appropriate information about supplier audits and conduct joint audits. The organization currently has nine active working groups focusing on creating the auditing infrastructure, monitoring the global environment and sharing timely and relevant information.

Those interested can download from the Rx-360 website a number of reports, such as the comprehensive report on the impact of a pandemic flu on the pharmaceutical supply chain, summaries of legislation and regulation, documentaries that demonstrate the size and scope of the problem, and various analytical methods including an analytical method to detect potential economic adulteration of acetonitrile. **(cont.)**

(Rx-360 Continued from previous page)

Rx-360 mission is to develop and implement a global quality system that meets the expectations of industry and regulators and helps assure patient safety by enhancing product quality and authenticity throughout the pharmaceutical supply chain. However, securing the supply chain is a journey that likely will never end and will require constant and continuous improvement by all interested parties.

Rx-360's web site is a resource for quality professionals and others. The website disseminates educational materials, as well as provides information and recommendations to help the community safeguard the integrity of the supply chain. In addition, Rx-360 utilizes E-Mail *Flash Reports*, Linkedin and Twitter to disseminate information. For more information on the topics in this article, please visit www.Rx-360.org.

Audit Sharing (Continued from Page 2)

The Rx-360 Standards Working Group

One of the sub-committees within Rx-360 that we sit on is focused on the standardization of audits and auditors and earlier this year we announced the launch of theRx-360 pilot program to share existing sponsor audits (the "Audit Sharing Pilot").

One of the functions of the sub-committee, and Rx-360 as a whole, is to both teach and share, pulling out the essential aspects of an audit and putting that into a "here's what we need to do" list.

Typically, on a three to four-day audit, the first few days are focused on the basics, such as the purity of water, the training, etc., which have to be undertaken before we can get to the more critical issues. When devising the audit sharing process, the sub-committee's thinking was that we should capture that information and leverage what we already know. From SAFC's point of view, as a supplier we would save on fewer audits and the time it takes to host them, while as a producer we would save by being a part of a consortium that can do 100 audits for the same cost in money or time that it would take my staff to do 20-30 audits.

The Audit Sharing Pilot Program

The Rx-360 audit sharing process has been designed to make available the wealth of supplier audit information that already exists within consortium member companies and the purpose of the initial pilot program is to determine the value to Rx-360 members of sharing existing audits, and the effectiveness of the audit sharing process. The pilot program aims to collect audit reports and responses associated with 30 suppliers in several regions of the world -- North America, Europe, China, and India.
The Working Group has sent initial communications to these suppliers inviting them to participate in the pilot program and has been following-up with each supplier in recent weeks to confirm participation and discuss questions.

The work of the Audit Standards Working Group is split into several sub-groups, as there are a wide variety of standards which are required. The Audit Standards Working Group and its sub-groups consist of 27 participants from 19 different companies and organizations. There are six sub-groups: APIs, Excipients, Supply Chain Security, Basic Chemicals, Packaging and Print. Of these sub-groups the first four are active and standards are being finalised. Wherever possible, existing standards are being adopted and Rx360 is working closely with other organisations. For example, PQG/IPEC are in the process of updating the excipients standards.

The standards will be used in a pilot to prove the whole auditing process. The current thinking is that a minimum of three standards will be used within the pilot programme. These are likely to be: API, Excipients and Basic Chemicals, in conjunction with the Supply Chain Security checklist, which is to be used alongside all of the other standards.

(Audit Sharing - Continued from previous page)

Collaboration key to success

As an industry we need to recognize that spending an inordinate amount of time gathering the same information a hundred different ways, is not helpful or efficient. Similarly, if we have a hundred different customers auditing a single location, while 99 other facilities go unaudited, that's not helping anybody either. Rx-360 is about not stepping away from your responsibilities, but being able to leverage and share information among companies. Safety is not supposed to be a competitive advantage- it is what we all have to achieve, and we have to achieve it together.

By working collaboratively, we will get more data and richer data, in a more efficient manner, to make better decisions.

NEPDA NERCSQA Joint meeting on Developing Compliant Training Programs And Genzyme Plant Tour September 8,2010

Bruce Rotker, Sparta Systems presents an i-Pad raffle prize to September meeting attendee and PDA Member Greta Davis, Lantheus Medical Imaging.

Our Fall program kicked off with a joint meeting between PDA and the New England Regional Chapter of the Society of Quality Assurance (NERCSQA) on *Establishing Compliant Personnel Training Systems* at the Framingham Sheraton. 165 people were in attendance reflecting the critical importance of training to productivity and quality. Before the meeting, 45 lucky (or rather fast acting) PDA and NERCSQA members were provided a tour of the state of the art Genzyme manufacturing facility in Framingham.

Special guest, PDA Senior Vice President of Science and Regulatory Affairs, **Rich Levy, PhD** provided the attendees with an overview of the organization of PDA Global and the many opportunities to get involved in PDA.

Joanna Gallant, Unit Manager, Genzyme Framingham Quality Training discussed how to build an effective OJT program and shared the details of the program currently being implemented at Genzyme.

Cheryl McCarthy, Associate Director, Quality Assurance at eClinical Solutions, and **Linda Hook-Dinnocenzo**, Associate Director Quality Partnership Management, Vertex Pharmaceuticals (NERCSQA President and Vice President/Program Chair, respectively), provided an overview of adult learning theory and how it can be applied to ensuring that your trainers are as effective as possible.

PDA New England Chapter would once again like to thank the speakers for their outstanding presentations, meeting organizer Louis Zaczkiewicz, the Genzyme tour guides, and last, but not least, our dedicated sponsors: **Accugenix, Baxter, Boston Analytical, Commissioning Agents, DBA Global, Genzyme, Iron Mountain, Masy Systems, Seidenader Equipment**, and **Sparta Systems**. Their generous support enabled us to provide cocktails and delicious appetizers.

The presentations will be posted on the NEPDA website and attendees will be notified when they are available.

Trying to get Noticed??

We offer vendors, consultants, operating companies and other organizations the opportunity to promote themselves and also support the NE PDA Chapter by sponsoring meetings and purchasing advertising in our newsletter. A **business-card size advertisement in our newsletter is only $100 per newsletter!**

The newsletter has the following reach:

- **Our direct e-mail distribution reaches over 1,800 contacts throughout New England.**
- **Our membership includes people from manufacturing, research, QA, QC, engineering, contract manufacturers, consultants, and regulatory.**
- **We promote the newsletter at New England PDA's bi-monthly dinner meetings, often with company tours, which regularly attract 50-100 attendees.**
- **We post the newsletter on our chapter's website at Global PDA (www.pda.org), an organization that has over 10,000 members.**

Deadline	Publication Date
Oct 15, 2010	Nov 2010
Jan 15, 2011	Feb 2011
April 15, 2011	May 2011
July 15, 2011	Sept 2011
Nov 15, 2011	Dec 2011

If you are interested in advertising in the newsletter or need more information, contact Melissa Smith at melissa@mjqualitysolutions.com