NEW ENGLAND PDA NEWSLETTER

19 May 10 Volume 5, Number 2 Page 1 of 5

Connecting People, Science and Regulation

Upcoming Events

New England Chapter

Sept 8, 2010

Dinner Meeting-Facility Tour:

Genzyme Framingham

Manufacturing Facility

Topic:

CGMP Compliant Personnel

Training Systems

Date:

September 8, 2010

Time:

Tour: 4:00-5:30 PM

Dinner and Presentation: 5:30 – 9:00 PM

Dinner Meeting venue:

Sheraton Framingham

1657 Worcester Rd,

Framingham, MA 01701

[Sterile Pharmaceutical Dosage Forms: Basic Principles]

[Virus Clearance – New Course]

[What Every Biotech Startup Needs to Know about CMC Compliance]

Risk-Based Analytical Method Validation

Cargo Screening of Pharmaceutical Shipments: What You Need to Know

By Jim Marcino
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In 2007, Congress passed the 9/11 Commission Act, which required that the Transportation Security Administration (TSA) create a system capable of screening all air cargo scheduled for transport on passenger aircraft.

A key component of this initiative is the Certified Cargo Screening Program (CCSP). Under CCSP, the TSA certifies cargo screening facilities (CCSF) located throughout the United States to screen cargo prior to tendering it to the airlines for shipment on passenger flights. Participation in the program is voluntary and designed to enable vetted, validated, and certified supply chain facilities to meet the 100 percent screening requirement that all cargo be pre-screened.

As the TSA's deadline for screening 100 percent of cargo is August 3 of this year, it is most important to understand your options in order to minimize transit delays and protect the integrity of your shipments.

Many shippers are realizing the value of taking control of their screening options. Some shippers have studied x-ray screening and found it to be detrimental to their products and packaging. Others have experienced having their shipments opened during airport inspections and have found that there is no documentation of how the shipment was inspected, how long the shipment was open, what may have been removed, and for how long. The TSA also points out that a back-log of unscreened cargo at the airlines is possible, resulting in missed flights and longer transits. This is especially true at major cities with a high volume of international traffic.

There are several screening alternatives that you should be aware of to protect your shipments and transit timelines.

The TSA has been working to enlist shippers of pharmaceutical product to become certified cargo screening facilities (CCSF). Shipper-based CCSFs are able to utilize existing regulatory processes to screen their product as part of their current quality control process before the product leaves the company's manufacturing and packaging facilities. For those shippers that become a CCSF, they would only need to implement a secure chain of custody to deliver their pre-screened cargo to the airlines. The TSA currently has a certification program by which transport providers are vetted to meet chain of custody requirements. This, coupled with the CCSF program, allows drug manufacturers to ship their product without the need for airport or third-party screening.

Companies that choose not to become a CCSF may, instead, align themselves with a transport provider that has CCSF capabilities, enabling shipments to be screened before tender to the airlines. If cold chain is a primary concern in the transport and screening process, a transport provider that specializes in cold chain capabilities, has the proper facilities and relies on documented procedures may be the best choice to ensure shipment integrity. It is important to note that CCSFs are certified by the TSA on a "location-by-location" basis and not on a company level. A transport provider able to screen in Chicago, for instance, may not necessarily be certified in other locations. A shipment screened at origin, but transferred to another carrier at an international gateway city may be subject to re-screening before export, so it is important to fully understand the screening capabilities of the transport provider.

Lastly, the TSA is also now certifying third-party companies to perform the screening function, referring to these types of operations as screening "car washes". Your transport provider may choose to use a third-party screener as an alternative to airport screening, with or without your knowledge or approval.

Who is screening your shipments? What are their processes and qualifications? You should know enough about the process to enquire about screening methods, as well as how your cold chain concerns will be managed.

Please know that screening methods at the airport and at third-party screening facilities can result in "alarms" or cause for concern that require more detailed screening and could include opening and physical inspection, per TSA regulations.

Controlling how your shipments are screened and having a detailed record of the screening processes and alarm resolutions could eliminate FDA red flags.

Should you require more information about the CCSP program and becoming a CCSF, more detailed information can be found at:
http://www.tsa.gov/what_we_do/layers/aircargo/certified_screening.shtm

Alternately, you can contact the TSA about the screening program directly at CCSP@DHS.GOV.

Jim Marcino, Director of Customer Service for World Courier Inc., worked with NEPDA to submit this article and has headed the company's TSA compliance efforts for more than 10 years. World Courier's TSA Compliance Department is at your service should you require assistance or have any questions regarding the content of this article. Please call 1-888-223-4461 to speak with a specialist or email Tim Redmond at redmond@worldcourier.com.

NEW ENGLAND PDA NEWSLETTER

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More on Cargo: FDA's New Cargo Theft Webpage!

By Melissa Smith
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On April 28, 2010, FDA issued a 'Cargo/Warehouse letter to Stakeholders'. The full contents of this letter can be found on the FDA website at http://www.fda.gov/ICECI/CriminalInvestigations/ucm209979.htm. A quick look at the website shows a posting of at least 12 cargo/warehouse thefts. This webpage contains the link http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm to FDA's Office of Criminal Investigations to report suspected criminal activity and also contains the press releases and notices about the thefts which has the information regarding what products were stolen, the lot numbers, how to check to see if what you are buying may be from a stolen shipment, what to do, and how to report it.

The following are excerpts from the FDA letter.

"FDA has been working with manufacturers, wholesalers, and retailers on ways to further secure our nation's supply chain from counterfeit, diverted, unapproved, and otherwise misbranded or adulterated products. We have now added stolen products to this effort. FDA is working with the medical products and infant formula supply chain to identify best practices and provide other guidance on how to prevent and respond to cargo/warehouse thefts."

"Prompt public notification of the theft is a critical step in protecting the public health because it alerts others in the supply chain and the public to look out for the stolen products and to be skeptical of offers for these products at unusually low prices or from a person outside the legitimate distribution chain. In addition, if persons in the supply chain are looking out for these products, it becomes more difficult for the thieves to sell the products back into the legitimate supply chain. If a firm experiences a cargo or warehouse theft, we strongly encourage it to prepare a public notice for posting on its website or as a press release as soon as possible after the theft. FDA is ready to provide comment on the public notice in an expeditious manner if the firm would like to share it with the agency before release."

The new webpage is http://www.fda.gov/ICECI/CriminalInvestigations/ucm182888.htm

PDA New England Chapter Has Significant Presence at 2010 PDA Annual Meeting

By Rusty Morrison, President-Elect (2011-2012 term)

The PDA 2010 Annual Meeting was held in Orlando, FL at the Gaylord Palms Resort and Convention Center from Monday, March 15th to Wednesday, March 17th. The following members of the PDA New England Chapter Board/ Planning Committee attended the meeting: Jerry Boudreault, President; Rusty Morrison, President-Elect; Louis Zaczkiewicz, Board Member at Large; Myron Dittmer, Board Member at Large; Melissa Smith, Newsletter Editor; and Amnon Eylath, Planning Committee member. The New England Chapter had the highest level of participation among all of the PDA's 21 local / regional chapters around the world.

Here's a snapshot of some of the activities our members performed at the meeting:

As the new co-chair of the Chapter Council, **Myron Dittmer** had the opportunity to meet many chapter leaders during a Council meeting, where more effective communication between local chapters and Global PDA and chapter leadership succession issues were discussed. Other important items discussed included improving chapter visibility and offerings to membership by enhancing website design and content, and providing mentoring and Best Practices to those chapters needing this help. Myron also attended the Visual Inspection of Parenterals Interest Group meeting moderated by John Shabushnig, PhD, where some of the "hot button" topics related to visual inspection of pharmaceuticals were discussed.

Amnon Eylath attended several significant networking meetings with members of the Biotech Advisory Board, PDA Leadership and FDA representatives. His attendance at the Task force meeting on "Phase Appropriate Application of GMP and Quality Systems to Drug Substance (API)" was very productive, with constructive participation of both PDA and FDA representatives. In addition, Amnon's attendance at the Risk Management Interest Group was especially helpful in learning about proposed changes to Eudralex Chapter 1 and how PDA intends to respond.

The annual meeting was very busy for **Melissa Smith** as she had two separate presentations to give, the first on the Analytical Method Lifecycle, and the second as an update on the progress of the Analytical Method Development Task Force, which she co-chairs with Earl Zablackis. Melissa also spent a lot of time outside of sessions talking with other attendees regarding the status of Method Development-Qualification-Validation Interest Group Task Force reports, including in-depth discussions with fellow members on many elements of the subject matter. It provided a great opportunity to discuss ideas and map out areas to pursue further.

It was **Louis Zaczkiewicz's** pleasure to represent our chapter at the Annual Meeting as both a participant and attendee. He attended the Sunday night PDA Awards Dinner, and spoke at the Monday morning New Member Breakfast as part of the PDA Membership Advisory Board. Later that afternoon, Louis co-chaired the North American Chapter Council meeting, where he's been helping guide PDA chapters since 2006. This meeting completed Louis' term, and he handed over the Chapter Council leadership to Myron Dittmer (past-President of the NEPDA) and Peter Noverini (Midwest Chapter). This was Louis's fifth consecutive Annual Meeting, and he hopes others will consider joining him at the 2011 meeting to be held April 11-15 in San Antonio, Texas.

NEPDA PRESIDENT'S MESSAGE

By Jerry Boudreault
President
Drug Development Resources, Inc.

Greetings NEPDA Members,

It gives me great pleasure to announce that the NEPDA Chapter Board has once again funded a $5,000 scholarship for a deserving NEPDA student chapter member transferring from Middlesex Community College to a four year program to continue their studies in life sciences or engineering! We are looking forward to great things from our student chapter this year. Many thanks to Mary Sullivan and the people at Millipore for hosting the 2010 student field trip to the Billerica bioprocessing facility in April. The students were very impressed and motivated by the tour and presentations. These tours are a great opportunity for them to see what work life will be life after graduation.

I met Mary at our NEPDA November dinner meeting up in Portsmouth, NH. After the meeting she told me that she was an MCC alumnus and would like to help us ensure that our first in the world PDA Student Chapter was a success. Since that day she has been providing guidance to the Student Chapter and organized the tour. That is a great example of one person stepping up and making a difference in our Chapter. The individual contributions of many talented people in our region like Mary make us a model for other PDA chapters worldwide. If you want to get involved, please send me an email or introduce yourself at one of our dinner meetings.

This is a Chapter election year. If you are interested in assuming a leadership role in our Chapter, the way to start is as a member of our Event Planning Committee. We meet every other month, five times per year, for two hours. Meeting times and locations are posted on the chapter website. It is a relaxed and friendly atmosphere. Come on down!
I look forward to serving over the next year and I hope to meet you soon at an NEPDA event.

Sincerely,

Jerry Boudreault
boudreault@ddres.com

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 purchasing advertising in our newsletter. A* business-card size advertising opportunities in our newsletter; at a cost of $100 per newsletter.**

The newsletter has the following reach:

- **Our direct e-mail distribution reaches over 2,800 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 75-125 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
July 15, 2010	August 2010
Oct 15, 2010	Nov 2010
Jan 15, 2011	Feb 2011

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