NEW ENGLAND PDA NEWSLETTER

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Connecting People, Science and Regulation

In This Issue:

March 11th Dinner Meeting

PDA Technical Report 27:
"Container-Closure Integrity"

Speakers:

Roger Asselta, Vice President of Technical Affairs, Genesis Packaging Technology
Heinz Wolf, General Manager, Packaging Technologies and Inspection LLC.

Dinner Meeting Location:

Hilton Garden Inn, 5 Wheeler Road, Burlington, Massachusetts 01803

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2008: Accomplishments!
2009: Expectations!

By Melissa J. Smith
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This is just a brief look at some of the great 2008 guidelines, publications, initiatives and what we may see in 2009! Some of these guidelines have fine illustrations which help translate them to practice, link their concepts together, and also provide insight into how you might use their concepts within one of your projects. If you need more information, the PDA/FDA meeting in September, 2008 was a really good source of information on risk assessment, for example. Read on for more details.

2008 Regulatory Accomplishments

The approval of the Q8 (R1) in January 2008 began the year. The modification to 21CFR210 and 211 under the FDA 21st Century Initiative came in at the end of the year, on December 6, 2008. What happened in-between? A lot-but here are some highpoints.

- Q3A(R) Impurities in New Drug Substances, Final Guidance
- Current Good Manufacturing Practices for Phase I Investigational Drugs Final Guidance
- End of Phase 2A Meeting Draft Guidance
- Process Validation: General Principles and Practices Draft Guidance
- Q4B had 4 annex additions published.

ICH Q8, Q9 and Q10 encompass the areas of Scientific foundation-Risk Assessment, Management and Communication-Oversight of Quality and Safety. These documents reshape our concepts of quality systems, risk assessment, and the design phase of our products. They are linked in their approaches to the Pharmaceutical Life Cycle, as they describe the inter-relationships of the concepts surrounding Quality by Design, Risk Management, and Pharmaceutical Quality System. These synergistic concepts help define strategic approaches in process development, analytical technologies, quality systems, and risk assessment. What is your control strategy? Have you assessed the associated risks with a proposed change to your release strategy? What are your product's Critical Quality Attributes?

These documents and other information on the FDA (www.fda.gov) and ICH (www.ich.org) websites are great 'reads' and can provide you some basic training tools, at no cost!

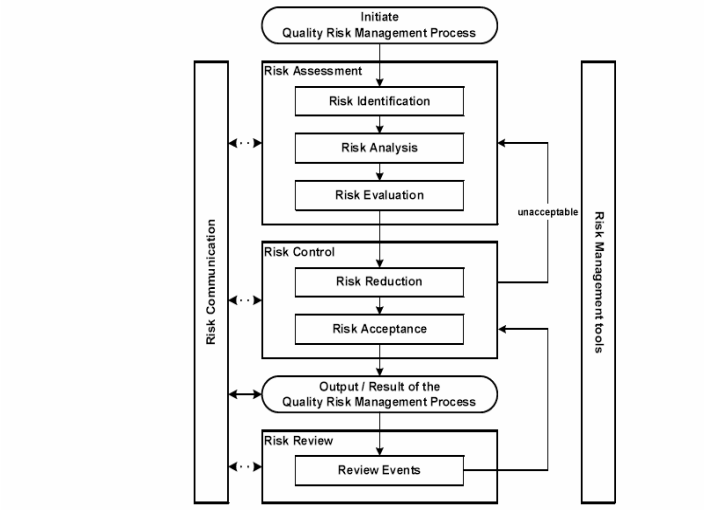
- For Quality based tools: http://www.asq.org/learn-about-quality/basic-concepts.html
- For a CDER overview and handbook: http://www.fda.gov/cder/handbook/index.htm

- For Technical information and links: http://www.biochemweb.org
- For Quality by design

http://www.amstat.org/meetings/fdaworkshop/presentations/2006/(1)Statistics%20in%20QbD%20Stats%20WS%2009-06.ppt

The following figures are taken from the Q9 and Q10 ICH documents. Take a look at the document and perhaps take an opportunity to investigate how to apply these principles, through using the available information on the internet and through participation in the resources available at PDA and through your New England chapter participation!

Figure 1: Overview of a typical quality risk management process



Reference: ICH Q9 "Quality Risk Management", Nov 2005

Annex 2

Diagram of the ICH Q10 Pharmaceutical Quality System Model

Reference: ICH Q10 Pharmaceutical Quality System, June 2008.

2009 Expectations

As we look forward to 2009, we may hear more on ICH Q11 which will cover Development and Manufacture of Drug Substance. The concept paper can be found at http://www.ich.org/LOB/media/MEDIA4523.pdf.

We have already had two additional annexes to Q4B approved-one for extractable volume of Parenterals and another for Particulate Contamination: Subvisible Particles.

To see Janet Woodcock's presentation on CDER 2009 Initiatives, go to http://www.fda.gov/cder/present/fda-cms summit2008/CMS_FDA_120408_CDER_Priorities_for_2009.pdf

CDER has posted its Guidance list for 2009. Among the ones listed are:

Assay Development for Immuongenicity
CMC-Postmarketing Plan
Contract Manufacturing
Non-Penicillin Beta-Lactam Contamination
Pharmaceutical Component Quality Control
Pharmaceutical Manufacturing Statistics

Keep an eye out for the new Guidances-take a look at the Q8-Q9-Q10 series-and get ready for more!

Rhode Island's Tech Collective:
A Valuable Resource to New England's Biotech Professionals

By Enith Morillo, M.S.
Supervisor Quality Control
Tedor Pharma Inc

RI Tech Collective is a non-profit organization with a mission to promote and strengthen the technological industry through education, training, and community building. Originally stemming from the RI Technology Council (RITEC), the Tech Collective has been gaining unparalleled momentum, providing the Biotech and Life Science industry with a variety of resources and events, including:

Bio Tuesdays:
This is a one-of-a-kind networking forum that provides professionals, executives, academia, and any one interested and/or involved in Biotech, an opportunity to share their interests and exchange ideas, for personal and professional growth. Held on a Tuesday every month, one of the best features of this event is *"Spotlight on your company"*, an opportunity to engage the crowd with a brief speech about your company and its services. A must-attend event for every entrepreneur!

Women In Technology:
With an aim to support women in technology, this program provides a platform for professional women to gather and discuss their successes and challenges. The most recent event, entitled "Where's the man in the suit? Manners for CEO's in Skirts" was a powerhouse, featuring Annie De Groot, M.D., Founder, CEO & CSO of EpiVax Inc., Kimball Hall, VP & General Manager of RI Operations at Amgen Inc., and Beth Zielinski-Habershaw, Ph.D., Molecular Pharmacology, Physiology and Biotechnology Instructor at Brown University. The evening was filled with thought-provoking conversation and advice from a panel of women who are driving the RI economy, providing proof of women breaking through the glass ceiling, and attaining positions of leadership in traditionally male-dominated fields.

BIOED Event Series:
Funded through the Biotechnology Industry Partnership Grant of the RI Governor's Workforce Board, the BIOED series took place in the fall of 2008 and consisted of 3 sessions focusing on Industry, Education and Government. The series brought together government officials, industry executives and professionals, and education authorities and specialists, in a unique forum to discuss Bioscience's present and future. Amongst the panelists were RI Lieutenant Governor Elizabeth H. Roberts, President and CEO of Neurotech USA Ted Danse, and Executive Director of Information Systems for Amgen Inc, Chris Bush.

Whether you are looking to make a difference in policy, advance your career through professional development, and/or network and socialize with other biotech professionals, RI Tech Collective has something for you. Attend the upcoming "I Belong" free event at Bryant University on February 19, 2009 and see for yourself all the right reasons to get involved! *www.tech-collective.org*

Dear PDA Members,

We invite you to submit a scientific abstract for presentation at
PDA's 4th Annual Global Conference on Pharmaceutical Microbiology.
The theme of this year's conference is **Bringing Microbiology to the Manufacturing Floor**.

October 5-8, 2009 | Bethesda, Maryland

Call for Papers Deadline – April 30, 2009

Suggested topics include, but are not limited to:

- Media fill design
- Microbiological aspects of cleaning validation
- Sterilization, disinfection and preservation
- Microbiological programs in non-sterile environments
- Trends in environmental monitoring
- Microbial identification in the pharmaceutical industry
- Compendial topics, such as objectionable organisms
- Setting alert/action limits
- New and/or alternative microbiological methods
- Emerging technologies in microbiological science which may apply to our industry
- Advances in Aseptic Processing which reduce the risk of microbial contamination
- Microbiological challenges related to Medical Devices/Combination Products
- Recent compliance issues in non-pending cases (FDA enforcement officers/auditors)

PDA's 4th Annual Global Conference on Pharmaceutical Microbiology will bring together all levels of industry professionals to network and benefit from a program that demystifies the underlying science of microbiology and seeks to solve the problems that our industry faces on a daily basis.

Join colleagues, peers and industry experts during this must-attend event.

NEPDA PRESIDENT'S MESSAGE

Jerry Boudreault
President
Drug Development Resources, Inc.

I would like to take the opportunity of the publishing of the first newsletter of NEPDA's 20th year, to wish all of our members and sponsors a happy and prosperous New Year. When I think about what has made the NEPDA chapter one of the strongest in the world over the last twenty years, two factors come to mind. One is geography. The dense concentration of life science businesses in New England makes it relatively easy for us to get together, share ideas and collaborate. It is a great and exciting place to be if you are in our business.

More important than geography, I believe, is the commitment by the membership. We have an outstanding and committed Board of Directors and Event Planning Committee. Additionally, we benefit from the wisdom and continuity that comes from the active participation of all of the past presidents since the inception of the chapter. As President of this great organization for the next two years, I will do my best to live up the high standards set by my predecessors. We have some fairly aggressive goals, and with your help we will achieve them.

Our first and foremost objective is to provide our members with growth opportunities. We realize that you may be too busy with life to be seeking out opportunities for extracurricular activities, but you may be interested if asked. That is how I got involved with NEPDA. I wasn't looking for more to do, but I was asked by then President-Elect, Myron Dittmer, to get involved in the Event Planning Committee. We want to reach out to you and present the opportunities that may be of interest. Here is a sampling of what NEPDA has to offer:

- Our bi-monthly dinner meetings provide opportunities for you to either learn from your peers and industry leaders about relevant issues, or for you to present to the members your own approach to common problems. If you have a need for information, let us know and we will organize a meeting around the topic. Do you have thoughts to share with the overall group? We want you as a speaker.
- Dinner meetings are also great networking opportunities. For a member who happens to be in transition, admission is reduced to $10.
- Business meetings are held every other month at different locations around the area. Location and schedule are posted on the NEPDA website. We plan dinner meetings, initiatives, and deal with routine chapter business. If you are interested in possibly assuming a leadership position in the chapter, the way is through the Event Planning Committee. Come check it out. You may end up as President one day.
- PDA publishes Technical Reports and the PDA Journal, and NEPDA publishes a newsletter. Do you want to write an article for publication, or participate in the development or revision of a technical report? Let's talk.

We need your input to stay relevant and we will measure our success by the number of members we attract. Our aim is to increase membership by 80 in 2009. Our second major objective is to strengthen the New England PDA Student Chapter. We started the first ever PDA student chapter at Middlesex Community College (MCC) in 2007. MCC has an outstanding biotech program that trains individuals to assume positions in the local life science economy. You probably have many MCC grads in your organization (or you may be an MCC grad yourself) that are doing great work.

Besides providing the students with the opportunities afforded all members, we will initiate a scholarship program for 2nd year student members and grads continuing on to a four year program, and provide one speaker per month from our membership that can spend an hour or so with the students discussing relevant topics in a casual setting. If you are interested in sharing your story with the students, please get in touch. If you happen to be an MCC grad, that is even better.

With the state of today's economy, there is no better time than now to be reaching outside your routine and get involved, so please come join us in continuing the tradition of excellence. I look forward to serving over the next two years and I hope to meet you soon at an NEPDA event.

Sincerely-Jerry Boudreault

The New England Chapter of the PDA is pleased to announce the availability of business-card size advertising opportunities in our newsletter; at a cost of $100 per newsletter (other conditions apply—please see full details in our "Newsletter Sponsorship Policy", hyperlink provided below). Since its inception in 1988, our chapter has seen a significant growth in membership and participation. Our 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, regulatory, etc.**
- **The newsletter is promoted at New England PDA's bi-monthly dinner meetings, often with company tours, which regularly attract 50-100 attendees.**
- **The newsletter is posted to our chapter's website at Global PDA (www.pda.org), an organization that has over 10,000 members.**

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:

1. ***Download and fill out the "Newsletter Sponsorship Policy" form located at the Chapter Resources link of the NEPDA website: http://pdachapters.org/newengland***
2. ***Email artwork along with a scanned copy of your completed form prior to the deadline to melissa@mjqualitysolutions.com***
3. ***Submit the completed form with check payable to***

Treasurer, New England PDA
77 Briar Patch Road
Stonington CT 06378

Deadline	Publication Date
April 15, 2009	May 2009
July 15, 2009	August 2009
October 15, 2009	November 2009

Questions:

About the newsletters and articles, advertising artwork? E-mail Melissa at melissa@mjqualitysolutions.com

About advertising opportunities? E-mail Melissa at melissa@mjqualitysolutions.com