PDA Parenteral Drug Association Metro Chapter

PDA METRO NEWSLETTER

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Connecting People, Science and Regulation®

President's Corner

By: Lara Soltis, PDA Metro Chapter President

Happy New Year! Can you believe it's "Twenty-Ten" already? It is also time for our second newsletter for the PDA Metro Chapter. The last quarter of 2009 was very eventful for the PDA Metro Chapter. We had our annual Vendor Night with FDA speaker, Capt. Joe McGiniss in October. Capt. McGiniss presented a lively commentary on the State of the Industry in the New Jersey District. We also had about 20 vendors who presented the newest products in Microbiology, QA/QA, Regulatory and Manufacturing. In December we sold out registrations to visit the Johnson & Johnson Sterile Process Technology (SPT) center in Raritan, NJ. It was exciting to learn about and tour the center that develops sterilization processes for all J&J companies and products by using ethylene oxide, ionizing radiation (gamma and e -beam), dry heat and moist heat sterilization and aseptic processing. All of the past presentations are available as PDFs on our website at http://www.pdametro.org/meetevents.htm
This first quarter of 2010 has such renowned speakers as Dr. Daniel Gold discussing "Impurities in Drug Substance and Drug Product." On March 2, Gloria Berios of Eli Lilly will speak on Standardizing Sterility Risk Assessment. In April we're holding our Fifth Annual PDA Metro Chapter Day Symposium with the theme of "Compliance in the New Decade and FDA Enforcement." A Joint Dinner Meeting with ASQ Princeton Section is coming up in May.
We're looking forward to seeing you at a meeting or event. To encourage your attendance we raffle off two PDA Memberships at every dinner meeting! Your input, comments and assistance is greatly appreciated; feel free to contact us at pdametro@optonline.net

FDA Finalizes QbD Guidance -- It's Time to Get Moving

By: William J. Bennett, Bennett Pharma Solutions, LLC

In November 2009, the FDA published as final the ICH Q8(R2) Guidance on Pharmaceutical Development. This guidance document is a composite of the two "pieces" of ICH Q8:

-the Q8 "parent" guidance -- which came into force in May 2006 and describes the suggested contents of the Pharmaceutical Development Section (3.2.P.2) of the Common Technical Document (CTD)

-the Q8 Annex -- which came into force in June 2009 as Q8(R1) and shows how concepts and tools (e.g., design space) outlined in the parent Q8 document could be put into practice for all dosage forms. The Annex was amended slightly in August 2009 to correct/clarify titles on several of the charts. More Details

Variability in the Bacterial Endotoxins Test

By: Karen Zink McCullough, MMI Associates

We've all heard the expression, "the error of the gel clot test is one two-fold dilution." This assumption describes the range of 50-200% of nominal value of label claim or PPC in a kinetic test, which is really a rough measure of the aggregate effect of different sources of variability in the assay.
We take for granted, and gladly accept the 50-200% range when we qualify gel clot reagents. If the assigned label claim is 0.125 EU/mL but our observed result is 0.25 EU/mL, we "win" and happily use the assigned label claim of 0.125 EU/mL in all subsequent calculations. With the kinetic test, if we recover 50-200% of the nominal value of the positive control spike, we "win". That's the way it works. More Details

Environmental Monitoring for Nonsterile Manufacturing

***By:* Radha Tirumalai, US Pharmacopeial Convention**

As indicated in a recent article in the November-December 2009 issue of the PDA Letter, USP is in the process of developing a new General Information Chapter (numbered over 1000) proposal on "Control Programs for No sterile Product Manufacturing". More Details

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FEATURED ARTICLES:

AREA OF INTERESTS:

Calendar of Events

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September 2009-
Janet Yao, Bristol Myers Squibb Co.

October 2009-
Bruce Eckman, WBE Consulting

January 2010-
Robert Dodemaide, ECO Animal Health

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