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# PDA METRO NEWSLETTER

Volume 3, Issue 1

June 2010

Metro  
Chapter

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## President's Corner

By: *Lara Soltis, PDA Metro Chapter President*

Happy Solstice! I hope you are all thinking of how to spend some time with your families to enjoy our lovely Tri-State summers. This is the third newsletter for the PDA Metro Chapter. 2010 has been very productive for our Chapter. There were three dinner meetings, in January, March and May, which discussed: Impurities in Drug Products by Dan Gold, Sterility Risk Assessment by Gloria Berrios, and Sterility by Design by Jim Agalloco, respectively. In February three Chapter Members accompanied me to present to the Stevens Institute of Technology Pharmaceutical Manufacturing Masters students on Career Paths in our local industry on their campus in Hoboken, NJ. Thank you, again, Len Mestrandrea, Enrique Dilone, and Bob Johnson. There are a myriad of career paths out there, getting in front of our college students is a good way to fill our industry's pipeline with great talent.

Our 5<sup>th</sup> Annual Full Day "Chapter Day" Conference was held in April and had presentations on such timely topics as: "Planned Revision to USP <1211> Sterilization and Sterility Assurance for Compendial Articles," "FDA's Revised Process Validation Guidance," "FDA Preapproval Inspections," "Preparing for PAIs," "483s - Not Here!" "USP <1117> Microbiology Best Laboratory Practices," and "Disposable Manufacturing, current USP Update." We were honored and pleased to have the following speakers: Jim Agalloco, Ellen Moskowitz, Kelli Dobilas, Robert Seltzer, Joel Schwartzman, and Radhakrishna S.Tirumalai. We are very appreciative of the speakers and volunteers who have made all of this possible with a special tribute to Bob Seltzer who has been chairing this undertaking since its inception.

At the May 12<sup>th</sup> meeting we distributed ballots for the PDA Metro Chapter 2010-2012 Executive Offices which begin in June. I'd like to wish a warm welcome to the incoming President, Robert A. Johnson and President Elect, Robert Seltzer. Lisa Smith will take on another term as Treasurer and I will now be the Chapter Secretary (and Immediate Past President). In the upcoming months I look forward to the endeavors that Bob Johnson will pursue and wish him all the best and my continued support.

We look forward to seeing you at an upcoming meeting! If you've attended in the past two years, you already know we raffle off two PDA Memberships at every dinner meeting! We appreciate all your input, ideas, comments and assistance; feel free to contact us at [pdametro@optonline.net](mailto:pdametro@optonline.net)

## GLOBAL STABILITY PROGRAM - a long journey to harmonization

By: *Kim Huynh-Ba, Technical Consultant, Pharmalytik*

In the current business strategy, pharmaceutical companies must work globally and collaboratively. Drug products are now manufactured in one country and may be marketed in over 100 countries. Therefore, it is imperative to be aware of the global regulations. We must not only to understand and comply with these regulations but also the differences among them as well as influences or harmonization efforts. In addition, one also must not lose sights on current industry practices and scientific judgments to develop a global program. [More Details](#)

## Qualification of Impurities in Drug Substances and Drug Products

By: *Karl A. Traul, Ph.D., K.A. Traul Pharmaceutical Consulting*

U.S. and international guidance, especially International Conference on Harmonization (ICH) Q3A(R2), ICH Q2B(R2), Q3C(R4) and VICH GL10R<sup>1</sup> require that drug manufacturers identify, quantify and qualify real or potential impurities in drug substances and drug products. These regulations apply to both human and veterinary drugs and are further delineated in terms of organic or inorganic materials and solvents. Identification and quantification are, generally, achieved with analytical methods. [More Details](#)

## NEWSLETTER STAFFS

### Newsletter Chair

Robert Johnson

### Newsletter

### Coordinator

Mary Huynh

### Distribution

Mary Manco

### Editorial Staff

Nate Manco

Jim Agalloco

Frank Steiner

Leticia Quinones

Robert Johnson

## PDA METRO CHAPTER

726 Route 202 South

Suite 320-347

Bridgewater, NJ 08807

Phone: 732-361-7000

Fax: 732-922-2148

E-mail: [pdametro@optonline.net](mailto:pdametro@optonline.net)

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