

SPEAKER PROFILES

Dr. David Albert, a NAMSA Senior Scientist, holds a Ph.D. in Chemistry, an MS with an emphasis in Biochemistry and a Doctorate in Podiatric Medicine. His primary expertise is in the areas of pharmacology and biochemistry, with over 25 years of laboratory experience. Dr. Albert is currently a member of the American Association for Clinical Chemistry, the American Chemical Society, the Association for the Advancement of Medical Instrumentation (AAMI), the Parenteral Drug Association (PDA), and the Ohio Academy of Science.

Dr. Molly Ghosh, Associate Director of Toxicology at NAMSA, holds a Ph.D. in Pharmacology and Toxicology and has done postdoctoral research at Purdue University. Her expertise is in the areas of molecular and genetic toxicology, cell-based assay development for pharmacological and toxicological studies, biocompatibility, target validation, and drug metabolism. She is an active United States representative on the technical committee (TC194) that establishes and reviews the genotoxicity (TC 194 WG 6, 10993-3) and cytotoxicity (TC 194 WG 5, 10993-5) testing guidelines for medical device industry. Dr. Ghosh has presented or published over 50 papers and serves as an Adjunct (prestige appointment) Associate Professor of Pharmacology and Toxicology in the college of Pharmacy at The University of Toledo.

David Parente, Senior Consultant & Manager of NAMSA Advisory Services, has more than 15 years of experience in process validation, chemical engineering, and quality control. He holds an MBA from Wilmington College. Mr. Parente is involved in the ISO TC 198 Sterilization and Packaging Standards committee and is a member of the ASTM F02 Flexible Barrier Materials group. He is affiliated with the American Society of Clinical Pathologists (ASCP), AAMI, PDA, and ASTM International.

Don Pohl, Manager of Technical Sales and Services, holds a Bachelor's degree in Biology from Ohio State University. His expertise is in sample preparation per ISO 10993-12 and test selection per ISO 10993-1. Previously, Mr. Pohl has held positions at NAMSA as GLP Study Director, Toxicology, Supervisor BPU/Sample Receiving, and Technical Specialist Laboratory Information Management Systems.

Gerry O'Dell is President of Gerry O'Dell Consulting, an organization that provides sterilization and microbiology consulting to the medical device and pharmaceutical industries. She has an M.S. in Microbiology from the University of South Florida and has approximately 8 years experience as an independent consultant in addition to over ten (10) years experience in the supervision and management of a laboratory and sterilization services group. Gerry is a member of ASM, Association for the Advancement of Medical Instrumentation (AAMI), ASTM, Regulatory Affairs Professional Society (RAPS), and has authored various industry publications.

Please visit www.NAMSA.com for a complete list of speakers.

SEMINAR LOCATION & ACCOMMODATIONS

Overlooking the Gulf of Mexico, The Hilton Clearwater Beach sits on 10 lush acres along a beautiful white sandy beach.

All guest rooms are spacious and beautifully appointed. Room amenities include down pillows, complimentary morning newspaper, coffee maker with gourmet coffee and tea as well as up-to-the minute technology such as dual line telephones with voicemail and high-speed internet access (Wayport).

Directions and parking information can be obtained on their Web site or by telephone:

Hilton Clearwater Beach Resort
400 Mandalay Avenue
Clearwater, FL 33767
(727) 461-3222
www.hilton.com

*Rooms are being held at a rate of \$139.00/night plus tax. You must reserve your room prior to **August 28, 2006** in order to receive this rate. Please state that you are with the NAMSA group when placing a reservation. Parking is complimentary.*

HOTELS LOCATED NEAR THE HILTON

Hampton Inn Clearwater – Central
21030 US Highway 19 North, Clearwater, FL 33765
(727) 797-8173 or www.hamptoninn.com

Sheraton Sand Key
1160 Gulf Blvd., Clearwater, FL 33767
(727) 595-1611 or www.sheratonsandkey.com

Radisson Hotel Clearwater – Central
20967 US Highway 19 North, Clearwater, FL 33765
(727) 799-1181 or www.radisson.com

For information, contact Rachael Lanning
Tel: (419) 662 4397 FAX: (419) 662 4386
E-mail: info@namsa.com
Or visit us online at www.NAMSA.com



> Seminar and Workshop

Developments in Medical Device Testing

September 28 & 29, 2006
Clearwater, FL

Trends in Pre-Clinical Testing and Clinical Trials

- Biocompatibility Testing
- ISO 10993: Latest Developments
- Materials Characterization
- Regulatory Requirements for Conducting Clinical Trials

Considerations for Manufacturing & Sterilizing Devices

- Sterilization Methods and Program Design
- Packaging Validation

Developments in Medical Device Testing

This seminar provides the most current information on testing required by regulatory bodies for market approval of medical devices and component materials.

The unique four-phase approach to testing discussed in this seminar will help regulatory affairs experts, quality assurance professionals, and R&D and process development engineers establish a comprehensive, organized program to meet product safety and regulatory compliance standards. Anyone involved in the design, development, or manufacture of medical devices will benefit from attending this seminar and workshop.

Participants will receive certificates of completion, reference materials, and the opportunity to interact with the seminar presenters, all of whom are experts in medical device testing.

PROGRAM OUTLINE

The seminar's two-day format provides you with the convenience of attending one or both sessions. Each day's session will include a "hands on" workshop where the participants develop a testing program for selected devices.

SESSION 1: THURSDAY, SEPTEMBER 28 8:00 AM - 5:00 PM

Trends in Pre-Clinical Testing and Clinical Trials

Biocompatibility - A streamlined approach to compliance with ISO Standard 10993, with special emphasis on recent developments in biocompatibility testing and implications for device manufacturers.

Materials Characterization - An update on the impact of the recently released Part 18: "Chemical Characterization of Materials," with guidance on compliance.

Understanding the Legal Requirements for Conducting Clinical Trials - An overview of the documentation and testing requirements necessary to conduct human clinical studies in compliance with FDA regulations and Good Clinical Practice principles. Special emphasis is given to the relationship between material testing and the methods of the product's clinical use.

SESSION 2: FRIDAY, SEPTEMBER 29 8:00 AM - 4:30 PM

Considerations for Manufacturing & Sterilizing Devices

Sterilization Methods & Program Design - A comprehensive approach to device validation programs with special emphasis on Ethylene Oxide and Radiation sterilization.

Packaging Validation

REGISTRATION & PAYMENT

Seminar fees include:

- Continental breakfast, lunch, and beverages
- A reception on Thursday evening – Guests from both sessions are encouraged to join the seminar speakers for beverages and hors d'oeuvres in a relaxed atmosphere
- All seminar materials (including the NAMSA Characterization Matrix™)

Session 1 Only – Thursday, Sept. 28, 2006 \$350
Session 2 Only – Friday, Sept. 29, 2006 \$350
Both Sessions – Sept. 28 & 29, 2006 \$625*

***A savings of \$75 when you register for both sessions by August 28, 2006.**

When registering 3 or more individuals from the same company, please inquire about our discounted group rate! Reserve your space today!

Registration Form

TO REGISTER – Contact Rachael Lanning

■ By phone: (419) 662-4397 or FAX this form to (419) 662-4386
You may also obtain registration information at www.NAMSA.com

Name

Title

Company

Address

City

State

Zip

Phone

Fax

E-mail

SELECT THE SESSION(S) YOU WISH TO ATTEND	COST PER PERSON	NUMBER OF ATTENDEES	SESSION TOTAL
Session 1 only - Sept. 28	\$350		
Session 2 only - Sept. 29	\$350		
Both Sessions - Sept. 28 & 29	\$625*		
TOTAL REGISTRATION COST			

** A savings of \$75 when you register for both sessions by August 28, 2006.*

PAYMENT METHOD

The following payment methods are accepted (check one):

Mastercard Visa American Express Check

Card Number

Exp. Date

Cardholder's Signature

Cardholder's Name (please print)

Upon receipt of payment, you will be sent a confirmation of your registration.

Seminar fees are non-refundable; however cancellations prior to August 28, 2006 will receive credit toward another NAMSA seminar. Seminar fees are also transferable to a colleague for the same event. Fees do not include hotel accommodations.