

Moving Forward – Together We Can Define the Direction

3rd Global Endotoxin Testing Summit



Sunday, 04 June – Wednesday, 07 June 2017

Annapolis, MD and Pickering Beach, DE

Agenda

Global Endotoxin Testing Summit 2017

Sunday, 04 June 2017

Welcome Reception

6:30pm – 8:30pm

- Light beverages and hors d'oeuvres will be served

Monday, 05 June 2017

I. Welcome and Introduction

8:30am – 8:45am

Opening Remarks

II. Horseshoe Crab Conservation and Impact on BET

8:45am – 9:30am

- The Pharmaceutical and Biomedical Industries' Role in Horseshoe Crab Conservation

Mr. Glenn Gauvry – Ecological Research & Development Group

9:30am – 10:15am

- The LAL Industry is the Principal Conservator of the Atlantic Horseshoe Crab

Dr. James Cooper – Endotoxin Consulting Services

10:15am – 11:00am

- TBD

Dr. Jack Levin, University of California School of Medicine, San Francisco

11:00am – 11:15am

BREAK

III. Low Endotoxin Recovery & Product Hold-time Studies

11:15am – 12:00pm

- Understanding Endotoxin: Lipid A Biosynthesis and Diversity

Dr. Jessica Hankins – US Food and Drug Administration, CDER

12:00pm – 12:45pm

- Case Studies for Low Endotoxin Recovery (LER) Product Hold-time Studies

Dr. Jan Erik Rau – Lonza Customer Manufacturing Services

12:45pm – 1:45pm

LUNCH

IV. Low Endotoxin Recovery & Product Hold-time Studies

1:45pm – 2:30pm

- Experiences Gained in a Contract Lab for Bacterial Endotoxin Testing

Dr. Johannes Reich – MicroCoat, GmbH

2:30pm – 3:15pm

- Biologics Are Different: Fever is Common in Biologics Administration

Mr. Kevin Williams – Hyglos, a BioMerieux Company

3:15pm – 3:30pm

BREAK

3:30pm – 4:00pm

- Q&A Roundtable with Day 1 Speakers

4:00pm – 4:15pm

- Wrap-up of Day 1

Details for dinner and beach activity for Tuesday, June 6th

END OF DAY 1

Dinner at 7pm – (Blackwall Hitch, 400 6th St, Annapolis, MD 21403)

Tuesday, 06 June 2017

I. Save the Crab!!

7:30am – 12:30pm

- Crab-flipping activity

Bus departs Annapolis at 7:30am for Pickering Beach, DE (~80-minute drive) for arrival by 9:00am – 9:30am

There will be a stop for snacks and to use the restroom.

High tide scheduled for 8:22am

12:30pm – 2:00pm

LUNCH

2:00pm – 2:30pm

- Boarding for departure from Pickering Beach no later than 2:30pm for return to Annapolis, MD by 4:00pm -4:30pm.

END OF DAY 2

Dinner at 6:00pm – (Pusser's Caribbean Grille – Annapolis Waterfront Hotel)

Wednesday, 07 June 2017

I. Future Testing Considerations

9:00am – 9:45am

- Detection and Quantification of Endotoxin in Engineered Nanomaterials and Nanotechnology-formulated Drugs

Dr. Marina Dobrovolskaia – Leidos Biomedical Research, Inc.

9:45am – 10:30am

Comparing Key Performance Aspects of Different MAT Technologies

Dr. Shabnam Solati – MAT Research

10:30am – 11:15am

- Endotoxin Detection in Gene and Cell Therapy Products

Mr. Allen Burgenson – Lonza Bioscience, Walkersville, MD

11:15am – 11:45am

- Ask the Speakers – Q&A session for all topics presented at the 3rd Global Endotoxin Testing Summit

II. Summit Wrap-Up

11:45am – 12:00pm

- Closing remarks

END OF DAY 3 – Summit Adjourned

Speaker Biographies



Allen L. Burgenson, Lonza Walkersville, US
Manager Regulatory Affairs

Allen has over 30 years of experience in industries regulated by the FDA, including Foods, Drugs, Biologics, Medical Devices, and Cosmetics. He has worked in R&D, QC, QA and Regulatory Affairs.

Allen is involved in several scientific organizations including, the Horseshoe Crab Advisory Panel for the Atlantic States Marine Fisheries Commission (ASMFC) and President of the Capital Area Chapter of the Parenteral Drug Association (PDA). He is not only involved in PDA activities on the local, national, and international level, but also served as a Program Committee member for the annual PDA/FDA Joint Regulatory Conference in Washington, DC. Allen served as the Chair for this meeting in 2004.



Glenn Gauvry, Ecological Research & Development Group, Inc. (ERDG)
Founder and Director

Glenn Gauvry is the founder and director of the Ecological Research & Development Group, Inc. (ERDG), a nonprofit organization established in 1995, whose mission is the conservation of the world's four horseshoe crab species, the only such organization in the world. Mr. Gauvry is a founding member of the International Union for the Conservation of Nature (IUCN) - Horseshoe Crab Species Specialist Group and chair of the Trade, Industry and Use Workgroup. He is also a founding member for the series of international workshops held in 2007, 2011 and 2015 on the science and conservation of horseshoe crabs.



James F Cooper, PharmD., Professor of Pharmacy at the Medical University of South Carolina

Before founding Endosafe in 1987, Dr. Cooper, a was Professor of Pharmacy at the Medical University of South Carolina. Last year he received the James P. Agalloco Award for teaching excellence at PDA. His thesis work under Dr. Jack Levin at The Johns Hopkins University in 1971 led to application of the bacterial endotoxin test (BET) for parenteral products. His publications span the history of LAL technology. Since retirement in 2001, he continues his consultation, teaching, publishing related to endotoxin issues, BET root-cause investigations and CGMPs for positron-emission tomography drugs.



Jessica Hankins, Ph.D., US Food and Drug Administration, CDER
Microbiology Reviewer

Jessica Hankins earned a B.S. in biology from East Tennessee State University and obtained her Ph.D. with distinction from Georgia Health Sciences University. Jessica's research focused on the biosynthesis of the *Vibrio cholerae* lipid A domain. She completed a post-doctoral fellowship at The University of Texas at Austin where she discovered a novel lipid A modification that confers polymyxin B resistance to the Gram-negative organism *Vibrio cholerae*. Jessica was a research scientist in the industry, prior to joining the Food and Drug Administration. Currently, Jessica is a microbiology reviewer in FDA's Center for Drug Evaluation and Research.



Dr. Dobrovol'skaia, Ph.D., Head of Immunology Section at the Nanotechnology Characterization Laboratory (NCL), Leidos Biomedical Research Inc. Senior Principal Scientist

Dr. Dobrovol'skaia's team develops, validates and qualifies performance of in vitro and ex vivo assays to support preclinical characterization of nanoparticles, and to monitor nanoparticle purity from biological contaminants such as bacteria, yeast, mold and endotoxin. Her group contributed to characterization and evaluation of more than 300 nanotechnology products submitted to the NCL for preclinical characterization; ten of these products are now in human clinical trials. Dr. Dobrovol'skaia is a member of several working groups on Nanomedicine, Oligonucleotide Safety and Endotoxin Detection. She has published more than 45 peer-reviewed papers regarding nanomaterial interactions with the immune system, prepared and edited two editions of the "Handbook of Immunological Properties of Engineered Nanomaterials", which received international recognition. Dr. Dobrovol'skaia is an invited speaker to numerous national and international nanotechnology-related conferences. She has served a 4-year term as a Special Associate Editor in Immunology for the "Nanomedicine: Nanotechnology, Biology and Medicine" Journal published by Elsevier and is currently an editorial board member for the Journal of Nanotoxicology and Nanomedicine by IGI Global.



Jack Levin, M.D., University of California School of Medicine
Professor of Laboratory Medicine and Professor of Medicine

Dr. Levin has been a member of the faculty of the University of California School of Medicine in San Francisco since 1982. Previously, he was Professor of Medicine at The Johns Hopkins Univ. School of Medicine, Baltimore, MD. Dr. Levin is the author or co-author of over 250 original research publications, reviews, and book chapters. He was Editor-in-Chief of the Journal of Endotoxin Research from 1998 to 2004. His studies of blood coagulation in *Limulus*, the horseshoe crab, performed at the Marine Biological Laboratory (Woods Hole, MA), identified the key role of amebocytes, the only type of circulating blood cell in the horseshoe crab, in blood coagulation. His recognition of the sensitivity of amebocytes and subsequently of lysates prepared from washed amebocytes to bacterial endotoxins led to his original description of the *Limulus* Amebocyte Lysate Test for the detection of bacterial endotoxins in 1964. His studies of the biological effects of bacterial endotoxins and utilization of the *Limulus* Test for detection of endotoxin in the blood of patients with various clinical disorders led to his receiving the Bang Award for research in bacterial endotoxins and to election as an honorary life member of the International Endotoxin and Innate Immunity Society. In 2014, Dr. Levin received a special award from the Parenteral Drug Association in recognition of the 50th anniversary of his initial description of the *Limulus* Amebocyte Lysate (LAL) Test.

Speaker Biographies



Johannes Reich, Ph.D. MicroCoat, GmbH
General Manager

Johannes Reich holds a PhD from the University Regensburg. He focused his research on the aggregation and interaction behavior of lipopolysaccharides as well as the related activity in limulus based detection systems. In 2016, Johannes joined Microcoat Biotechnology GmbH and has recently been appointed General Manager. Johannes Reich also received a degree in Business Administration from the University of Applied Science in Regensburg, Germany. While pursuing his degree, he worked as Product Manager for the department "Drugs of Abuse" at Profos AG.



Drs. Shabnam Solati, MAT Research
Co-founder

Drs. Solati is a biomolecular researcher with 25 years of experience, and Monocyte Activation Test (MAT) specialist for over 11 years. Shabnam has done extensive research in the field MAT under the mentorship of Prof. Lucien Aarden. She is co-founder and lead scientist at MAT Research. Her most recent project is the development of a new MAT kit using cryopreserved PBMC.



Kevin Williams, Hyglos, a BioMerieux Company
US Endotoxin Senior Scientist

Kevin spent over 30 years at Eli Lilly & Company developing endotoxin assays and detection technology in the quality control lab. Kevin is a recognized expert in the field of endotoxin detection and authored the reference book Endotoxins: Pyrogens, LAL Testing and Depyrogenation (Drugs and the Pharmaceutical Sciences, 2nd and 3rd Editions). In addition to publishing papers in leading industry journals and other forms of media, he is a frequent speaker at endotoxin related industry events.

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