Bioscience Solutions

Lonza

Feel The Pulse of Endotoxin Detection and Impact Its Future

4th Global Endotoxin Testing Summit – Agenda

Monday – Thursday, 11 – 14 June 2018
Annapolis, MD & Pickering Beach, DE

Global Endotoxin Testing Summit 2018

Monday, 11 June 2018

Welcome Reception/Evening Registration

6:30pm – 8:30pm

– Light beverages and hors d'oeuvres will be served

Tuesday, 12 June 2018

7:00am – 8:30am

– Continental Breakfast/Final Registration (Outside Emil Nobs Room)

I. Welcome and Introduction

8:30am – 8:45am

– Opening Remarks

II. Origins

8:45am – 9:15am

– The Limulus Amebocyte Lysate (LAL) Test: Discovery, Performance, and Future Use
Jack Levin, M.D. University of California School of Medicine, San Francisco

9:15am – 9:45am

– The Role of Compassion in a Sustainable Conservation Strategy
Glenn Gauvry – Ecological Research & Development Group

9:45am – 10:15am

– Why is Industry 4.0 a Revolution? Requirement (Technical, Regulatory & Mindset), Benefits, Possible Implementation Strategies
Dr. Hiroshi Nakano – CSL Behring

10:15am – 10:30pm
BREAK

III. A Look Closer

10:30am – 11:00am

– Recombinant Factor C: Natural Occurrence, Structure, Specificity, and r-Assay Performance
Mr. Kevin Williams – Hyglos, a Biomerieux Company

11:00am – 11:30am

– rFC – The Road Less Traveled - An Implementation Update and Shared Learning
Mr. Jay Bolden – Eli Lilly

11:30am – 12:00pm

– Current Trends in Bacterial Endotoxin and Pyrogen Testing
Dr. Johannes Reich – MicroCoat, GmbH

12:00pm – 1:00pm
LUNCH

IV. Low Endotoxin Recovery, Masking, Product Hold-Times and Interferences

1:00pm – 1:30pm

– LER Technical Report Update and FDA Case Studies: Problematic LER Studies, Mitigation, and More
Dr. Jessica Hankins – United States Food and Drug Administration

Tuesday, 12 June 2018 (continued)

1:30pm – 2:00pm

– Understanding the Reason for LER
Dr. Felix Weyer – MicroCoat, GmbH

2:00pm – 2:30pm

– LER studies on Complex Vaccine Matrices
Ms. Marine Marius – Sanofi Pasteur

2:30pm – 3:00pm

– Endotoxin Masking – Case Studies from a Contract Manufacturer of Pharmaceuticals
Dr. Jan Erik Rau – Lonza

3:00pm – 3:30pm

– Interferences in Endotoxin Testing - Case Studies on Difficult Sample Matrices and Ways to Overcome Them through Different Testing Methodologies
Dr. Stefan Gärtner – Labor L+S AG

3:30pm – 3:45pm
BREAK

3:45pm – 4:45pm

– Q&A Roundtable with Day 1 Speakers
Dr. Jessica Hankins, Dr. Johannes Reich, Dr. Jan Erik Rau, Mr. Jay Bolden, Mr. Kevin Williams, Ms. Marine Marius, Jack Levin, M.D., Mr. Glenn Gauvry, Dr. Felix Weyer, Mr. Stefan Gärtner, Dr. Hiroshi Nakano

4:45pm – 5:00pm

– Wrap-up of Day 1
Details for dinner and beach activity for Wednesday, 13 June

END OF DAY 1

Dinner at 7:00pm (Galway Bay Irish Restaurant & Pub)

Wednesday, 13 June 2018

I. Save the Crab!!

7:30am – 12:30pm

– Crab-flipping activity (Horseshoe Crab Sanctuary Beach) 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 along the way.
High tide scheduled for 9:50am

12:00pm
Bus departs Pickering Beach

12:30pm – 2:00pm
LUNCH – Sambo's, Leipsic, DE

2:00pm – 2:30pm

– Boarding for departure from Sambo's no later than **2:30pm** for return to Annapolis, MD by 3:30pm – 4:00pm.

END OF DAY 2

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

Thursday, 14 June 2018

I. Future Testing Considerations

7:00am – 8:30am

– Continental Breakfast (Outside Emil Nobs Room)

8:30am – 9:00am

– Detection and Quantification of Endotoxin in Engineered Nanomaterials and Nanotechnology-formulated Drugs
Dr. Marina Dobrovolskaia –Leidos Biomedical Research, Inc.

9:00am – 9:30am

– MAT Assay: Purpose, Control, Compliant and Correlative
Mrs. Tammy Thurman – Pfizer

9:30am – 10:00am

– Pyrogen Detection with the Cryopreserved PBMC-based MAT Cell Set: Performance, Study Examples and Challenges
Dr. Eelo Gitz – Sanquin Reagents B.V.

10:00am – 10:30am

– Streamlining Your QC Testing – Automated Endotoxin Testing and Process Optimization
Mr. Allen Burgenson – Lonza Bioscience

10:30am – 10:45am
BREAK

10:45am – 11:30am

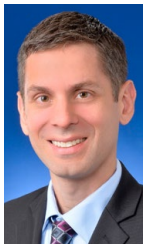
– Q&A Roundtable with Day 1 & 3 Speakers
Dr. Jessica Hankins, Dr. Johannes Reich, Dr. Jan Erik Rau, Mr. Kevin Williams, Ms. Marine Marius, Jack Levin, M.D., Mr. Glenn Gauvry, Dr. Felix Weyer, Mr. Stefan Gärtner, Mr. Jay Bolden, Dr. Marina Dobrovolskaia, Dr. Eelo Gitz, Mr. Allen Burgenson, Mrs. Tammy Thurman, Dr. Hiroshi Nakano

11:30am – 11:45am

– Wrap-up Day 3
Closing Remarks

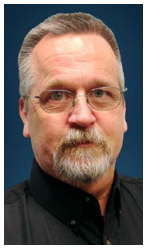
END OF DAY 3 – Summit Adjourned

Speaker Biographies



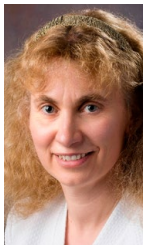
Jay Bolden, Senior Consultant Biologist
Eli Lilly & Company

Mr. Jay Bolden is an Senior Consultant Biologist in the Eli Lilly and Company Global Quality Laboratories. He is an internal endotoxin subject matter expert and leads a team with global QC oversight for developing, validating, transferring and troubleshooting endotoxin, microbiology, QPCR and ELISA methodologies. Jay holds a B.S. in Biology and an Environmental Studies certificate from Indiana University, and has over 18 years of industry experience in development, process and laboratory microbiology, and microbiology laboratory leadership.



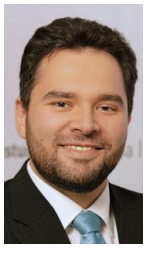
Allen L. Burgenson, Lonza Walkersville, US
Global Subject Matter Expert, Testing Solutions
Lonza Bioscience

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.



Dr. Dobrovolskaia, Nanotechnology Characterization Laboratory (NCL), Senior Principal Scientist, Head of Immunology Section

Dr. Dobrovolskaia directs characterization related to nanomaterials' interactions with components of the immune system. She received her M.S. degree from the Kazan State University and Ph.D. from the N.N. Blokhin Cancer Research Center of the Russian Academy of Medical Sciences in Moscow, Russia, the MBA degree from Hood College in Frederick MD, and completed two postdoctoral trainings at the National Cancer Institute in Frederick, MD and the University of Maryland in Baltimore, MD. She is also a member of Project Management Institute and a certified Project Management Professional. Her areas of expertise include cell signaling, innate immunity, immunotoxicity of complex drug formulations, bioanalytical methodology, and endotoxin detection and quantification



Dr. Stefan Gärtner, Labor L+S AG, Labor LS,
Head of a Speciality Department

After his qualification as biological laboratory technician at Labor LS in 2005 Stefan worked as technical specialist in the field of different pyrogene detection methods. In 2015 he finished his studies at Provadis School of International Management and Technology with a Bachelor degree in Biopharmaceutical Sciences. Since then, he is head of a specialty department at Labor LS for the implementation, validation and routine testing of rapid and alternative methods within the quality control of sterile products.

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., a nonprofit organization established in 1995, whose mission is the conservation of the world's four horseshoe crab species. Mr. Gauvry is also a founding member of the IUCN Horseshoe Crab Specialist Group. ERDG believes environmental stewardship can thrive within a growing economy through healthy partnerships between government, industry, environmental groups and communities, therefore works to inspire and assist in-dividuals and organizations to solve problems, change behaviors and promote sound decisions

Dr. Eelo Gitz, Sanquin Reagents,
Project Manager, Product Development

Eelo obtained his PhD in Biomedical Sciences at the University of Utrecht (the Netherlands). After a post-doctoral study in the field of platelet biology at the University of Birmingham (the UK), Eelo joined Sanquin Reagents (Amsterdam, the Netherlands) where he is currently working as project manager product development. During the last 4 years, he has been working on the development and production of a highly sensitive Monocyte Activation Test (MAT) assay based on cryopreserved peripheral blood mononuclear cells (PBMC) and now coordinates all MAT activities at Sanquin.

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.

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

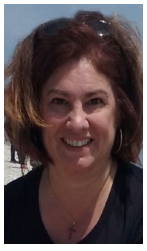
Jack Levin, M.D. has been a member of the faculty of the University of California School of Medicine in San Francisco since 1982. Previously, he was Professor of Medicine at The Johns Hopkins Univ. School of Medicine, Baltimore, MD. Jack Levin, M.D. is the author or co-author of over 250 original research 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, Jack Levin, M.D. 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.

Ms. Marine Marius, Sanofi Pasteur, Analytical Research and Development Scientist

Marine Marius started in the North American division of ARD in Toronto and is currently in the European division in France. She leads the development, validation and implementation of rapid microbiology methods (bacteriology and molecular biology) for legacy and new investigational products

Dr. Hiroshi Nakano, CSL Behring,
Sr. Manager for Quality Automation

Master in inorganic biochemistry at the ETH. Ph.D. in Bioinformatics and Molecular Biology in the organic Chemistry Department of ETH. He started his professional experience in instrumental environmental analysis and programmed own LIMS and SDMS based on spreadsheet and databases. His accomplishment includes an implementation of a commercial LIMS with almost complete automation or order management and laboratory processes. He is responsible for operational readiness, tech transfer, automation and the introduction of a LIMS system for a new laboratory in Brazil, from scratch. Today, he is a member of the BOS Organization of a global pharma company and is responsible for quality automation at the local site in Switzerland.



Tammy Thurman, Scientist in Pfizer's Analytical Research and Development, Division of Biotherapeutics Pharmaceutical Sciences.

Tammy developments, optimizes and qualifies bioassays, supports in-process endotoxin testing and performs all low endotoxin recovery studies. She has a considerable amount of cell based functional assay expe'rience and has worked for the past several years supporting Pfizer's Biosimilar Projects. Pfizer has a diverse portfolio including monoclonal antibodies, conjugates, therapeutic proteins and vaccines. Tammy was previously an employee of Pharmacia, Monsanto and Searle. She received her B.S. in the Teaching of Biology from the University of Illinois (Champaign, IL U.S.).

Dr. Jan Erik Rau, Head of QC Microbiology and SME for Microbiology at Lonza, Visp, Switzerland

Jan studied biology in Bremen, Germany, and has a PhD in Marine Microbiology from University of Bremen. The PhD was obtained within the International Max Planck Research School of Marine Microbiology (MarMic). In 2011, Jan started working at Lonza in Visp, Switzerland. As part of his role as Manager of the QC Microbiology Department, he is responsible for design and evaluation of endotoxin masking /demasking studies.

Dr. Johannes Reich Ph.D., Microcoat Biotechnology GmbH, General Manager

Johannes Reich holds a Ph.D. 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.

Dr. Felix Weyer, Microcoat Biotechnologie GmbH in Bernried, Project Leader

Felix Weyer studied Chemistry at the University of Freiburg and received his Ph.D. at the Biochemistry Center of Heidelberg University. After his degree, he worked as a research scientist at Heidelberg University before he joined the Microcoat Biotechnologie GmbH in Bernried as a project leader. Here, he is responsible for the development of specific demasking strategies in biologicals, and handles all scientific questions related to endotoxin detection.

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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