



Bioscience Solutions

**Lonza**

# 5<sup>th</sup> Global Endotoxin Testing Summit

## Where Science Meets Inspiration

### Agenda



Monday – Wednesday, 3 – 5 June 2019  
Annapolis, MD & Pickering Beach, DE

# 2019 Endotoxin Testing Summit

## Sunday, 2 June 2019

### Welcome Reception, Pick-up Registration Bags

- 6:30pm: Speaker Check-in
- 6:30pm – 8:00pm
  - Emil Nobs Room:  
Beverages and hors d'oeuvres will be served

## Day 1

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### Monday, 3 June 2019

### Breakfast, Pick-up Registration Bags

- 7:00am – 8:00am
  - Outside Emil Nobs Room

### Welcome and Introduction

- 8:00am – 8:15am
  - Opening Remarks (Emil Nobs Room)

### Session 1: A Retrospective History

- 8:30am – 9:15am
  - Keynote Speaker:  
Jack Levin, M.D.  
The Limulus Amebocyte Lysate (LAL) Test:  
Discovery, Applications, and Future Trends  
in Endotoxin Detection

- 9:15am – 9:45am
  - BET: Myths and Legends  
Mrs. Karen McCullough

- 9:45am – 10:00am
  - Q&A Discussion, Session 1

- 10:00am – 10:15am  
REFRESHMENT BREAK (Outside Emil Nobs Room)

### Session 2: Natural Progressions

- 10:15am – 10:45am
  - The Definition of Endotoxin  
Mr. Kevin Williams

- 10:45am – 11:15am
  - Endotoxin Methods: Back to the Future?  
Mrs. Tammy Thurman

- 11:15am – 11:45am
  - Recombinant Factor C: Progressive Endotoxin  
Detection One Year In  
Mr. Jay Bolden

- 11:45am – 12:00pm
  - Q&A Discussion, Session 2

- 12:00pm – 1:00pm  
LUNCH (Patio)

### Session 3: Writing on the Wall

- 1:00pm – 1:30pm
  - PDA Technical Report 82,  
Low Endotoxin Recovery (LER)  
Mr. Allen Burgenson

- 1:30pm – 2:00pm
  - Mitigation Strategies for Low Endotoxin Recovery  
Dr. Ruth Röder

## Monday, 3 June 2019 (continued)

- 2:00pm – 2:15pm
  - Q&A Discussion, Session 3

- 2:15pm – 2:30pm  
REFRESHMENT BREAK (Outside Emil Nobs Room)

### Session 4: The Significance of Survival

- 2:30pm – 3:00pm
  - Compare and Contrast: The Threats, User Groups  
and Conservation Efforts between the Atlantic  
and the Asian Horseshoe Crab Species  
Glenn Gauvry

- 3:00pm – 3:30pm
  - Facing the Challenge of Horseshoe Crab  
Conservation in Mexico  
Dr. Jaime Zaldivar

- 3:30pm – 4:00pm
  - A Bird Whose Life Depends on a (Horseshoe) Crab  
Mrs. Deborah Cramer

- 4:00pm – 4:15pm  
REFRESHMENT BREAK (Outside Emil Nobs Room)

- 4:15pm – 4:30pm
  - Q&A Discussion, Session 4

- 4:30pm – 4:45pm
  - Insight into Crabs in their Natural Environment  
Glenn Gauvry

- 4:45pm – 5:00pm
  - Wrap-up, Day 1  
Details for Dinner and Tuesday Beach Activity

- 5:00pm – 5:30pm
  - Book Signing with Deborah Cramer  
“The Narrow Edge A Tiny Bird, An Ancient Crab &  
An Epic Journey”

- Dinner at 7:00pm (Galway Bay)
  - Arrive to restaurant at 6:30pm

END OF DAY 1

## Day 2

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### Tuesday, 4 June 2019

### Save the Horseshoe Crab!!

- 6:00am – 7:00am
  - Breakfast at hotel (Location TBD)
  - Meet in Lobby to Board Bus

- 7:15am
  - Bus departs Annapolis at 7:15am for Pickering  
Beach, DE. (~80min drive) for arrival by 9:00am.  
There will be a stop for snacks and restroom  
break. High tide at 11:06am

- 9:15am
  - Group Picture on Beach, upon arrival

- 11:45am
  - Board the bus, depart Pickering Beach

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

- 2:30pm
  - Depart restaurant no later than 2:30pm for return  
to Annapolis, MD by approx. 4:00pm (time)

- 4:00pm
  - Arrival to Annapolis, MD

- 5:30pm
  - Cocktails - Harborview Room,  
Annapolis Waterfront Hotel

- 6:00pm
  - Dinner

END OF DAY 2

## Day 3

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### Wednesday, 5 June 2019

- 7:00am – 8:30am
  - Breakfast (Outside Emil Nobs Room)

### Session 5: Regulatory Changes in Europe

- 8:30am – 9:00am
  - History of Pyrogen Detection and Future Trends  
– Mr. Stefan Gärtner

- 9:00am – 9:30am
  - Pyrogen Detection with a Cryopreserved PBMC-  
based MAT assay  
Dr. Eelo Gitz

- 9:30am – 9:45am
  - Q&A Discussion, Session 5

- 9:45am – 10:00am  
REFRESHMENT BREAK (Outside Emil Nobs Room)

### Session 6: Innovations in Automation and Data Integrity

- 10:00am – 10:30am
  - Endotoxin Automation Case Study from a CMO  
Dr. Jan Erik Rau

- 10:30am – 11:00am
  - Importance of Proper Systems for Pyrogen Testing  
Mr. Josiah Hosie

- 11:00am – 11:15am
  - Q&A Discussion, Session 6

### Closing Round Table & Summit Wrap-up

- 11:15am – 11:45am
  - 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 Bi-ology and an Environmental Studies certificate from Indiana Univer-sity, and has over 19 years of industry experience in development, process and laboratory microbiology, and microbiology laboratory leadership.



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

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.



**Deborah Cramer**, Visiting Scholar at MIT and Author

Deborah has written three books about the sea and the sea edge – Great Waters; Smithsonian Ocean: Our Water World, and The Narrow Edge: A Tiny Bird, An Ancient Crab, and An Epic Journey, in which she accompanied endangered shorebirds along their extraordinary migration from Tierra del Fuego up to the Arctic. The Narrow Edge received the Best Book Award from the U.S. National Academy of Sciences, and the Rachel Carson Book Award from the Society of Environmental Journalists. She has also written about horseshoe crabs and red knots for Audubon, BBC Wildlife, and the New York Times. Perhaps you have heard her talking about these amazing animals on NPR.



**Dr. Stefan Gärtner**, Labor LS SE & Co. KG, Bad Bocklet,  
Germany

Stefan studied Biopharmaceutical Sciences at Provdadis School of International Management and Technology in Frankfurt. Having more than 15 years of experience in the field of different pyrogen detection methods he is head of department for the microbial quality control of sterile products at Labor LS SE & Co. KG.



**Glenn Gauvry**, Founder and Director, Ecological Research and  
Development Group

Glenn Gauvry is the founder and director of the Ecological Research & Development Group Inc. (ERDG) a nonprofit wildlife conservation organization established in 1995, whose mission is the conservation of the world's four horseshoe crab species, the only such organization in the world. Glenn is a founding member of the International Union for the Conservation of Nature (IUCN) - Horseshoe Crab Specialist Group and head of the Trade, Industry and Use working group. He is also a founding member of the international series of workshops on the science and conservation of horseshoe crabs held in the USA - 2007, Hong Kong - 2011, Japan - 2015 and China - 2019. Prior to ERDG, Glenn served as Senior Technical Coordinator on an internationally recognized oil spill rapid response team, focused on mitigating the impact of oil spills on native wildlife species. Glenn is the Mayor of the town of Little Creek, Delaware, where he has served three terms. Originally trained as an industrial designer, Glenn has an extensive background in product design and manufacturing. Glenn is also veteran of the United State Air Force, where he served as an Air Traffic Controller.



**Dr. Eelo Gitz**, Project Manager, Sanquin Reagents,  
The Netherlands

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.

**Josiah Hosie**, Product Strategist, Lonza Walkersville, US

Josiah has 15 years of product development experience on a variety of software applications working on data visualization engines and laboratory systems. In 2010, he joined Lonza as the technical lead for WinKQCL™ software platform where he led the development of the WinKQCL™ 5 and 6 platforms integrating with over 20 types of microplate readers and providing seamless interfaces with information management systems such as LIMS or MODA™. Recently, he coauthored a chapter on Data Integrity in the soon to be published "Endotoxin Detection and Control in Pharma, Limulus, and Mammalian Systems".



**Jack Levin, M.D.**, Founder of the Limulus Amebocyte Lysate (LAL) Test, University of California School of Medicine, San Francisco

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.



**Karen Zink McCullough**, Principal Consultant at MMI Associates

Ms. McCullough has over 35 years of experience in the Pharmaceutical Industry, and has worked in aseptic manufacturing, oral dosage, and diagnostics sectors. She is a highly respected speaker and trainer both nationally and globally. Karen's current interests are the use of microbiological assays as tools for process control. Ms. McCullough is a charter member and current Chair of the LAL Users' Group. She is an elected member of the Microbiology General Chapters Expert Committee of the United States Pharmacopeia and serves as a member of the United States delegation to TC2-9, WG02, revision to ISO 14698 (Biocontamination standard). She recently edited the book, "The Bacterial Endotoxins Test: A Practical Guide", which provides background and advice on a range of topics related to the compliant performance of the Bacterial Endotoxins Test.



**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. Ruth Röder**, Project Leader Endotoxin Services. Microcoat Biotechnologie GmbH

Ruth studied Biochemistry and holds a PhD from the Ludwig-Maximilians-University, Munich. In 2016 she has joined the Microcoat Biotechnologie GmbH, where she has been focusing her work on the monocyte activation test (MAT) comparing the application of different cellular test systems. In 2017 she has joined the endotoxin detection service team as a project leader. She is working on projects concerning low endotoxin recovery including the development of specific demasking strategies.



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

Tammy develops, 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 experience 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 and has been with the company for over 20 years.



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

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.



**Dr. Jaime Zaldívar-Rae**, Research Coordinator, Anáhuac Mayab University, Founder Proyecto Mex

Dr. Zaldívar-Rae is a biologist and holds a doctorate degree in biomedical sciences from the Universidad Nacional Autónoma de México (UNAM; National University of Mexico), specializing in behavioral ecology. Over the past 25 years he has taught undergraduate and graduate courses at UNAM, the National School of Anthropology and History (ENAH) and Anahuac Mayab University (UAM). In 2007, he was appointed Sub-director for Endangered Species Conservation Programs at Mexico's National Commission for Natural Protected Areas (CONANP). He was later hired as a postdoctoral researcher at UNAM's Multidisciplinary Unit for Education and Research in Sisal, Yucatan. In 2010, Dr. Zaldívar-Rae became a full-time professor and researcher at UAM's Schools of Medicine and Psychology, and as of January 2013, he is the University's Research Coordinator.

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