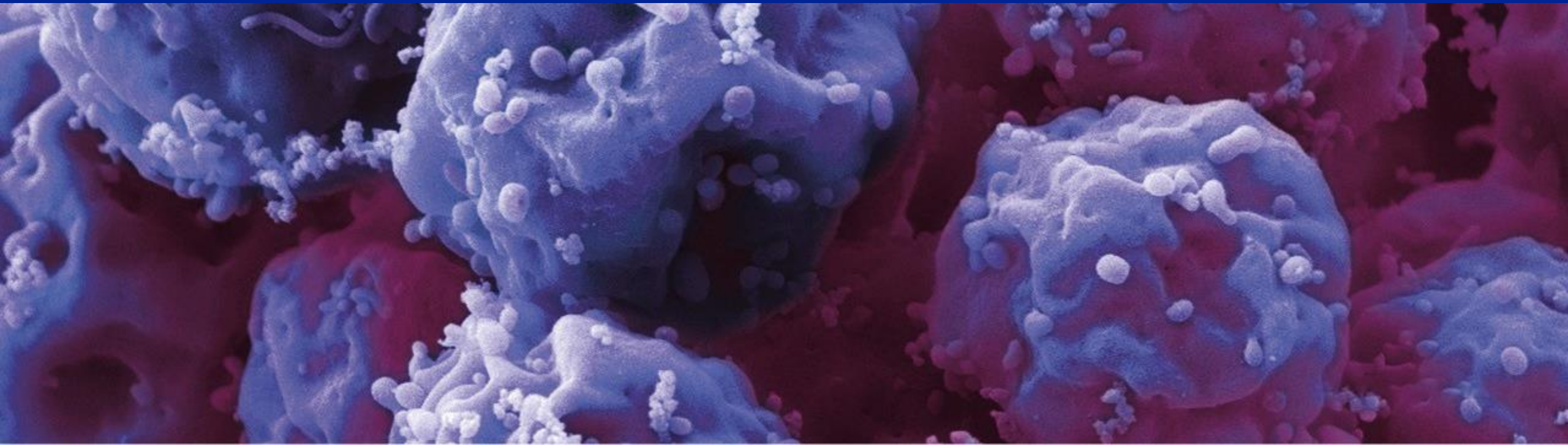


2025 Endotoxin Testing Summit

Americas Agenda

Business Use Only



Tuesday, 10 June 2025

Americas Agenda Day 1

Time:00	Annapolis Waterfront Hotel
> 8:30 am – 8:45 am	Welcome
> 8:45 am – 9:15 am	The Limulus Amebocyte Lysate (LAL) Test: History, Applications, and Future Trends in Endotoxin Detection Dr. Jack Levin, Professor of Laboratory Medicine, Professor of Medicine, University of California School of Medicine, San Francisco
> 9:15 am – 10:00 am	Advancing Endotoxin Detection with USP Chapter <86> and Recombinant Reagents Allen L. Burgenson, Testing Solutions Global SME, Lonza Bioscience
> 10:00 am – 10:30 am	Horseshoe Crab Conservation Reimagined: The Path of Balance and Harmony Glenn Gauvry, President of ERDG
> 10:30 am – 10:45 am	Coffee Break
> 10:45 am – 11:45 am	Crossing the Great Divide: Nebula® Multimode Plate Reader for Sustainable Bacterial Endotoxin Testing Ben Claywell – Principal Scientist, Eli Lilly and Company
> 11:45 am – 12:30 pm	Some Endotoxins Are Not Like the Others: Using the MAT to Accurately Determine Pyrogenicity Dr. Djikolngar (Djik) Maouyo (PhD), Director and President at PyroDex LLC
> 12:30 pm – 1:15 pm	Lunch
> 1:15 pm – 2:00 pm	Endotoxin Testing Approaches to Assess RNA-LNP Product Safety Dr. Cleyton Crepaldi Domingues (PhD), R&D Manager, Lonza Bioscience
> 2:00 pm – 2:45 pm	PyroTec® Pro for cGMP Testing Rachel Orlen, Manager/Christopher Mauro, Technical Lead, Microbiological Control, LOTTE Biologics LLC
> 2:45 pm – 3:00 pm	Coffee Break
> 3:00 pm – 3:45 pm	Building a Sustainable QC Lab: Digital Transformation for Efficiency and Impact Staci Williams, Informatics Engineer, MODA®
> 3:45 pm – 4:30 pm	Demystifying LER (Low Endotoxin Recovery) Allen L. Burgenson, Testing Solutions Global SME, Lonza Bioscience
> 4:30 pm – 4:45 pm	Panel Discussion
> 4:45 pm – 5:00 pm	Closing Remarks



Wednesday, 11 June 2025

Americas Agenda Day 2

Time:00	Lonza Walkersville
▶ 07:30 am – 12:00 pm	Crab-flipping activity (Pickering Beach) (~80-minute drive) for arrival by 9:00am – 9:30am
▶ 12:00 pm – 1:30 pm	Lunch
▶ 1:30 pm – 3:00 pm	Return to hotel



Our Speakers



Allen Burgenson

Allen L. Burgenson has more than 40 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, regulatory affairs, and now marketing as a subject matter expert for endotoxin detection. Allen is involved in several scientific organizations, including serving as chair of the Horseshoe Crab Advisory Panel for the Atlantic States Marine Fisheries Commission (ASMFC) and as a former president of the Capital Area Chapter of the Parenteral Drug Association (PDA).



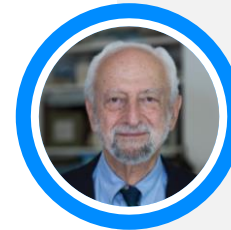
Glenn Gauvry

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.



Ben Claywell

Ben is a Principal Scientist at Eli Lilly and Company. He has worked at Lilly for over 7 years and supports global bacterial endotoxins testing through site training and transfer, method development and verifications, and new technology evaluation. Ben has a BS in Biochemistry from Purdue University.



Dr. Jack Levin

Jack Levin, M.D., pioneered the Limulus Amebocyte Lysate (LAL) test in 1964, revolutionizing bacterial endotoxin detection. His work with horseshoe crab amebocytes has had lasting impact in biomedical science. He is a recipient of the Bang Award, PDA honors, and the AAAS Golden Goose Award for transformative research.



Dr. Cleyton Domingues (PhD)

Dr. Domingues is a chemist with a Ph.D. in biochemistry. He was a Postdoctoral Fellow at Tufts University and Harvard University and later a Research Associate at George Washington University. His research focused on membrane solubilization and stem cell therapy for diabetes and obesity. After transitioning to industry, he specialized in biosafety testing. Currently, at Lonza, he serves as a people manager and technical lead, overseeing R&D projects on product and assay development for endotoxin testing.



Dr. Djik Maouyo

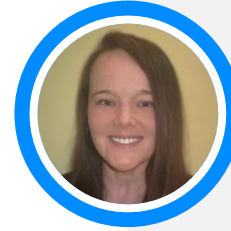
Before founding PyroDex LLC in February 2017, Dr. Maouyo was a Senior Scientist at Lonza Bioscience for over 9 years, leading R&D teams in rapid microbial detection. He previously held faculty positions at the University of Maryland School of Medicine and Johns Hopkins University, following postdoctoral fellowships at Johns Hopkins and the University of Montreal, and a Ph.D. in biology from the University of Sherbrooke. Dr. Maouyo contributed to the European Pharmacopeia chapter on the Monocyte Activation Test and is a recognized expert in MAT science and technology. He is a member of the Consortium of Rapid Microbial Testing Methods at the American National Institute of Standards and Technology.

Our Speakers



Christopher Mauro

Chris is a Technical Lead for the Microbiological Control Department at LOTTE Biologics with 22 years of experience in Quality Control Pharmaceutical Manufacturing and is a graduate of SUNY College of Environmental Science and Forestry. He has been the laboratory lead during validation, implementation, and continued use of the PyroTEC PRO.



Staci Williams

Staci Williams is a Presales Engineer in Lonza's Informatics division, specializing in the MODA® platform. She supports clients in digital transformation for their quality and manufacturing processes. Before joining Lonza, she held various quality-focused roles, ensuring GMP compliance in biologics, vaccines, and cell and gene therapy manufacturing. She holds a Bachelor's degree in Biochemistry from New York University and a Master's degree in Regulatory Science from Johns Hopkins University.



Rachel Orlen

Rachel is a Manager in the Microbiological Control department at LOTTE Biologics, specializing in endotoxin and molecular microbiology testing. She has over 15 years of experience in biotechnology and quality control, spanning GLP and GMP operations. She supported the Windows 10 upgrade for WinKQCL and assisted in implementation of the PyroTec Pro system. Rachel holds a B.S. in Genetic Engineering from Cedar Crest College.