ASSOCIATES OF CAPE COD, INC.

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PROTECTION THROUGH DETECTION

1st ANNUAL ENDOTOXIN FORUM

The Expanding Role of Recombinant BET in Europe and Beyond

6–7 OCTOBER 2026

Andaz Prague | Prague, Czech Republic

The Endotoxin Forum was established to bring together professionals from across the pharmaceutical, biotechnology, and medical device industries to discuss these changes in a practical and meaningful way. Over the next two days, internationally recognized experts will share scientific perspectives, discuss current regulatory developments, present real-world implementation experiences, and explore the future of bacterial endotoxin testing.

Our goal is to create an environment where attendees can learn from one another, exchange ideas, ask questions, and build lasting professional relationships. Whether your organization is just beginning to evaluate new technologies or is already implementing them, we hope this forum provides valuable insights that you can take back to your laboratory and organization.

What You'll Explore

SCIENCE
The evolution of bacterial endotoxin testing and the science supporting recombinant technologies.

REGULATION
European and global regulatory perspectives shaping the use of recombinant BET.

EQUIVALENCY
Real-world evaluation of recombinant reagents alongside traditional LAL methods.

VALIDATION
Water, product and medical-device case studies addressing practical validation considerations.

IMPLEMENTATION
Roadmaps, business considerations and lessons for organizations transitioning to rBET.

SUSTAINABILITY
Ecological responsibility, supply security and the changing drivers behind endotoxin testing.

DAY ONE

Inspiration, Regulation And Drivers Of Change

Moderator: Matt Stevenson – ACC

8:00–9:00	**Registration**
9:00–9:20	Welcome to ACC's 1st Annual Endotoxin Forum *AJ Meuse, PhD., President and CEO, Associates of Cape Cod, Inc. (ACC)*

SESSION 1 | The inspiration behind the revolutionary shifts in endotoxin testing

9:20–10:00	Recombinant Bacterial Endotoxin Testing: A Generational Change *Jay Bolden, Eli Lilly*
10:00–10:40	Building the Business Case for rBET – Review of Novartis Global Project *Kevin Peters, Novartis*
10:40–11:00	**Coffee Break**

SESSION 2 | Review of global regulatory developments in endotoxin testing

11:00–11:40	European Perspectives on the Use of Recombinant BET *Tim Sandle, PhD., Kedrion Biopharma*
11:40–12:20	Recombinant Bacterial Endotoxin Testing: The Global Framework *Jay Bolden, Eli Lilly*
12:20–1:30	**Lunch**

SESSION 3 | The practical drivers of change in endotoxin testing

1:30–2:00	Balancing Industry Needs with Ecological Responsibility and Supply Chain Security *Brett Hoffmeister, Associates of Cape Cod Inc. (ACC)*
2:00–2:40	Recombinant Cascade Reagent and Limulus Amebocyte Lysate: A Detailed Analysis of Endotoxin Testing Methods *Shady Kamal, Galderma*
2:40–3:00	**Coffee Break**

SESSION 4 | Deep technical dive into recombinant cascade reagents

3:00–4:30	Concurrent Track 1: Foundations of recombinant cascade reagents, including a practical demonstration *Dan Jennings and Alice Kenwright, Associates of Cape Cod, Inc. (ACC)*
3:00–4:30	Concurrent Track 2: Advanced applications of rCR *Veronika Wills, Associates of Cape Cod, Inc. (ACC)*
4:30	**Conclusion of Day 1**
5:30–7:30	**Evening Social Reception** Continue the dialogue in a relaxed setting with fellow attendees, speakers, and industry experts. The reception will feature canapes, refreshments,, and an atmosphere designed to encourage meaningful professional conversations and new collaborations.

DAY TWO

Application & Implementation Of Recombinant BET

Moderator: Professor Tim Sandle, PhD.

8:30–9:00	**Arrival**
9:00–9:20	Opening Session and Recap of Day 1

SESSION 5 | Equivalency evaluation of rCR vs. LAL

9:20–9:50	Recombinant Bacterial Endotoxin Testing in the Medical Device Contract Laboratory *Jason Rogers, STERIS*
9:50–10:30	TBD *Speaker Name, Speaker Company*
10:30–10:5	**Coffee Break**

SESSION 6 | Case studies on validation and strategic transition to rCR

10:50–11:20	Validation of rCR for Water Testing *Kerry Skinner, Kedrion Biopharma*
11:20–11: 50	Validation of rCR for a New Finished Product *Veronika Wills, Associates of Cape Cod, Inc. (ACC)*
11:50-12:20	Endotoxin Testing of Pharmaceutical Products Using Synthetic Reagents *Poppy Cliffe, AstraZeneca*
12:20–1:30	**Networking Lunch**

SESSION 7 | Global implementation of rCR

1:30–2:00	Recombinant Bacterial Endotoxin Testing: Practical Implementation *Jay Bolden, Eli Lilly*
2:00–3:00	Work Groups – rCR in Practical exercises: Developing a Roadmap for Your Transition to rBET *Group A: Water revalidation – Kerry Skinner | Group B: New product validation – Veronika Wills |* *Group C: Legacy product validation – Poppy Cliffe*
3:00–3:15	**Coffee Break**

SESSION 8 | The path forward

3:150–3:50	Panel Discussion: The Path Forward – Overcoming Barriers to Adoption of Recombinant Reagents
3:500–4:00	Closing Remarks
4:00	**Forum Adjourns**

Meet The Speakers

Jay Bolden

Senior Director, Global Quality Laboratories | Eli Lilly and Company | **Keynote Speaker**

A bacterial endotoxins subject matter expert, Jay leads global quality-control oversight for endotoxin, microbiology and virology test methods and serves on the USP Microbiology Expert Committee. During more than 26 years at Eli Lilly, he has helped advance the use of non-animal recombinant endotoxin testing.

Veronika Wills

Director, Global Technical Services | Associates of Cape Cod, Inc. (ACC) | **Forum Technical Chair, Speaker**

Veronika is a globally recognized expert in endotoxin and glucan detection for pharmaceuticals and medical devices. Since joining ACC in 2007, her work has included complex-sample testing, validation, troubleshooting, audits, regulatory support, and the assessment and implementation of recombinant cascade reagent technologies.

Jason Rogers

Senior Manager, Sterility Assurance & Microbiology | Steris | **Speaker**

Jason Rogers is Senior Manager of Sterility Assurance & Microbiology for the STERIS Applied Sterilization Technologies TechTeam. He has 20 years of experience in the medical device, industrial sterilization, and contract laboratory testing industries. He represents STERIS on AAMI standards committees including Microbial Methods, Ethylene Oxide Sterilization, Biocompatibility and Sterility Assurance, and supports customers with test-method development and investigations involving bioburden, endotoxin, sterility testing, and cleanroom environmental excursions. Jason holds a bachelor's degree in Biology from the University of Minnesota Twin Cities and a master's degree in Microbiology from Colorado State University.

Poppy Cliffe

Senior Scientist, Global Product Development | AstraZeneca | **Speaker**

Poppy supports microbiological control strategies for pharmaceutical products within AstraZeneca Global Product Development. Her current work focuses on validation and implementation of product endotoxin testing using synthetic reagents, including scientific, regulatory, and product-specific considerations.

Brett Hoffmeister

Manager, Sustainability Initiatives | Associates of Cape Cod, Inc. (ACC) | **Remote Speaker**

Brett leads ACC sustainability initiatives supporting responsible resource management and sustainable endotoxin testing. With more than 22 years in LAL manufacturing, he is an ACC subject matter expert on horseshoe crab conservation and chairs the Atlantic States Marine Fisheries Commission Horseshoe Crab Advisory Panel.

Kevin Peters

VP, Global Head of Quality, Aseptics, Biologics, Cell and Gene Therapies | Novartis | **Speaker**

Kevin Peters serves as VP, Global Head of Quality for Aseptics, Biologics, Cell and Gene Therapies at Novartis. His forum presentation examines the business case for recombinant BET through the experience of a global implementation project.

Tim Sandle, PhD

Head of QA GxP Compliance, Sterility Assurance and Quality Risk Management | Kedrion Biopharma

Moderator / Speaker

Professor Sandle has more than 30 years of experience in pharmaceutical microbiology, quality assurance and biopharmaceutical processing. His expertise includes BET, sterility, bioburden, environmental monitoring, contamination control, sterility assurance, GxP compliance and quality risk assessment. He also serves as a consultant, technical adviser and scientific author.

Shady Kamal, PhD

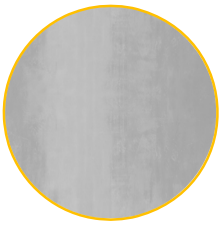
Principal Scientist, Manufacturing Science & Technology | Galderma | **Speaker**

Shady specializes in microbiological method development and validation, contamination control, aseptic manufacturing and bacterial endotoxin testing for injectable biopharmaceuticals. He serves on the EDQM Bacterial Endotoxin Testing Working Party and contributes to the revision of PDA Technical Report 82.

Alice Kenwright

Laboratory Manager | Associates of Cape Cod, Inc. (ACC) | **Speaker**

Alice is the CTS Laboratory subject matter expert and has led implementation of rCR testing using PyroSmart NextGen®, including instrument validation, technician qualification and SOP development. She is also developing a product validation procedure adaptable to customer and current Ph. Eur. requirements.



Kerry Skinner

Head of Microbiology | Kedrion Biopharma | **Speaker**

Kerry Skinner is Head of Microbiology at Kedrion Biopharma. Her forum contributions focus on recombinant cascade reagent validation for water testing and practical considerations for water revalidation during the transition to recombinant BET.

Daniel Jennings

Technical Services Lead, Europe | Associates of Cape Cod, Inc. (ACC) | **Speaker**

Daniel holds a degree in Biology and has nine years of experience in quality control and technical support within the endotoxin testing industry. He supports pharmaceutical and medical device companies as they evaluate and transition to more sustainable recombinant endotoxin testing methods.