

AGENDA

THE FUTURE IS NOW

2019 BPSA
INTERNATIONAL SUMMIT

INNOVATION • REGULATION • COMMERCIALIZATION



Bio-Process Systems Alliance
Advancing Single-Use Worldwide

JULY 22–24, 2019
WASHINGTON, DC
FOUR SEASONS HOTEL



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MONDAY, JULY 22, 2019

- Noon – 6:00 PM **Summit Registration** | DUMBARTON FOYER
EVENTS LEVEL
- Noon – 2:00 PM **BPSA New Member Luncheon** | ALGONQUIN ROOM
By invitation only EVENTS LEVEL
- 4:00 – 6:00 PM **BPSA Annual Meeting** | DUMBARTON ROOM
All BPSA Members EVENTS LEVEL
- 6:00 – 7:30 PM **Opening Night Reception** | SEASONS
MEZZANINE LEVEL

GROUP ON OWN FOR DINNER

TUESDAY, JULY 23, 2019

- 8:00 AM – 6:00 PM **Summit Registration** | BALLROOM FOYER,
EVENTS LEVEL
- ALL GENERAL SESSIONS** | CORCORAN BALLROOM SALON A, EVENTS LEVEL
- 8:00 AM **Continental Breakfast** | BALLROOM FOYER,
EVENTS LEVEL
- 8:30 AM – 12:30 PM **MORNING PRESENTATIONS** | **CRITICAL ISSUES**
- 8:30 – 8:45 AM **Chairman's Opening Remarks**
*Jeffrey Carter, Consumables Product Strategy Leader,
GEH Life Sciences, BPSA Chair*

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- 8:45 – 9:45 AM **Supplier Innovations Critical to Full CGT Production**
Brian Murphy, Director, Global Manufacturing Science and Technology, Celgene
- 9:45 – 10:00 AM **BREAK**
- 10:00 – 11:00 AM **Industry Trends in Platform Technologies: Process and Product**
Paul Slaman, Deputy Director, Manufacturing Technology, Emergent Biosolutions
- 11:00 AM – 12:30 PM **Sustainable Solutions: Issues Around Managing Plastic Waste**
- 11:00 – 11:50 AM **Alliance to End Plastic Waste**
Steve Russell, Vice President of Plastics Division, American Chemistry Council
- 11:50 AM – 12:30 PM **BPSA Member Sustainability Initiatives**
Moderator
Mark Petrich, Director—SUS Engineering, Merck & Co., Inc. BPSA Vice Chair

Presenters
Ken Davis, Global Marketing Manager, Nordson Medical
Meredith Daley, Engineer, Sustainability Productivity, Thermo Fisher Scientific
Russell Darley, Director of Global Innovation & Development, Sealed Air
- 12:30 – 1:25 PM **NETWORKING LUNCHEON** | CORCORAN BALLROOM B, EVENTS LEVEL
- 1:25 – 1:45 PM **A Tribute to John Boehm, BPSA Immediate Past Chair**
- 1:45 – 2:00 PM **SNAP* | BPSA EUROPEAN ADVISORY COUNCIL UPDATE**
Stephen Brown, Executive Director, Naobios
Hélène Pora, Vice President Technical Communication & Regulatory Strategy, Pall Biotech
- 2:00 – 2:15 PM **SNAP* | TRANSIT TESTING PROJECT UPDATE**
Rich Salzstein, Business Development Manager, Smithers Rapra
Elisabeth Vachette, Head of Product Management Bags/Mixing/Tanks, Sartorius Stedim Biotech
- 2:15 – 6:00 PM **AFTERNOON PANELS | BPSA PRIORITY TECHNICAL ISSUES: PART 1**
- 2:15 – 3:00 PM **Continuous Processing**
Moderator
Janmeet Anant, Regulatory Advocate, Millipore Sigma

Presenters
David Chau, Senior Application Engineer, 3M
James Furey, General Manager, Pendotech

*Snaps are 10-minute updates on subjects of interest

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- 3:00 – 3:15 PM **SNAP* | BPSA SCHOLARSHIP PROGRAM RECIPIENT**
Texas A&M National Center for Therapeutics Manufacturing (NCTM)
Jenny Ligon, Workforce Development Director, NCTM
Logan Jeffery Ardrey, Student Scholarship Recipient
- 3:15 – 3:30 PM **SNAP* | BPSA SCHOLARSHIP PROGRAM RECIPIENT**
North Carolina State Biomanufacturing Training and Education Center (BTEC)
Gary Gilleskie, Acting Director, BTEC
Brenda Ijeomah, Student Scholarship Recipient
- 3:30 – 4:45 PM **Single-Use Sterilization: Current and Future Processes and Impacts on Capacities: E-Beam, Gamma, and X-Ray**
Moderator
Ken Baker, CEO, AdvantaPure/NewAge Industries, Inc.
- Presenters*
Larry Nichols, CEO, Steri-Tek
Jeffrey Noyes, Director, Corporate Accounts, Applied Sterilization Technologies, Steris
Mark A. Smith, Managing Director, Ionaktis
Richard Wiens, Director, Strategic Supply, Gamma Technologies, Nordion
- 4:45 – 6:00 PM **Extractables & Leachables: Supplier Approach to Regulatory and End-User Requirements**
- Plastic Materials & Components Used in the Manufacturing of Drug Products**
Speaker
Desmond G. Hunt, Principal Scientific Liaison, USP
- Moderator*
Joseph St. Laurent, President & CSO, Chemic
- Presenters*
Sarah Brophy, Director of Analytical Services, VR Analytical
Genine Dale, Analytical Services and QC Director, Saint-Gobain
James Hathcock, Sr. Director, Regulatory and Validation Consulting, Pall BioTech
- 6:00 – 7:00 PM **NETWORKING RECEPTION** | BALLROOM FOYER, EVENTS LEVEL
- GROUP ON OWN FOR DINNER

WEDNESDAY, JULY 24, 2019

GENERAL SESSION | CORCORAN BALLROOM SALON A, EVENTS LEVEL

- 8:00 AM **Continental Breakfast** | BALLROOM FOYER, EVENTS LEVEL
- 8:30 – 8:45 AM **Opening Remarks**
Mark Petrich, Director—SUS Engineering, Merck & Co., Inc. BPSA Vice Chair

*Snaps are 10-minute updates on subjects of interest

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8:45 AM – 12:00 PM **PANEL DISCUSSIONS | BPSA PRIORITY TECHNICAL ISSUES: PART 2**

8:45 – 9:15 AM **System Integrity Assurance**

BPSA Integrity Assurance Committee Update

Hélène Pora, Vice President Technical Communication & Regulatory Strategy, Pall Biotech

Ensuring System Integrity Through Design and Testing: A Case Study

Mark Petrich, Director—SUS Engineering, Merck & Co., Inc. BPSA Vice Chair

9:15 – 9:30 AM **SNAP* | BPSA/BPOG CHANGE NOTIFICATION IMPLEMENTATION EFFORTS**

Jeffrey Carter, Consumables Product Strategy Leader, GEH Life Sciences, BPSA Chair

9:30 – 9:45 AM **SNAP* | PARTICULATES PAPER UPDATE**

*James Vogel, Founder & Director, The Bioprocess Institute
Klaus Wormuth, Principal Scientist, Sartorius Stedim Biotech*

9:45 – 10:00 AM **Break and Hotel Checkout**

10:00 – 10:15 AM **SNAP* | CGT WHITE PAPER & NEXT STEPS**

Brendan Lucey, Vice President of Business Development, Gemini Bio-Products

10:15 – 11:45 AM **Business Outlooks on CGT, MAB, & Future Markets**

Moderator

Eric Langer, President and Managing Partner, BioPlan Associates

Presenters

Manjula Aysola, Regulatory Affairs Manager, Millipore Sigma

Michael Gillmeister, Senior Scientist, REGENXBIO Inc.

Joe Petrosky, Global Vice President of Sales, PBS Biotech

Paul Slaman, Deputy Director, Manufacturing Technology, Emergent BioSolutions

11:45 AM – 12:00 PM **Wrap Up & Next Steps**

Jeffrey Carter, Consumables Product Strategy Leader, GEH Life Sciences, BPSA Chair

*Snaps are 10-minute updates on subjects of interest

continues...

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