2024

BPSA℠

Bio-Process Systems Alliance

Advancing Single-Use Worldwide

CHARTING THE FUTURE OF SINGLE-USE: STRATEGIES FOR SUCCESS

JULY 22 - 24, 2024, FOUR SEASONS HOTEL, WASHINGTON, DC

Wifi pass code BPSA2024

AGENDA > SPEAKERS >

BPSALLIANCE.ORG

WELCOME TO BPSA'S SUMMIT!

Mark Petrich
Chair, BPSA
Krystal Biotech, Inc.

2024 BPSA International Single-Use Summit Attendees,

Welcome to the 11th BPSA Summit! On behalf of the BPSA Board of Directors, our sponsors, and the BPSA staff, I would like to welcome all of you to the Four Seasons Georgetown and to Washington, DC! Thank you for joining us. I hope that you enjoy the program, the social events, and the opportunity to network with your industry colleagues. Special thanks go to the BPSA Program Planning Committee who organized this great event. Under the expert direction of Jeanette McCool, the volunteers on this committee have created a valuable event that I am sure you will enjoy.

Last year we celebrated our 10th edition of the BPSA Summit. The 11th edition may not sound like a milestone, but it is. Every year is worth celebrating! I hope that you will take the opportunity over the next few days to celebrate how far the industry has come, and to participate in shaping what comes next.

The theme of this Summit is "Charting the Future of Single-Use: Strategies for Success." The BPSA activity "pillars" reflected in the program are elements of our strategy that will help forecast the future and enable us to work toward success. The BPSA strategy pillars are: Networking, Education, Technical, Promotion and Marketing, Advocacy, and Industry Data. I expect that you will see these categories reflected in the program and the discussions we have this week.

I want to thank all the BPSA member companies and sponsors for their ongoing support and participation in the Alliance. Thank you to our committee chairs and committee participants who work throughout the year identifying challenges and opportunities for the single-use industry. Their work output includes technical reports, advocacy communications, webinars, and Summit content. You will see the results and work-in-progress of many of BPSA's committees this week.

BPSA needs motivated individuals to help us look to the future and develop tools that are needed for success as an industry. I hope that this week's program will motivate you to get involved in activities that are meaningful to you. Whether it is joining a technical committee, sharing BPSA's impressive library of technical reports, or attending events like the Summit and our webinars, your participation will advance the industry and contribute to improved products for the patients we all serve. As the bioprocessing industry continues to evolve, BPSA will continue to promote the interests of members, address new challenges, and advance the single-use industry worldwide.

I wish you an interesting and rewarding week!

PROGRAM COMMITTEE

2024 BPSA SUMMIT PROGRAM COMMITTEE

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Nick Troise
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BPSA is always striving for a better Summit experience. Fresh ideas and perspectives are always welcome. Please consider joining the Summit Program Planning Committee and contact our team to learn more.

Chris Clark, BPSA Executive Director, cclark@socma.org
Jeanette McCool, BPSA Senior Director, jmccool@socma.org
Tatiana Letcheva, Senior Manager, AMS Operations, tletcheva@socma.org

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BPSA sponsors support BPSA events and sustain BPSA's advocacy of single-use manufacturing technologies. The International Single-Use Summit would not be possible without their generous support.

To learn more and become a sponsor, contact our team at bpsa@socma.org.

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Chair:

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Cytiva

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Chair:

Magali Barbaroux
Sartorius

X-RAY STERILIZATION COMMITTEE

Co-Chairs:

James Hathcock
Cytiva

Samuel Dorey
Sartorius

OTHER COMMITTEES

MARKETING/MEMBERSHIP COMMITTEE

Chair

Ralph Daumke
PendoTECH

For more information about BPSA's technical committees and how to get engaged, please visit our **website** or contact our team.

AGENDA

MONDAY, JULY 22ND

8:00 AM – 5:00 PM **SUMMIT REGISTRATION** | Ballroom Foyer - Events Level

8:30 AM – 4:00 PM **CONCURRENT COMMITTEE MEETINGS (MEMBERS ONLY)** | Ballroom Salons

8:30 AM – 9:45 AM

INTERCHANGEABILITY MEMBER DISCUSSION | Ballroom B

10:00 AM – 11:30 AM

SUSTAINABILITY COMMITTEE | Ballroom A
Magali Barbaroux, *Sartorius, Chair*

AUTOMATION COMMITTEE | Ballroom B
Hernan Parma, *RENOLIT Healthcare, Co-Chair*
Stuart Tindal, *Sartorius, Co-Chair*

11:30 AM –1:00 PM

LUNCH BREAK – **GROUP ON OWN**

1:00 PM - 2:30 PM

CELL & GENE THERAPY COMMITTEE | Ballroom A
Brendan Lucey, *Entegris, Chair*

INTEGRITY ASSURANCE COMMITTEE | Ballroom B
Patrick Evrard, *Cytiva, Chair*

2:30 PM - 4:00 PM

X-RAY STERILIZATION COMMITTEE | Ballroom A
James Hathcock, *Cytiva, Co-Chair*
Samuel Dorey, *Sartorius, Co-Chair*

CONTINUOUS BIOPROCESSING COMMITTEE | Ballroom B
David Chau, *Solventum, Co-Chair*
Davinder Chawla, *Sanofi, Co-Chair*

4:00 PM – 5:30 PM

BPSA ANNUAL MEMBERSHIP MEETING (MEMBERS ONLY) | Ballroom A

5:30 PM – 7:00 PM

WELCOME RECEPTION | Seasons Restaurant | Mezzanine Level

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AGENDA

TUESDAY, JULY 23RD

8:30 AM – 5:00 PM	**SUMMIT REGISTRATION** | Ballroom Foyer - Events Level
8:30 AM – 5:00 PM	**ALL SESSIONS BALLROOM AND BALLROOM FOYER, EVENTS LEVEL**
8:30 AM	**BREAKFAST BUFFET**
9:00 AM – 9:15 AM	**CHAIRMAN'S WELCOME & OPENING REMARKS** Mark Petrich, *Krystal Biotech, BPSA Chair*
9:15 AM – 10:00 AM	**ECONOMIC OUTLOOK AND TRENDS FOR THE SINGLE-USE INDUSTRY** Eric Langer, *BioPlan Associates, Inc.* Todd Kapp, *Wautoma Biotech, BPSA Vice Chair*
10:00 AM – 11:00 AM	**GLOBAL REGULATORY LANDSCAPE FOR LIFE SCIENCES** Michael Heyl, *Hogan Lovells US LLP* Lowell Zeta, *Hogan Lovells US LLP*
11:00 AM –11:15AM	**BREAK**
11:15 AM – 12:00 PM	**PFAS AND MATERIALS MANAGEMENT: TODAY'S COMPLEX LANDSCAPE AND WHAT'S AHEAD** Brian Chung, *Syensqo* Lorraine Gershman, *Daikin America, Inc.* Kirsten Strahlendorf, *Sanofi, BPSA 2nd Vice Chair, BPSA SAC Chair* Jay West, *American Chemistry Council*
12:00 PM – 1:30 PM	**NETWORKING LUNCHEON** | Ballroom B
1:30 PM – 2:15 PM	**NAVIGATING THE FUTURE OF X-RAY STERILIZATION IN SINGLE-USE SYSTEMS** Samuel Dorey, *Sartorius, BPSA X-Ray Committee Co-Chair* James Hathcock, *Cytiva, BPSA X-Ray Committee Co-Chair* Larry Nichols, *Steri-Tek, Inc.* Deepak Patil, *STERIS*
2:15 PM – 2:30 PM	**BREAK**

AGENDA

TUESDAY, JULY 23RD

2:30 PM – 3:15 PM

ADVANCING CELL AND GENE THERAPY WITH SINGLE-USE TECHNOLOGIES: OPPORTUNITIES AND OBSTACLES

Moderator: Paul Priebe, *Consultant, BPSA Scientific Advisory Council Member*
Dominic Clarke, *Cryoport, International Society for Cell & Gene Therapy Chair*
Brendan Lucey, *Entegris, BPSA Cell & Gene Therapy Committee Chair*
Ping Wang, *Johnson & Johnson*

3:15 PM – 4:00 PM

IS THERE A ROLE FOR SINGLE-USE IN A CIRCULAR ECONOMY?

Moderator: Magali Barbaroux, *Sartorius, BPSA Sustainability Committee Chair*
Michael Van Brunt, *Reworld & Board Chair, U.S. Circular Economy Coalition*

4:00 PM – 5:00 PM

KEYNOTE SESSION: LIFE SCIENCES & BIOPROCESSING INSIGHTS: A FIRESIDE CHAT

Moderator: Matthew Pillar, *Bioprocess Online*
Udit Batra, *Waters Corporation*
Mark Petrich, *Krystal Biotech, BPSA Chair*

WEDNESDAY, JULY 24TH

8:30 AM – 1:00 PM **ALL SESSIONS BALLROOM AND BALLROOM FOYER, EVENTS LEVEL**

8:00 AM

BREAKFAST BUFFET

8:30 AM – 8:45 AM

VICE CHAIRMAN'S WELCOME & OPENING REMARKS

Todd Kapp, *Wautoma Biotech, BPSA Vice Chair*

8:45 AM – 9:15 AM

OFFICE OF INDUSTRIAL BASE MANAGEMENT & SUPPLY CHAIN/ BARDA UPDATE

Wayland Coker, *Supply Chain Optimization Office, Industrial Base Management and Supply Chain*
Robert Huffman, *Manufacturability & Resilience Program, BARDA*

9:15 AM – 10:00 AM

SUPPLY CHAIN RESILIENCY PANEL DISCUSSION: MANUFACTURING CAPACITY AND SUPPLY CHAIN CONTINUITY

Moderator: David Radspinner, *VintaBio*
Monica Cardona, *MilliporeSigma*
Timothy Martin, *Division of Pharmaceutical Countermeasures Infrastructure, BARDA*
Hernán Parma, *RENOLIT Healthcare*
Eric Westhaus, *Merck & Co. Inc.*

AGENDA

WEDNESDAY, JULY 24TH

10:00 AM – 10:30 AM	**TECHNOLOGY TRENDS SHAPING THE FUTURE OF SINGLE-USE BIOPROCESSING** Joe Lutz, *Siemens Industry, Inc.* Pamela Docherty, *Siemens Industry, Inc.*
10:30 AM – 10:45 AM	**BREAK AND HOTEL CHECK-OUT**
10:45 AM – 11:45 AM	**AN INDUSTRY SNAPSHOT: ASME-BPE, ASTM, BIOPHORUM, DECHEMA, ETC.** Moderator: Jeff Carter, *Cytiva, BPSA Past Chair* Monica Cardona, *MilliporeSigma* Ralph Daumke, *PendoTECH* Milena McFeeters, *Re ined Sciences & ASME-BPE Chair* Jim Vogel, *The BioProcess Institute*
11:45 AM – 12:15 PM	**IMPACT OF SUPREME COURT & FTC DECISIONS ON REGULATORY RULEMAKING** Conor Kelly, *Webster Chamberlain & Bean, LLP*
12:15 PM – 12:30 PM	**BPSA INDUSTRY DATA SNAPSHOT: SUS RELIABILITY** Patrick Evrard, *Cytiva* Steve Teslik, *K545 Analytics*
12:30 PM – 12:45PM	**WRAP-UP & ADJOURNMENT** Mark Petrich, *Krystal Biotech, BPSA Chair* Chris Clark, *BPSA Executive Director*
12:45 PM – 1:30 PM	**BOARD AND SPONSOR BROWN BAG LUNCH (INVITATION ONLY)**

SAVE THE DATES!

2024 BPSA EUROPEAN ROUNDTABLE MEETING
OCTOBER 10-11, 2024 | MILAN, ITALY

2025 BPSA INTERNATIONAL SINGLE-USE SUMMIT
JULY 21-23, 2025 | WASHINGTON, DC

SAVE THE DATE

2025

BPSA INTERNATIONAL SINGLE-USE SUMMIT

JULY 21-23, 2025
FOUR SEASONS, WASHINGTON, DC

WWW.BPSALLIANCE.ORG

MAGALI BARBAROUX | SARTORIUS

Magali Barbaroux completed her Ph. D. at the University of Paris in Material Science and Engineering. She has over 25 years of experience in polymer science for healthcare applications. She started her career with research into silicone for drug delivery and migration of active substance through polymeric membrane. She joined Sartorius in 2000 and contributed to the development of Single-Use products optimized for bioprocessing applications. She now belongs to the Sartorius Corporate Research and manages the Advanced Polymers related research programs, with a strong focus on environmental sustainability and opportunities brought by the New Plastic Economy in biotech applications.

UDIT BATRA | WATERS CORPORATION

As President and CEO of Waters Corporation, Dr. Udit Batra brings more than two decades of leadership and operational expertise in healthcare and life sciences. He has a proven track record of leading multi-billion-dollar global organizations and driving results at the top of the industry.

Before joining Waters in September 2020, Udit served as CEO of MilliporeSigma, a global business with $8 Billion in sales and over 22,000 employees. In 2015, Udit led the formation of MilliporeSigma, the largest merger in the life science tools industry at the time and built it into one of the top performers in the industry with record sales growth and margin development. From 2011-2013, as CEO of Merck KGaA's consumer health business, Udit led a period that doubled the business's profitability and achieved organic growth in the top tier of the industry.

Earlier in his career, Udit served in a range of leadership positions at Novartis. In addition to leading Corporate Strategy and Global Public Health and Market Access for Vaccines and Diagnostics, he also served as president of the Australia Pharma business. During his tenure, this subsidiary became the fastest-growing business amongst competitors in Australia and in Novartis. Throughout his career, Udit has championed science education, especially for low-income students, developed and promoted women's leadership, and has been a strong advocate for increasing diversity across the organizations he has led.

Udit has received numerous leadership accolades and recognition, including 2023 University of Delaware Alumni Wall of Fame, 2022 PharmaVOICE Hall of Fame, 2021 Mass Technology Leadership Council's Tech Top 50, 2020 New Englander of the Year by the New England Council, 2019 New England Choice Awards Business Person of the Year, PharmaVOICE Top 100 Most Inspirational People (2017 - 2019, Boston Business Journal's 2019 Power 50, and the 2016 CPhI Pharma CEO of the Year.

Currently, Udit is a board member of Boston Children's Hospital's Trust Board and the Analytical, Life Science & Diagnostics Association (ALDA. He also serves on the Advisory Councils of the Chemical Engineering Departments of Princeton University where he earned his Ph.D. in Chemical Engineering and the University of Delaware where he earned a B.S. in Chemical Engineering.

SPEAKERS

MICHAEL VAN BRUNT | REWORLD

Michael Van Brunt is currently VP Environmental and Sustainability at Reworld, where he is responsible for corporate sustainability strategy and reporting and environmental compliance, permitting, and monitoring. He leads Reworld's lifecycle analysis team and is a licensed professional engineer with over twenty years of experience in industry and consulting. He is currently the board chair of the Circular Economy Coalition. He earned a B.S. and Masters in Agricultural and Biological Engineering from Cornell University.

MONICA CARDONA | MILLIPORESIGMA

Monica Cardona is a Senior Program Manager for Single Use & Integrated Systems at MilliporeSigma. Working cross-functionally with Plant Quality, Operations, R&D, Regulatory, Emprove®, Quality Services and Commercial teams, Monica creates and implements product portfolio enhancement programs that differentiate MilliporeSigma's product offering, improve customer satisfaction and drive portfolio growth.

She has worked in Life Sciences for over 20 years. Monica has experience in business development, product management, and new product development & introduction (NPD/NPI). She has had several global roles in technical, strategic, and operational marketing. Monica holds a bachelor's degree in biology from Hofstra University and a Masters in Biology from Adelphi University. She has published and lectured internationally on a wide range of filtration, validation and single use bioprocessing topics. Monica has worked at State Chemical, Pall Life Sciences and Cantel Medical. She is on the Board of Directors at the he Bio-Process Systems Alliance (BPSA) and on the Single Use Expert Committee at BioPhorum.

JEFF CARTER | CYTIVA

Jeff Carter has been a supplier to the bio/pharmaceutical manufacturing industry for over thirty years, and he has been with Cytiva/GE Healthcare since 2005, serving in R&D and Marketing capacities. His present role is Director of Upstream Applications. He is active in organizations such as ASTM E55 (where he leads the subcommittee on Single Use equipment) and BioPhorum. He is Chairman Emeritus of the Board of BPSA and a member of the BPSA Scientific Advisory Council. Dr. Carter holds a PhD degree from Penn State University in molecular microbiology.

SPEAKERS

BRIAN CHUNG | SYENSQO

Brian Chung is a Sr. Key Account Manager at Syensqo. Brian has been with Solvay companies since 2005 in various technical, marketing and management roles. Brian currently serves the Medical device and Biopharma markets within the Life Solutions team at Syensqo.

DOMINIC CLARKE | CRYOPORT

Dr. Dominic Clarke currently serves as Vice President of Technical Operations, IntegriCell at Cryoport after spending the past 2 years as CSO at Discovery Life Sciences. Previously, he held the role of Director of Global Cell Therapy Strategy and Innovation at Charles River Laboratories (CRL) with overall responsibilities for developing and expanding the cell supply business unit. Prior to joining CRL, he was the Global Head of Cell Therapy at HemaCare where he helped expand overall visibility and market growth. He started his career in cryobiology and led the research & development efforts for BioLife Solutions before transitioning to delivering industry leading single-use solutions at Charter Medical. Dominic has nearly 20 years in cell & gene therapies and has been serving as the Chair of the International Society for Cell & Gene Therapies (ISCT) Process Development and Manufacturing industry sub-committee for the past 5 years.

RALPH DAUMKE | PENDOTECH

Ralph is currently a Market Manager for PendoTECH, responsible for the market development in Europe and MEA and supporting distributors and clients in all questions around single-use sensors. He is a member of the board of directors of the Bio- Process Systems Alliance (BPSA) as well as for DECHEMA's expert group on Single-Use Technologies for biobased applications.

Since 1996, he has held different positions in Sales and Marketing in different fields of Biotech and Pharma. From 2014 – 2021, Ralph was a Global Market Manager Life Sciences for FILTROX Group with worldwide responsibility for the FILTROX Group Life Science business incl. Business Development, marketing and product development and management for applications and products in the field of Life Sciences and especially for the single-use product line.

With a degree in biotechnology, including time at the Massachusetts Institute of Technology (MIT) during his course of study, Ralph is an expert on single-use systems for upstream and downstream processing in the development and production of biopharmaceuticals.

SPEAKERS

PAMELA DOCHERTY | SIEMENS

Pamela Bruen Docherty, Enterprise Account Executive-Life Sciences, Siemens
Mrs. Docherty has 25+ years' experience in process automation with over twenty of them focusing on pharmaceutical production. Pam is involved IFPAC, BioPhorum and ISPE.

SAMUEL DOREY | SARTORIUS

Samuel is Principal Scientist, Materials and Irradiations, within Sartorius Product Development. Samuel has a strong focus on the radiation application effects on materials used in single use systems for biopharmaceutical processes. Samuel is involved in promoting and facilitating the application of alternative ionizing radiations to gamma with X-rays, co-chairing BPSA X-ray initiative and attending industry groups in that field, making the links with regulatory bodies. He's also member of the ASTM E61 and of the Irradiation Panel and he is authoring papers on gamma/X-ray/ Ebeam impacts on plastic materials. Samuel is thus part of the Team Nablo initiative in relationship with PNNL/TAMU and Aix-Marseille University to conduct and spread-out specific material compatibility upon the different irradiation technologies.

PATRICK EVRARD | CYTIVA

Patrick Evrard joined Cytiva in 2017, to provide expert technical support to customers for single-use systems. He joined in 2018 the Technical Communication and Regulatory Strategy team, combining the technical content with validation and regulatory perspectives.

Before joining Cytiva, he led for more than 10 years a global technical team in charge of developing and implementing at global level single-use technologies in GSK Vaccines' commercial manufacturing operations, including critical sterile applications. Patrick is member of the BPSA Board and chair of the BPSA Integrity Assurance Committee. He has been participating since 2012 in several single-use technology industry work groups of BPSA, BioPhorum Operations Group (BPOG), American Society of Mechanical Engineers (ASME BPE), ASTM International and PDA and is co-author of several guidance documents and standards of these organisations.

LORRAINE GERSHMAN | DAIKIN AMERICA, INC.

Lorraine joined Daikin America, Inc. (DAI) in 2022 as Director of Government Affairs and Advocacy. In this role, she leads DAI's advocacy and external affairs team, with a focus on environmental and chemical issues. She engages regularly with customers to provide policy support and is a member of the extended leadership team, providing strategic advice to top leadership in the U.S. and overseas. Her extensive technical expertise and policy knowledge resulted in numerous appearances before regulatory agencies, elected officials, and stakeholder groups.

Prior to joining DAI, Lorraine was part of DuPont's Washington D.C.-based government affairs team, where she led federal advocacy efforts on environmental and chemical issues, including climate change, sustainability, and water issues.

Earlier roles included serving as the Vice President of Regulatory Affairs for the National Oilseed Processors Association (NOPA) and Senior Director of Regulatory Affairs for the American Chemistry Council (ACC), as well as environmental engineering positions with consulting firms Malcolm Pirnie and GeoTrans, Inc.

She holds M.C.E. and B.S. degrees in Civil and Environmental Engineering from Johns Hopkins University and is a registered Professional Engineer in Virginia. She lives in Falls Church, VA with her husband Alex and two teenaged sons, Cooper and Parker.

JAMES HATHCOCK | CYTIVA

Dr. James Hathcock is Senior Director of Regulatory and Validation Strategy at Cytiva, which includes responsibility for safe and successful end-user implementation of technologies enabling biopharmaceutical manufacturing. James has led chemical and performance characterization of Medical and Biotech components, as well as relevant technical packages supporting regulatory filings. He is an active member of ASME-BPE, ASTM, PDA, ISPE, BPSA and BioPhorum.

MACHAEL HEYL | HOGAN LOVELLS US LLP

Mike Heyl helps medical device companies navigate myriad regulatory and business matters. He guides clients through U.S. Food and Drug Administration (FDA) regulations, requirements, and compliance issues. These issues include FDA's Quality System Regulation (QSR); adverse event reporting; recall reporting requirements; FDA inspections and enforcement actions, such as Warning Letters; defense strategies; and corrective and remedial action plans.

He represents large multinational corporations facing FDA and criminal enforcement, and helps small startups develop and implement postmarket compliance programs. Because he understands FDA's requirements for importing and exporting medical devices, Mike is frequently called on to negotiate the release of detained goods being imported to the United States.

ROBERT HUFFMAN | BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

Mr. Robert ("Bob") Huffman joined BARDA's Pharmaceutical Countermeasures Infrastructure Division (PCI) in May 2021 to support supply chain management for the manufacturing of COVID-19 vaccines and therapeutics, including coordinating with ex-US governments, interagency partners, manufacturers, and key supply chain partners to mitigate personnel and material issues and coordinating Defense Production Act issues with ASPR, the White House, and industry partners. He currently serves as the Director for PCI's Manufacturability and Resilience program, which seeks to expand the Nation's domestic capability to rapidly manufacture vaccines and other medical countermeasures during a public health emergency (PHE).

Prior to joining BARDA, Mr. Huffman served as a member of Defense Department's (DOD) Covid-19 Operation Warp Speed team, and acted as liaison and Other Transaction Authority (OTA) Lead for DoD's Joint Program Executive Office (JPEO) establishing outreach, strategy, and policy for JPEO's two large OTA vehicles. Previously, he supported the Defense Threat Reduction Agency (DTRA), where he served as the Chief Information Officer, the technical team lead for the Russia-DOD nuclear weapons disposal inventory system, and was the Deputy for Technology Transition and Information Systems in the Joint Science and Technology Office. Additionally, he co-led a pandemic preparedness working group for the White House's Office of Science and Technology Policy (OSTP).

TODD KAPP | WAUTOMA BIOTECH

Todd currently serves as Vice-Chair of the Board of Directors at Bio-Process Systems Alliance, providing strategic direction in the championing of single-use biotechnologies on the global stage. He has been an active member with BPSA for nearly two decades. Todd has been the Marketing Committee Chair, CGT Committee Chair, Secretary/Treasurer, Co-Chair for the first Summit Planning Committee and participated in many other BPSA initiatives and endeavours.

Outside of BPSA, Todd is CEO – Business Development for the start-up company Wautoma Biotech. Prior to Wautoma Biotech, Todd most recently worked for Entegris, where he was Global Commercial Development Director – Life Sciences. Under his leadership, Entegris Life Sciences evolved from a new player with minimal sales into a prominent competitor. This success was fuelled by Todd's decades of experience in the life sciences industry, and specifically with single-use products. He is highly strategic, with a long-standing commitment to the value of single-use systems that bring together equipment and consumables.

CONOR KELLY | WEBSTER, CHAMBERLAIN & BEAN, LLP

Conor Kelly's practice includes lobbying and government relations, antitrust, and association law. He provides counsel to a variety of nonprofits and trade associations and monitors legislation and regulations affecting their interests. Conor graduated from George Washington University Law School in May, 2020. He received his BA in History and Government with high honors from the University of Virginia, where he served as an opinion editor and member of the editorial board of The Cavalier Daily.

Prior to joining Webster, Chamberlain & Bean, Conor served as counsel on the Senate Committee on Rules and Administration for Senator Amy Klobuchar. In that role, he helped to guide the For the People Act through markup.

ERIC LANGER | BIOPLAN ASSOCIATES, INC.

Eric has over 25 years' experience in life sciences market assessment, valuation, marketing, management, and publishing. Senior manager at biopharmaceutical supply companies; experienced biotechnology strategist; his team has advised 100s of companies on marketing strategy development, valuation, pricing and message strategy. Developed strategic plans based on quantitative analysis of market trends and buyer needs in valuation services, pricing, and analysis. He teaches graduate biotechnology marketing at Johns Hopkins University and biomedical valuation to the NIH Graduate School.

BRENDAN LUCEY | ENTEGRIS

Brendan Lucey oversees the go-to-market strategy for Life Sciences at Entegris. He has previously been on the board of the Bio-Process Systems Alliance and now is the chair of the Cell and Gene Therapy Committee. A biologist by training, now focused on improving the way biologics are manufactured. He as previously worked at CDMO, Single-use suppliers, and cell therapy providers (Lonza, Sartorius, ILC Dover, Gemini Bio). He is excited to continue to help get medicines to market faster and more safely, to improve lives all over the world.

JOE LUTZ | SIEMENS

Joe Lutz is an Enterprise Account Executive focused on life sciences accounts at Siemens Digital Industries. Based in the greater Philadelphia area, his main goals are to build relationships, learn about industry challenges and help solve them. Prior to joining Siemens, Joe earned a bachelor's degree in mechanical engineering and worked for 6 years as an engineering consultant for GSK and 11 years leading R&D and sales at his prior company in the petrochemical industry.

TIMOTHY MARTIN | BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

Dr. Martin is currently a Senior Engineer at Biomedical Advanced Research and Development Authority (BARDA) within the Administration for Strategic Preparedness and Response (ASPR), Washington, D.C., where he currently leads a supply chain resiliency team. For the past 20 years, he has worked in various roles related to biomanufacturing, including securing domestic bioprocessing capacity at BARDA, regulation of biologics and devices at FDA, process engineering at COOK Pharmica (now Novo) CDMO, and biologics development in academia. Dr. Martin holds a PhD in Biological Sciences from the University of Nebraska.

MILENA MCFEETERS | REFINED SCIENCES INC.

Milena McFeeters is currently the President of Refined Sciences Inc., a corporation that manufactures single-use assemblies for bioprocessing applications. Previously, Milena worked at The BioProcess Institute, since December 2019, holding the title of Associate. Before this, Milena worked at Steridose Inc. (2002 to 2019) a company that manufactures multi-use components and equipment for bioprocessing. From 2016 to 2019, she served as the company's CEO.

Ms. McFeeters is the current ASME BPE Standards Chairperson and past Chair of the Polymeric Materials (PM) Subcommittee and Multi-Use Components (MC) Subcommittee.

Milena holds Master of Business Administration (M.B.A.) and a degree in Chemical Engineering.

SPEAKERS

LARRY NICHOLS | STERI-TEK, INC.

Larry began working in the E-beam industry for Nutek Corp in 1996 as the business manager. He soon assumed the position of Operations Manager, overseeing the shipping/receiving department as well as the machine operators. While at Nutek, he held the positions of Quality Manager, VP of Operations, and VP of Business Development. In 2009, he assumed the position of CEO. In 2010, he became active on the committees ISO/AAMI 11137 and ASTM Dosimetry working group. When Nutek closed in 2016, he co-founded Steri-Tek, where he assumed the role of CEO. Larry earned his BS degree in Business Management from Cal Poly in San Luis Obispo, CA.

HERNÁN PARMA | RENOLIT HEALTHCARE

Mr. Parma has over 15 years of experience including research in polymer science and engineering, plastics processing to finished consumer products, sales, marketing and product management for components used in medical devices and biotechnology. Currently, Hernan leads Sales and Product Management for RENOLIT Healthcare in North America and has helped shape the company strategy on their current and future portfolio of films and complementary products intended for single-use bioprocessing. Hernan has been an active member of BPSA since 2012 and has participated in various BPSA committees. Hernan is currently serving in the Board of Directors and co-chairs the Automation committee.

DEEPAK PATIL | STERIS APPLIED STERILIZATION TECHNOLOGIES

Deepak Patil is Vice President, Sterilization Science and Technology at STERIS Applied Sterilization Technologies. Deepak joined AST in 2000 as a Dosimetry Analyst with the then titled Dosimetry Services group. He has subsequently held positions of increasing leadership responsibility throughout his 24 year career, building a strong team of technical scientists and professionals. Deepak is a recognized industry leader serving as an executive committee member on the ASTM E-61 Radiation Processing Committee, and has been a regular speaker/presenter at the International Meeting of Radiation Processing, the ASTM Global Radiation Processing Workshop, as well as many other industry and Customer events. Deepak will lead the consolidation of the STERIS AST Radiation and GasTechnical teams into one Customer-focused team.

SPEAKERS

MARK PETRICH | KRYSTAL BIOTECH, INC.

Mark Petrich is Vice President, Process Development and Validation at Krystal Biotech, Inc. Before joining Krystal, Mark held leadership roles at Merck & Co. in single-use systems engineering, pilot plant operations, supplier relationship management, and laboratory automation engineering. Mark is active in professional organizations and currently serves as Chair of the BPSA board of directors. He has been a frequent speaker at industry events and has co-authored over 50 publications. Mark received the BioProcess International "Industry Champion" award for promoting collaborative efforts in design, qualification, and application of single use technologies in biopharmaceutical manufacturing. Mark started his career in the Chemical Engineering department at Northwestern University where he was the M.E. Fine Junior Professor of Materials and Manufacturing. Mark is a licensed Professional Engineer and holds degrees in Chemical Engineering from Washington University (BS) and University of California, Berkeley (PhD).

MATTHEW PILLAR | BIOPROCESS ONLINE

Matthew Pillar is the chief editor at BioProcess Online and host of the Business of Biotech podcast, where he interviews leading innovators in the biopharma industry on their approaches to biologics development, manufacturing, regulatory, clinical, and commercial efforts. Prior to joining Life Science Connect, he spent 20 years covering tech-centric industries as they navigated AI, machine learning, IoT, and other emerging technologies. His chief and executive editorial experience includes tenures with Software Executive, Channel Executive, Business Solutions, and ISR magazines, where he routinely interviewed international technology builders and influencers.

PAUL PRIEBE | CONSULTANT

Mr. Paul Priebe currently works as an independent consultant. He primarily consults on bioprocess technology commercialization, product and market strategy, product management and go-to-market approaches. He specializes in all aspects of single use technologies for bioprocess applications. Previously he spent close to 4 years at Qosina, where he led product and market strategy and launched the Qosina BioProcess brand and product portfolio. His nearly 18 years previous experience at Sartorius Stedim biotech included leadership roles in product and application management for all Sartorius bioprocess technologies, with a specialty in single use technology. He is a current member of ASME BPE and the BPSA Scientific Advisory Council and served as a long-time board member of the BPSA, and active member of the PDA, ASTM E55 and Biophorum Supply Partner Phorum. He was a contributing author of PDA TR66 and ASTM E3051 and served on several important task groups within ASME BPE.

DAVID RADSPINNER | VINTABIO INC

David is CEO of VintaBio Inc, a Cell and Gene Therapy CDMO in Philadelphia, PA. Prior to this role, David was President of Biotherapeutics at ILC Dover leading the team in areas of single-use powder and liquid handling and content, and isolator solutions. David had the role of VP of Commercial for the Americas and BioPark Program leader within Cytiva and led the sale and integration of the HyClone Cell Culture business from Thermo Fisher Scientific to GE Healthcare. While at Thermo Fisher Scientific, David led Marketing, Global Sales and Product Management for Bioprocess and was a member of the BPSA Board of Directors.

David has over thirteen years in pharmaceutical development, manufacturing, regulatory and quality and more that fifteen years in Life Science business roles. David holds a PhD in Analytical Chemistry from the University of Arizona.

KIRSTEN STRAHLENDORF | SANOFI

For the last 19 years, Kirsten Strahlendorf has been working in Research and Development at Sanofi in Toronto, Canada. She is the Global Senior Unit Head of the BioProcess Engineering Unit pertaining to Vaccine Drug Product Development. Kirsten holds a Professional Engineering license, an Honours degree in Biological Engineering from the University of Guelph, a Master's of Engineering from the University of Toronto and a Project Management designation from the Project Management Institute.

Kirsten takes a seat as Vice-Chair on the Executive Board of Directors for the Bio-Process Systems Alliance and is the Chair of the Scientific Advisory Council in the Organization. A driver in the bioprocessing community, she has published several journal articles. Kirsten manages a bioprocess design and scale-up laboratory for vaccine formulations in addition to a team of expert engineers. Finally, she leads the global Formulation and Delivery VITA Subdomain and CMC early phase drug product lead for new meningitis vaccines. Her focus lies in automation and PAT systems for novel biotechnology products decades away from being marketed.

In her personal life, Kirsten enjoys her four children (while not enjoying so much turning socks right-side in, mass lunch production assemblies, and batch cooking).

JIM VOGEL | THE BIOPROCESS INSTITUTE

James Dean Vogel, P.E., Founder and Director, is an expert with over 36 years of experience in the biopharmaceutical, food, and cosmetics industries. His interest in pharmaceutical engineering took flight early in his college career and has grown into a strong passion. He leads a team of engineers and specialists who help BPI provide valuable, customized solutions for a complex industry. In addition to Suppliers and End Users, The BioProcess Institute is engaged with organizations whose experts spearhead the creation and maintenance of the standards used in biopharmaceutical processing.

SPEAKERS

PING WANG | JOHNSON & JOHNSON

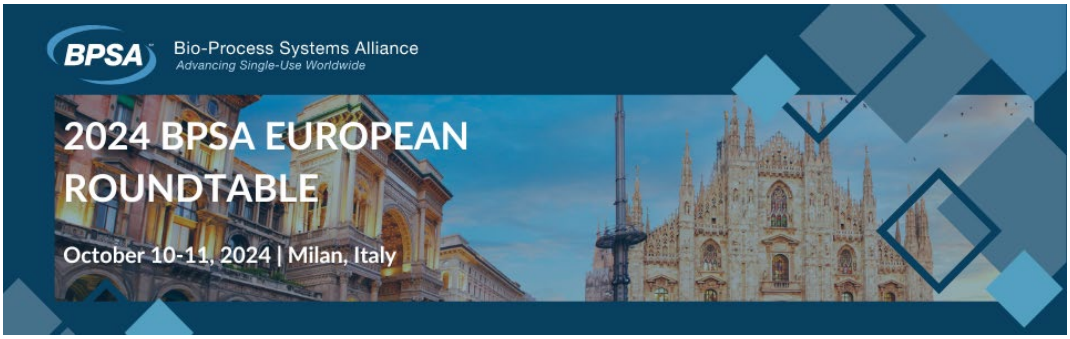
Dr. Ping Wang is a Director of Material Sciences with Johnson & Johnson. He leads J&J's global effort in evaluation, selection and assessment of single use materials for the manufacturing, packaging and delivery of large molecules and CGT products. He is a board member of ELSIE Consortium. He is also an active member of Biophorum and BPSA. He has a Ph.D. in pharmacy. He is also a holder of MBA and Regulatory Affairs Certificate (RAC).

LOWELL ZETA | HOGEN LOVELLS US LLP

Bridging his experience at the highest levels of the FDA and regulatory practice, Lowell Zeta provides sophisticated legal counsel to life science clients on critical regulatory and compliance matters impacting their essential medicines and product portfolios. Innovative startups and global biopharmaceutical companies and their investors seek his strategic guidance on matters that require an integrated analysis of the science, data, and the law.

He counsels extensively on product quality, safety, and compliance with current good manufacturing practice (GMP) requirements and data integrity standards for clinical and commercial stage products, with a focus on next generation products with complex manufacturing and global supply chain considerations. He helps to resolve complicated quality issues, including by advocating for clients before FDA in regulatory meetings, inspection and enforcement action, and government investigations.

UPCOMING EVENTS



BPSA Mission

TO FACILITATE, GLOBALLY, THE DEVELOPMENT AND MANUFACTURING OF BIOPHARMACEUTICALS THROUGH THE IMPLEMENTATION OF ROBUST, SAFE AND SUSTAINABLE SINGLE-USE TECHNOLOGIES.

The Bio-Process Systems Alliance (BPSA) was formed in 2005 as an industry-led international industry association dedicated to encouraging and accelerating the adoption of single-use manufacturing technologies used in the production of biopharmaceuticals and vaccines.

BPSA Members

Learn about the BPSA network and view list of members here.

BPSA Industry Resources

Visit our resource library for latest technical guides and webinars on key industry topics.

For more information, please visit www.bpsalliance.org, or contact our team:
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