Bio-Process Systems Alliance

Advancing Single-Use Worldwide

Seventh Annual BPSA International Single-Use Summit

AGENDA › SPEAKERS ›

JULY 12–14, 2017 | WASHINGTON, DC | FOUR SEASONS HOTEL

Single-Use Saves

Bio-Process Systems Alliance

Advancing Single-Use Worldwide

Mark Your Calendars...

2018 BPSA International Single-Use Summit

JULY 9–11, 2018 | WASHINGTON, DC | FOUR SEASONS HOTEL

2018 European Single-Use Summit

SEPTEMBER 24–26, 2018 | LOCATION TO BE ANNOUNCED

John Boehm
CPC
Chairman, BPSA

WELCOME

Dear BPSA Members and Industry Colleagues:

On behalf of the BPSA Board of Directors, it is our distinct pleasure to welcome you to Washington, DC and the 2017 edition of the BPSA International Single-Use Summit, our 7th consecutive annual business event. Seven years – what a run it has been! And there is more to come, as this meeting will again be the event-of-the-year, with a focus this year on how Single-Use Saves.

Being here in Washington, DC with us this week is a testament to your interest in and commitment to your career choice in the energetic and growing business area of biologics and bio-processing, and the critical nature of what we do. BPSA's role in promoting and advancing member interests has never been more prevalent.

Over the past year, as was reported during our 2017 Annual Membership Meeting, the Board of Directors has significantly enhanced the value proposition of the Alliance. We have expanded our Agenda to cover a market data effort, a sustainability committee, and a cell and gene therapy committee. BPSA has also established the European Advisory Council creating a platform for our European BPSA members to discuss Europe-specific SUT challenges. Recently, our marketing committee took on the role of revamping our website, with a great result. We published two new technical guides just recently on change management and system integrity assurance. All this information can be seen and easily accessed on the new, colorful website.

Thanks to our membership committee our total membership numbers are up, and our member-retention rate is above 95%. Our budget and spending targets are all on track, thanks to our members and sponsors – we could not do it without you! Our success is due to your investment and commitment to us and we thank you.

This week's 7th annual conference highlights the vibrant, growing and essential nature of markets for Single-Use Systems. This will include BPSA's role in smoothing the road to further global adoption of essential polymeric bio-processing platforms, and the real benefits our industry provides, with an eye toward emerging markets.

To this point, over the next two days we have expert panels arranged to delve into all aspects of Single-Use Saves – this year's Summit theme.

Savings in some respects is the water, energy, resources, and capital-savings that are inherently favorable in deploying and operating plastic versus stainless steel-based bio-processing platforms. We have an integrated and comprehensive discussion of these issues on the docket this week, with an eye toward how we will integrate "green strategies" into our business models.

Savings in another respect is the saving of lives. We have put together a comprehensive panel to cover the emergence of cell and gene therapies as an evolving market for precision plastics which will enable new and critical life-saving vaccines and treatments. Our cell therapy panel, featuring guests

from around the globe, will delve into the needs, requirements and expectations of this emergent area, which promises cures for both rare and common diseases, using precision medicine. And there is more, much more, to our 2017 Agenda. Most importantly, we hope you use the Summit's networking opportunities to meet and greet your industry peers, whether they be colleagues, customers or competitors. BPSA is the Single Voice for Single-Use and networking and partnering remain a key ingredient to the success and growth of our businesses.

In closing, we thank you for your participation this week, and wish you a memorable and productive visit to our nation's capital. Now let's raise the curtain on the 2017 BPSA Summit!

John Boehm
CPC
Chairman of the Board
Bio-Process Systems Alliance (BPSA)

Kevin D. Ott
Executive Director
Bio-Process Systems Alliance (BPSA)
Washington, DC

PROGRAM SPONSORS

BPSA sponsors support BPSA events and sustain BPSA's advocacy of single-use manufacturing technologies. The 7TH Annual International Single-Use Summit would not be possible without their generous support. Become a BPSA sponsor by contacting Jeanette McCool at **mccoolj@socma.com**.

PLATINUM SPONSOR

Thermo SCIENTIFIC

GOLD SPONSOR

CPC™

GOLD SPONSOR

GE Healthcare

GOLD SPONSOR

MilliporeSigma

GOLD SPONSOR

PALL Life Sciences

GOLD SPONSOR

RENOLIT
Rely on it.

GOLD SPONSOR

SAINT-GOBAIN

SILVER SPONSOR

AdvantaPure® NewAge Industries

SILVER SPONSOR

CHEMIC LABORATORIES, INC.

SILVER SPONSOR

Entegris

SILVER SPONSOR

Nordson MEDICAL

SILVER SPONSOR

PENDOTECH
Adding Value To Your Process

SILVER SPONSOR

SaniSure®
Solution Based Innovation

SILVER SPONSOR

sartorius stedim biotech

2017 BPSA BOARD OF DIRECTORS

John Boehm (2018)
BPSA Chair
CPC

Jeffrey Carter, PhD (2018)
BPSA First Vice-Chair
GE Healthcare Life Sciences

Mark A. Petrich, PhD, PE (2018)
BPSA Second Vice-Chair
Merck & Company, Inc.

Kenneth L. Bibbo (2017)
BPSA Treasurer
Jacobs Engineering Group

Janmeet Anant (2017)
Millipore Sigma

Ken Baker (2017)
AdvantaPure/NewAge Industries

Kenneth R. Davis (2018)
Nordson Medical

Michael Goodwin (2017)
Thermo Fisher Scientific

Eric Isberg (2018)
Entegris, Inc.

Hélène Pora, PhD (2018)
Pall Life Sciences

Paul Priebe (2018)
Sartorius Stedim North America

Kirsten Strahlendorf (2017)
Sanofi Pasteur

Joseph St. Laurent (2018)
Chemic Laboratories, Inc.

CHAIRMEN EMERITI

Jerold Martin

Richard Sullivan

BPSA
Bio-Process Systems Alliance
Advancing Single-Use Worldwide

www.bpsalliance.org

AGENDA

The wireless Internet pass code is **BPSA17**

WEDNESDAY, JULY 12, 2017

Noon – 6:00 PM — **Summit Registration** | CORCORAN BALLROOM FOYER, MEETING LEVEL

4:00 – 6:00 PM — **BPSA Annual Meeting** | THE GEORGE WASHINGTON ROOM, LOBBY LEVEL
All BPSA Members

6:00 – 7:00 PM — **Welcome Reception** | THE GEORGE WASHINGTON ROOM AND TERRACE, LOBBY LEVEL

THURSDAY, JULY 13, 2017

8:00 AM – 5:00 PM — **Summit Registration** | CORCORAN BALLROOM FOYER, MEETING LEVEL

ALL GENERAL SESSIONS | CORCORAN BALLROOM SALON A, MEETING LEVEL

8:00 AM — **Continental Breakfast** | CORCORAN BALLROOM MEETING LEVEL

8:30 AM — **Chairman's Opening Remarks**
John Boehm, Business Unit Manager, Bioprocessing, CPC, BPSA Chair

9:00 –10:00 AM — **OPENING KEYNOTE** | **From the Frontlines: What's Going on in Washington?**
Eliana Johnson, National Political Reporter, POLITICO

SNAP LEARNING OPPORTUNITY | **BPSA's Integrity Assurance White Paper**
Hélène Pora, Ph.D., Vice President, Single-Use, Pall Life Sciences

10:00 – 10:15 AM — **BREAK**

10:15 – 11:15 AM — **The Application of Single-Use Technologies in Medical Countermeasure Development & Manufacturing for Emerging Pathogens**
Michael Angelastro, Deputy Director of Manufacturing, US Biomedical Advanced Research and Development Authority (BARDA), US Health & Human Services

The wireless Internet pass code is **BPSA17**

11:15 AM – 12:15 PM **USP <665> Polymeric Components and Systems Used in the Manufacturing of Drug Products**
Michael Eakins, Ph.D., Vice-Chair, Packaging and Distribution Expert Committee, United States Pharmacopoeia

12:15 – 1:30 PM **NETWORKING LUNCHEON** | NO SCHEDULED SPEAKER

1:30 – 1:40 PM **SNAP LEARNING OPPORTUNITY | How to Implement Single-Use? The BPSA Technical Guides**
Kirsten Strahlendorf, Senior Scientist – BioProcess R&D/Formulation & Stability Platform, Sanofi Pasteur

1:40 – 2:00 PM **SNAP LEARNING OPPORTUNITY | BPSA/BPOG Single-Use User Requirements Template**
Sabrina Restrepo, Ph.D., Associate Director, Sterile & Validation Center of Excellence, Merck & Co., Inc.

2:00 – 6:00 PM **AFTERNOON PANEL | TIME, RESOURCES & LIVES: SINGLE-USE SAVES**
Moderators: Mark Petrich, Ph.D., P.E, Director, Single-Use Systems Engineering, Merck & Co., Inc. and Tad Radzinski, President, Sustainable Solutions Corporation

- **SUT Life Cycle Assessment and Management**
  Bill Flanagan, Director, Ecoassessment Center of Excellence, Resource & Environmental Strategies, GE
- **Energy-from-Waste: Ensuring No Waste is Ever Wasted**
  Michael E. Van Brunt, P.E., Director, Sustainability, Covanta

3:30 – 3:45 PM **BREAK**

3:45 – 4:00 PM **SNAP LEARNING OPPORTUNITY | BPSA's European Outreach: The European Advisory Committee**
Stephen Brown, Chief Technical Officer, BE Vaccines, Committee Co-Chair

AFTERNOON PANEL | *continued*

- **How SUT Adoption Has Opened a Path to More Creative Options in Biomanufacturing**
  David Radspinner, Global Business Leader, GE BioParks, GE Healthcare

- **Case Study: Integrating Single-Use Components for a Modular Commercial Drug Substance (DS) Process**
  Kristie Apgar, Associate Principal Scientist, Bioprocess Clinical Manufacturing and Technology, Merck & Co., Inc.
  Sabrina Restrepo, Ph.D., Associate Director, Sterile & Validation Center of Excellence, Merck & Co., Inc.
  Dusan Ruzic, Senior Scientist, Vaccine Process Development and Commercialization, Merck & Co., Inc.

The wireless Internet pass code is **BPSA17**

6:30 – 8:30 PM **Federal City Skyline Reception** | THE GEORGE WASHINGTON UNIVERSITY CITY VIEW ROOM AND TERRACE 19TH AND E STREETS, NW

Shuttle buses to the Off-Property Venue will begin from the front of the hotel at 6:30 PM. Shuttle buses will begin returning to the hotel beginning at 8:30 PM.

FRIDAY, JULY 14, 2017

GENERAL SESSION | CORCORAN BALLROOM SALON A, MEETING ROOM LEVEL

8:00 AM **Continental Breakfast** | CORCORAN BALLROOM, MEETING LEVEL

8:15 – 8:45 AM **Opening Remarks and SNAP LEARNING OPPORTUNITY | BPSA/BPOG Change Control Paper #2: Implementation and Next Steps**

Jeffrey Carter, Ph.D., Strategic Projects Leader, GE Healthcare, BPSA Vice Chair

8:45 – 9:15 AM **Single-Use Market Acceleration: How Big, How Soon, How Fast?**

Eric Langer, President and Managing Partner, BioPlan Associates

9:15 AM – 12:15 PM **CELL & GENE THERAPY PANEL**

Introduction: Eric Isberg, Director, Life Sciences, Entegris, Inc.

- **Case Study #1: Single-Use for In-Vitro Processing and Delivery of Cell Therapy**

  Tamar Harel-Adar, PhD; Product Development Manager; Cellect Bio, Israel
- **Materials for Single-Use Systems for Cell Therapy: Advances in Materials**

  Topic Leader – Eva Heintz, Global Market Manager – Healthcare, Solvay Specialty Polymers U.S.A., LLC

  Presenters: Jayanthi Grebin, Product Manager, Life Sciences, Entegris, Inc.

  James Hicks, Technical Development Engineer, Solvay Specialty Polymers U.S.A., LLC

  Amy Plançon, Sr. Specialist Industry Management, Healthcare, Sabic

10:30 – 10:45 AM **Break for Hotel Check Out**

GENE & CELL THERAPY PANEL | *continued*

- **Case Study #2: Single-Use for Delivery of Cell Therapy Products**

  Topic Leader – Dominic Clarke, Ph.D., Global Product Manager, Cell Therapy & Bioprocessing, Charter Medical

  Presenter: Alan K. Smith, Ph.D., Executive Vice President, Technical Operations, Bellicum Pharmaceuticals, Inc.

The wireless Internet pass code is **BPSA17**

GENE & CELL THERAPY PANEL | *continued*

- **Topic Connection (et al.) Technology in Clinical Settings; Learnings for the SU Industry**
  Ken Davis, Global Market Manager – Biopharm, Nordson Medical
  Scott Herskovitz, Vice President, Sales and Marketing, Qosina Corporation
- **How BPSA Is Addressing the Cell & Gene Therapy Market**
  Dominic Clarke, Ph.D., Global Product Manager, Cell Therapy & Bioprocessing, Charter Medical, CGT Committee Chair

12:15 – 12:30 PM **Wrap Up & Next Steps**
John Boehm, CPC, BPSA Chair

"To Go" box lunches will be provided.

SPEAKERS

MICHAEL ANGELASTRO | BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)

Mike Angelastro is the Deputy Director of the Division of Manufacturing, Facilities & Engineering in the Biomedical Advancement Research Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Mike joined the BARDA in October 2007 and, over the last several years, has been the principal Project Officer for numerous major procurement actions that are focused on strengthening our Nation's capacity to respond to biological threats through infrastructure and manufacturing process improvements. Specifically, he oversees the 'Centers for Innovation in Advanced Development and Manufacturing' (CIADM) program within the BARDA. Mike works closely with U.S. Government team members/ stakeholders, subject matter experts/consultants, as well as our industry performers, to ensure timely delivery of project milestones and programmatic objectives. Mike received his BS in Chemical Engineering from Drexel University in Philadelphia, PA. Prior to joining BARDA, Mike worked for Merck & Co., Inc. for nine years as a Senior Engineer in the vaccine manufacturing division and served as direct facility and process support for several viral vaccines at the West Point, PA plant site. At Merck, Mike served as a key contributor during scope development and execution of significant process upgrade projects as well as new facility construction and in-place renovation activities.

KRISTIE APGAR | MERCK & CO., INC.

Kristie Apgar Associate Principle Scientist – Biologics Clinical Manufacturing and Technology (Merck & Co., Inc.). In her current role, Kristie provides technical support for the manufacture of vaccines and biologics clinical candidates at the Biologics Pilot Plant in West Point, PA. She has lead multiple programs, including process scale up and tech transfer activities. Prior to joining Merck Research Laboratories, she was a member of the startup team for the purification of Gardasil® in the Manufacturing Division. She holds a B.S. in Chemical Engineering from The Pennsylvania State University.

JOHN BOEHM | COLDER PRODUCTS COMPANY

John Boehm is responsible for CPC's bioprocessing business. He joined CPC in 2001 and has held leadership positions in engineering, marketing, and business development. John holds a Bachelor of Science in Mechanical Engineering from Grove City College, PA and a Master of Business Administration from the University of St. Thomas in St. Paul, MN.

John is presently serving as Chairman of the Bio-Process System Alliance (BPSA). His participation in BPSA has included vice chair, education chair and connector sub-committee chair working on projects including component quality test matrices, technical white papers, educational road shows and the annual International Single-Use Summit. His industry involvement includes authoring and presenting on connection solutions, aseptic processing and implementation of single-use technologies.

STEPHEN BROWN | BE VACCINES

Stephen Brown is Executive Director, BE Vaccines, Nantes, France. BE Vaccines is part of Biological E Ltd, Hyderabad, India. Steve holds a BSc in Microbiology from University of Wales, Cardiff and a PhD in Fermentation Technology from University of Kent at Canterbury UK. His Postdoctoral was at the ETH Zurich, Switzerland. Steve's career has focused on human and animal vaccines and gene-based medicine product development, manufacturing site management and facility design and construction. He joined Biological E. Ltd, in November 2013. Previously worked at, G.D Searle (UK), Transgene, Merial and Vivalis (France).

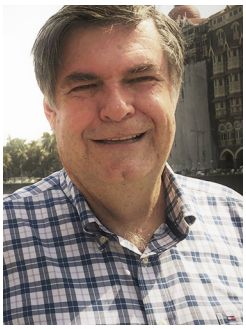
Steve is a member of PDA, ISPE and ASTM and joint author of PDA SUS TR66. He is Bio E's key contact for the Bio-Process Systems Alliance and Co-Chair of BPSA's European Advisory Council (2017).

JEFF CARTER | GE HEALTHCARE LIFE SCIENCES

Jeff has been active in organizations such as the Parenteral Drug Association, ASTM E55, BPOG, and ASME-BPE, and is first vice chair of the BioProcess Systems Alliance. His present role within GE is to serve as a voice for evolving regulatory and de facto expectations related to the global implementation of single-use manufacturing. Dr. Carter holds a PhD degree from Penn State University in molecular microbiology.

DOMINIC CLARKE, PH.D. | CHARTER MEDICAL

Dominic Clarke, Ph.D., has 15+ years of experience in cell therapy. He is the Global Product Manager for Charter Medical's cell therapy single-use portfolio used to develop flexible closed-system solutions for clinical and commercial production. Previously, Dr. Clarke was the Director of Research & Development at BioLife Solutions, developing critical cold chain solutions. He has authored or co-authored over 25 peer-reviewed papers and has been the Principal Investigator on multiple NIH awarded grants. He received his Ph.D. in Cell & Molecular Biology from the State University of New York at Binghamton and performed his post-doctoral studies in Cellular & Developmental Biology at Syracuse University Upstate Medical Center.



KEN DAVIS | NORDSON MEDICAL

Ken Davis has over 25 years of product management/marketing experience in pharmaceutical, medical device and high tech industries. He has been working, most recently, for Value Plastics, Inc. a Nordson Company in Fort Collins Colorado. He earned both a Bachelor of Science in Business Administration and an MBA degree throughout his career.

Ken is also a current Bio-Process Systems Alliance (BPSA) Executive board member, chairing the marketing committee. He also initiated the BPSA recommendation establishing a single-use polymer specification for hygienic connectors to address the industry's concern over a lack of non-stainless steel standard. This initiative is now being adopted by the ASME BPE standards body. Mr. Davis is a member of the ASME BPE task group working on this specification.

MICHAEL N. EAKINS, PH.D. | EAKINS & ASSOCIATES

Dr. Michael Eakins is the Founder and Principal Consultant of Eakins & Associates with over 35 years' experience in pharmaceutical research and development. At Eakins and Associates, Michael provides experience and advice on parenteral primary packaging, especially on glass delamination and glass defects, the selection and product development in glass and plastic pre-filled syringes, and on extractables and leachables for parenteral packaging and manufacturing components. He regularly lectures on these topics worldwide for the USP.

Michael was responsible for the pharmaceutical development of diagnostic radiology products at E. R. Squibb and Bristol-Myers Squibb and for global packaging initiatives for contrast media at Bracco SpA.

Michael was the Vice-Chair of the USP Packaging, Storage and Distribution Expert Committee in the 2005-2010 and 2010-2015 cycles and is currently Vice-Chair of the USP Packaging and Distribution Expert Committee for the 2015-2020 cycle. He is an active member of the Parenteral Drug Association, being the co-chair of the Glass Defects Task Force that revised Technical Report 43 and was a member of the Elastomers and Seals Defects Task Force responsible for Technical Report 76 published in 2016. He obtained his Ph.D. from London University and has contributed to over 60 publications and 8 USA patents.

BILL FLANAGAN | GE

Bill Flanagan leads the Ecoassessment Center of Excellence for the General Electric Company. The Center was founded to assess the environmental impacts of products throughout their entire lifespan, from raw materials extraction through reuse, recycling, or disposal at the end of product life. The team works with the various GE businesses and the GE Ecomagination leadership team to support GE's product and technology sustainability strategies, applying a variety of tools and approaches including environmental life cycle assessment.

Bill is also Chair, Board of Directors, of the American Center for Life Cycle Assessment (ACLCA), the membership and advocacy organization for LCA professionals in North America, and serves on the Board of Directors of the Forum for Sustainability through Life Cycle Innovation (FSLCI) and the External Advisory Board for the University of Michigan's Center for Sustainable Systems. He is a LCA Certified Professional and was awarded the Lifetime Individual LCA Leadership Award in 2014 from the ACLCA.

Bill graduated from Virginia Tech in 1985 and received a PhD in Chemical Engineering from the University of Connecticut in 1991.

JAYANTHI GREBIN | ENTEGRIS, INC.

Ms. Grebin joined Entegris in 2015 as a Product Manager of its LifeScience Single Use Product. She came to Entegris from a CMO as an application engineer who makes wiring harness for X-ray and MRI machine, after working for Pall Life Science from Pall's acquisition of ATMI LifeSciences in February of 2014. In her current role, Ms. Grebin's primary responsibilities includes assisting new product development and a team member that develops and launches new single use products into the life sciences market.

Ms. Grebin joined ATMI LifeSciences in 2013 as its global project manager for Integrity™ Single-Use Fluid Technologies. While there, she managed projects (new and existing) of the Integrity line, Single Use mixing platforms, 2D and 3D bioprocess vessels and powder transfer vessels including the Cell Culture product platforms. Prior to that, she worked as application engineer for Industrial pumping companies. Ms. Grebin is a member of ISPE and PDA and a member in Bio-Process Systems Alliance (BPSA) as well as BioPhorum Operations Group.

Ms. Grebin has a degree in Electrical and Biomedical/Clinical Engineering from California State Long Beach California.

TAMAR HAREL-ADAR, PH.D. | CELLECT BIO, ISRAEL

Dr. Harel-Adar joined Cellect Biotherapeutics in 2016 as a product development manager. Cellect is a clinical stage company developing innovative stem cell selection technology. In her current role, Dr. Harel-Adar is heading the development of Cellect's leading products, the single-use stem cells selection devices.

Prior to joining Cellect, Dr. Harel-Adar worked for ExceeMatrix between 2014-2016, as R&D manager and for CollPlant LTD between 2010-2014, as product development engineer. There, she led the development of biomaterial based medical devices in the field of cardiovascular, wound healing and orthopedics.

Dr. Harel-Adar holds a PhD in biotechnology engineering and has a vast experience in biomaterials and tissue engineering. In 2011, Dr. Harel-Adar has been awarded the International 2011 Barenholz Prize for Innovation in Applied Research.

EVA HEINTZ | SOLVAY SPECIALTY POLYMERS U.S.A., LLC

Dr. Eva Heintz has been with Solvay for approximately 11 years. She was trained as a chemist, managed Solvay's Analytical and Material Testing Department prior to moving into her current role as the Global Marketing Manager for Solvay Specialty Polymer's Healthcare group. Eva is responsible for Solvay efforts in the Biopharma & Drug Delivery area as well as Additive Manufacturing in Healthcare.

SCOTT HERSKOVITZ | QOSINA CORPORATION

Scott Herskovitz, VP Sales and Marketing for Qosina. Scott has been in sales and marketing roles focused on single-use components for medical device and pharmaceutical manufacturing since 2006. Prior to that, he worked in the Sales and Marketing of Ethylene Oxide Sterilizers. Scott has a Bachelor's degrees in Business from the State University of New York at Buffalo and an MBA degree from the Rotterdam School of Management in the Netherlands.

JAMES HICKS | SOLVAY SPECIALTY POLYMERS U.S.A., LLC

Jim has been with Solvay for 26 years and holds a B.S. in Chemistry. Jim provided R&D product development support for the Sulfone Polymers Group and Material Testing Labs. Jim's primary activities for Solvay Specialty Polymers are in technical support and application development in the healthcare market; providing design review, material recommendations, processing support, failure analysis and educational training in metal to plastic conversions. Jim also has extensive experience in extrusion of high-temperature polymers.

ERIC ISBERG | ENTEGRIS, INC.

Mr. Isberg joined Entegris in 2014 as the director of its life sciences business. He came to Entegris from Pall Corporation, which he joined as part of Pall's acquisition of ATMI LifeSciences in February of 2014. In his current role, Mr. Isberg's primary responsibilities include leading a team that develops and launches new single use products into the life sciences market.

Mr. Isberg joined ATMI LifeSciences in 2012 as its global product manager for Integrity™ Single-Use Fluid Technologies. While there, he managed the Integrity line of single-use mixing platforms, bioprocess vessels and powder transfer vessels. Prior to that, he worked for Computype as its life sciences market manager and Thermo Fisher Scientific as its bioprocessing market manager.

Mr. Isberg is a member of ISPE and PDA and a member of the Board of Directors for the Bio-Process Systems Alliance (BPSA).

Mr. Isberg has a degree in Biology from Gustavus Adolphus College and holds several patents related to single-use filling systems.

ELIANA JOHNSON | POLITICO

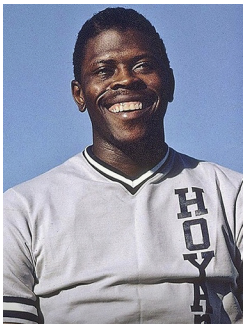
Eliana Johnson takes you inside the ever-evolving national political scene with candid, non-partisan insights on the power players making headlines and the latest policy developments in Washington.

Eliana Johnson, POLITICO's national political reporter, offers fresh, non-partisan, behind-the-scenes analyses of what's going on in Washington. Previously serving as Washington editor of National Review, where she was lead reporter of the 2016 elections, she was also a producer at Fox News Channel, a research associate at the Council on Foreign Relations, and a staff reporter for the New York Sun.

From the Trump administration to the Republican Congress to the headlines of the day, her sharp journalistic experience and up-to-the-minute insider status make her an ideal choice to break down the most important issues of the day with audiences.

ERIC LANGER | BIOPLAN ASSOCIATES

Eric Langer has over 20 years' experience in biotechnology and life sciences international marketing, strategic marketing management, market research, and publishing. He has held senior management and marketing positions at biopharmaceutical supply companies. He has published, edited and authored numerous books, reports, and major studies on topics including Advances in Biopharmaceutical Technology in China, Advances in Large-scale BioManufacturing, etc. He lectures on pricing and channel management, and teaches at Johns Hopkins University and American University: Biotech Marketing, Services Marketing, and Marketing in a Regulated Environment. He has launched and managed marketing programs for product lines ranging from $500k to $500 million. In 1989 he co-founded BioPlan Associates, Inc. to provide market analysis, assessment and marketing strategies to biotech and healthcare organizations.



JEANETTE MCCOOL | ROQOPS

Jeanette McCool is the principal partner of RoqOPS, an event and operations management firm based in Silver Spring, MD. McCool is also employed by Ott Consulting, LLC, assisting with the firm's various projects and clients, including BPSA.

McCool's varied career experience includes owner of a professional men's basketball team, paralegal and law office manager, and seventeen years at the National Association of Manufacturers, serving as Vice President, Meeting Management and Assistant Corporate Secretary. McCool is a native of Washington, D.C. and a product of its Catholic schools, Immaculata Preparatory School for Young Women and Georgetown University.

KEVIN OTT | OTT CONSULTING, LLC

Kevin Ott is the principal partner of Ott Consulting, LLC, based in McLean, Va.

Ott serves as Executive Director of the Bio-Process Systems Alliance (BPSA), a national corporate trade association comprised of the producers and users of disposable plastics-based bio-process manufacturing platforms used in drug therapy production. BPSA is an independent affiliate of the Society of Chemical Manufacturers and Affiliates (SOCMA) based in Washington, D.C.

Ott spent twelve years as Group Vice President of the Elastomers Product Division of the Rubber Manufacturers Association, and another seven years as an offshore oil and gas leasing advocate for the National Association of Manufacturers in their Environment and Natural Resources Division.

Ott is a native of Washington, D.C. He is a graduate of the University of Virginia with a degree in Environmental Sciences.

MARK A. PETRICH | MERCK & CO., INC.

Mark A. Petrich is Director – Single Use Systems Engineering at Merck & Co., Inc. and serves as second vice chair of the Bio-Process Systems Alliance (BPSA). Mark's team is responsible for developing best practices for deploying single use technologies in vaccine and biologics manufacturing. His activities in BPSA have included End User Committee chair, initiation of the Sustainability Committee, co-authorship of the BPSA white papers on particles, quality agreement template, and integrity, and participation on the organizing committees for several Summits. Mark has been a panelist and speaker at several Summits including delivering the keynote address at the 2016 European Summit (Barcelona). BioProcess International selected Mark for their 2016 Industry Champion award.

AMY PLANÇON | SABIC

Amy Plançon is a 27-year veteran of the packaging industry, having obtained her first degree from Michigan State University in Packaging Engineering. After working in Melbourne Australia for Amcor Ltd she moved to Chicago and held a Marketing Manager position with BP where her focus was on materials for drug delivery devices, pharmaceutical packaging, and medical products. She joined SABIC in The Netherlands in 2014 and currently holds a Sr. Specialist Industry Management position in the Healthcare business unit. In her role she manages projects related to the biopharmaceutical industry, including drug delivery, parenteral products and packaging, and Single-Use manufacturing technology. She currently represents SABIC on the BPOG/BPSA Change Notification Committee for Single Use Technology. Amy received an MBA in International Business from Dominican University in Chicago, and an MSc in Health, Population and Society from the London School of Economics.

HÉLÈNE PORA | PALL LIFE SCIENCES

Dr. Hélène Pora is Vice President Single Use Technology within Pall Life Sciences, where she has the global responsibility for the marketing and development of Pall single use technology. Hélène has been instrumental in the development of Pall single use technologies for the last 18 years. She is as well heavily involved in quality and regulatory aspects of single use technology. Hélène has over 30 years of experience working for the biopharmaceutical industry, the last 25 years within Pall Corporation.

She speaks regularly at conferences about single use technology with a strong focus on validation and over all process integration aspects, she is as well involved in different working groups in the industry involved in standards development and is on the board of BPSA and SUTAP.

DAVID RADSPINNER | GE HEALTHCARE

In March 2016, Radspinner was appointed as the General Manager for the new GE BioPark business. Prior to this position, David helped position for sale, integrate and run the Life Sciences Cell Culture (HyClone) business within GE for 3 years. Before that, David served in various senior global Product Management, Sales and Business Development roles within Thermo Fisher Scientific for over 8 years. David earned a Ph.D. in Analytical Chemistry from the University of Arizona and spent over 14 years in developing, manufacturing and characterizing pharmaceuticals for several multinational pharmaceutical companies.

TAD RADZINSKI | SUSTAINABLE SOLUTIONS CORPORATION

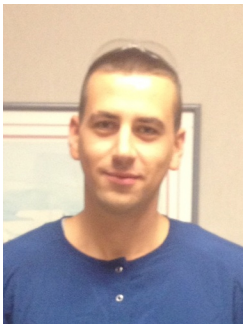
With over 30 years of practical experience, Tad Radzinski is a leading expert in corporate responsibility and environmental management. Tad, co-founder and president of Sustainable Solutions Corporation, delivers consultative services to companies in a wide range of global industries. Tad is additionally co-founder of and Certification Officer at GreenCircle Certified, LLC, providing third-party verification of environmental claims and ensuring transparency in the green marketplace. Formerly the EPA's Waste Minimization Program National Expert, Tad has been a trusted advisor for Fortune 500 companies including ASSA ABLOY, Unilever, Merck, Stanley Black & Decker, Saint-Gobain, and Kohler. Tad understands the need for companies to generate value in an increasingly complex marketplace. He delivers the framework to utilize corporate responsibility to implement proactive change, lead your industry, and ensure the long-term success of your business. Tad is an adjunct professor at Villanova University, teaching graduate classes such as Sustainable Buildings and Operations and Principles of Sustainable Development.

SABRINA RESTREPO | MERCK & CO., INC.

Sabrina Restrepo, Ph.D., Associate Director – Global Sterile & Validation Center of Excellence (Merck & Co., Inc.). Sabrina's responsibilities at Merck have included technical operations support in several areas such as deployment of single-use systems in vaccine manufacturing, technical collaborations with single-use systems' suppliers, regulatory remediation plans, cell culture media and drug substance manufacturing. Currently, she is a member of the Single-Use Network (SUN) Council at Merck and the leader of the single-use mixing and validation sub-teams.

Her experience prior to joining Merck includes; development and manufacturing of cell culture media products, process characterization and improvement of drug substance and development of biological wastewater technologies.

She holds a BS and MSc degrees in Chemical Engineering from Universidad Nacional de Colombia and PhD degree in Engineering from the University of Akron, Ohio.



DUSAN RUZIC | MERCK & CO., INC.

Dusan Ruzic, Senior Scientist– Vaccines Process Development & Commercialization (Merck & Co., Inc.). Dusan's responsibilities at Merck have included process development, characterization, tech transfer, & facility start of various vaccine and biologics products. He holds a BS and MS degrees in Chemical Engineering from Drexel University.

ALAN SMITH | BELLICUM

Alan Smith, Executive Vice President, Technical Operations, joined Bellicum in October 2015. He has over 30 years of experience in R&D, Manufacturing and Quality roles in cellular therapeutics and previously served as Bellicum's Senior Vice President of Manufacturing. Prior to that, Dr. Smith was Vice President of Research & Development and Cellular Therapeutics for LifeNet Health, and its wholly owned subsidiary, The Institute of Regenerative Medicine. Prior to consulting to the cell therapy industry for a number of years, Dr. Smith served as President and Chief Executive Officer for Cognate BioServices, and COO and SVP Research & Development for Osiris Therapeutics. Previously, he led the R&D functions for Aastrom Biosciences and Geneic Sciences, and he served as Director of Cell Separations Research & Development at Baxter Healthcare. He is a former Adjunct Professor at Eastern Virginia Medical School, California State University – Long Beach and Utah State University. Dr. Smith earned his Bachelor of Science in Chemistry at Southern Utah University and his doctorate in Biochemistry at Utah State University.

KIRSTEN STRAHLENDORF | SANOFI PASTEUR

For the last 12 years, Kirsten Strahlendorf has been working as a Senior Scientist in Research and Development at Sanofi Pasteur in Toronto. She holds a Professional Engineering license, an honours degree in Biological Engineering from the University of Guelph, and a Master's of Engineering from the University of Toronto.

Kirsten takes a seat on the Board of Directors for the Bio-Process Systems Alliance. A driver in the bioprocessing community, she has published several journal articles. Kirsten manages a bioprocess design and scale-up laboratory for vaccine formulations. Her focus lies in automation and isolation systems for novel biotechnology products decades away from being marketed.

In her personal life, Kirsten enjoys her three small children who understand that their mother makes "needles with medicine" for work.

MICHAEL E. VAN BRUNT, P.E. | COVANTA

Michael Van Brunt is a licensed professional engineer with over fifteen years of experience in industry and consulting. Michael is currently Senior Director of Sustainability at Covanta where his primary focus is on sustainability reporting, climate change, carbon offset project development, and life cycle assessment. He currently serves on the board of the National Recycling Coalition. He earned a B.S. and Masters in Environmental Engineering from Cornell University.

Bio-Process Systems Alliance

Advancing Single-Use Worldwide

Federal City Skyline Reception

THURSDAY | JULY 13 | GEORGE WASHINGTON UNIVERSITY

City View Room and Terrace | 19th and E Streets, NW

Shuttle buses to the Off-Property Venue will begin from the front of the hotel at 6:30 PM. Shuttle buses will begin returning to the hotel beginning at 8:30 PM.

BPSA 2017 SUMMIT PROGRAM COMMITTEE

A conference of this caliber would not be possible without the support of our sponsors and volunteers. We thank the 2017 Summit Program Committee for their time and effort on behalf of BPSA.

Chairs

Dominic Clarke
Charter Medical

Ralph Daumke
Filtrox AG

Scott Herskovitz
Qosina

Amy Plançon
Sabic

Sabrina Restrepo
Merck & Co., Inc.

Janmeet Anant
Millipore Sigma

Ken Baker
AdvantaPure/NewAge Industries

James Barry
Pall Life Sciences

Ken Bibbo
Jacobs Engineering

John Boehm
CPC
Summit Program Committee Board Sponsor

Jeff Carter
GE Healthcare

Ken Davis
Nordson Medical

Mike Felo
Millipore Sigma

Mike Ginsberg
Qosina

Jayanthi Grebin
Entegris

Eva Heintz
Solvay

Eric Isberg
Entegris

Todd Kapp
Tamarack Business Development

Greg Love
Bürkert Fluid Control Systems

Sandra Medlin
SaniSure

Richard Mirro
Eppendorf

Hernán Parma
American Renolit

Mark Petrich
Merck & Co., Inc.

Hélène Pora
Pall Life Sciences

Joseph St. Laurent
Chemic

Maria Stazzone
Qosina

Kirsten Strahlendorf
Sanofi Pasteur

Danielle Taylor
Qosina

BPSA is always striving for a better Summit experience. Fresh ideas and perspectives are always welcome. Please consider joining the 2018 Summit Program Planning Committee. To Join: email Jeanette McCool at **mccoolj@socma.com**.

Kevin and Jeanette would like to thank our Summit support team, who year after year bring their very best, so that you can experience the very best:

Tommy Southall, graphics designer extraordinaire!
Judy Thayer, meeting planner without compare!
Caron Turner, our remarkable registration director.

BPSA MEMBERS

Adello BIOLOGICS

AdvantaPURE® NewAge Industries

ARKEMA INNOVATIVE CHEMISTRY

ARTeSYN Biosolutions

BE Biological E. Limited

Boston ANALYTICAL THE LIFE SCIENCES DIVISION OF ALPHA ANALYTICAL, INC.

btec Biomanufacturing Training and Education Center

bürkert FLUID CONTROL SYSTEMS

CharterMedical

CHEMIC LABORATORIES, INC.

chemical solutions ltd. trace elemental analysis

CPC™

CORNING

DOW CORNING

Entegris

eppendorf

ERTELALSOP The First Name in Liquid Filtration

FILTROX

GEA

GE Healthcare

GEMÜ®

gsk GlaxoSmithKline

HIGH PURITY NEW ENGLAND ...Client / Vendor Relationships - - we bring VALUE ! !

ILC DOVER creating what's next | DoverPac containment solutions

BPSA MEMBERS

BPSA MEMBERS

TAMARACK Business Development Enterprises

Thermo SCIENTIFIC

3M

VR ANALYTICAL

VWR We Enable Science

WATSON MARLOW Fluid Technology Group

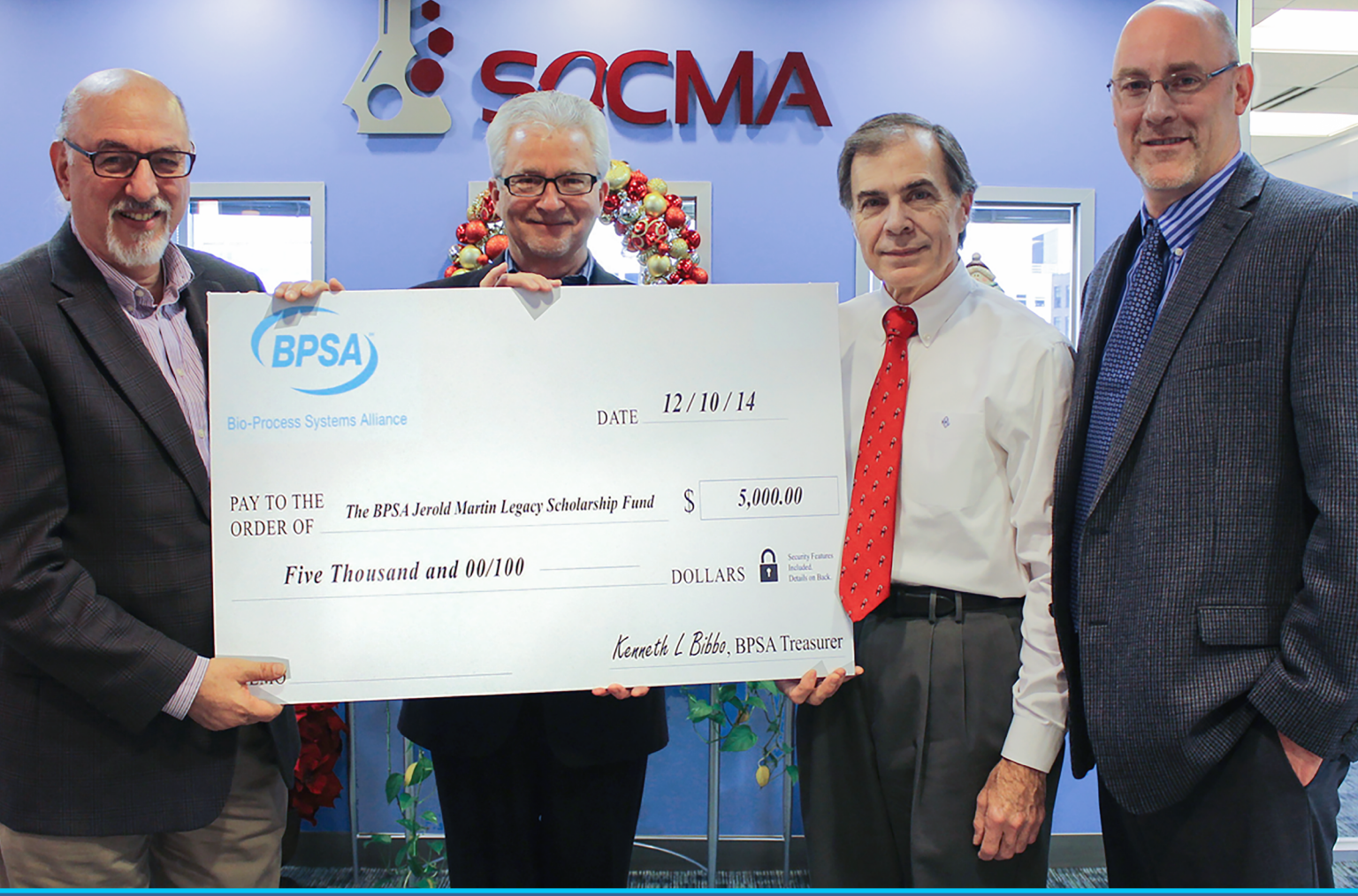
WINPAK

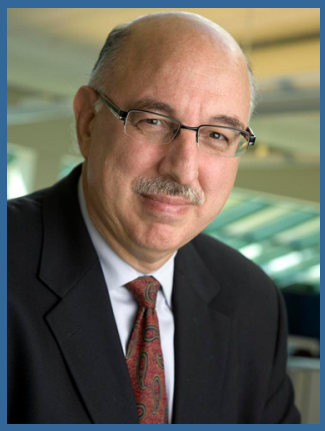
BPSA MISSION

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 corporate member trade association dedicated to encouraging and accelerating the adoption of single use manufacturing technologies used in the production of biopharmaceuticals and vaccines. BPSA facilitates education, sharing of best practices, development of consensus guides and business-to-business networking opportunities Among its member company employees.

For more information about BPSA, ask a staff member during the conference, visit www.bpsalliance.org.





THE JERRY MARTIN LEGACY SCHOLARSHIP FUND

In 2015, BPSA established the Jerry Martin Legacy Scholarship Fund, in order to provide a scholastic grant or monetary award to an institution(s) of higher learning on behalf of an individual(s) to further their field of study or commend their activities for the advancement of single-use technology or to reward an individual for such related activities.

Contributions to the scholastic grant and award fund by Member companies and/or Individuals will be treated as “sponsorships” and cannot be considered tax deductions per IRS 501c6 regulations. Should you wish to contribute to the fund, please contact Jeanette McCool, **mccoolj@socma.com** and she will generate an invoice.