



Bio-Process Systems Alliance
Advancing Single-Use Worldwide



BPSA International
Single-Use Summit



COLLABORATION, TECHNOLOGY & INNOVATION: SHAPING THE FUTURE OF SINGLE-USE

JULY 10 - 12, 2023, FOUR SEASONS HOTEL, WASHINGTON, DC



Wifi pass code **BPSA23**

AGENDA > SPEAKERS >
[BPSALLIANCE.ORG](https://www.bpsalliance.org)



Mark Petrich
Chair, BPSA
Krystal Biotech, Inc.

Welcome to BPSA'S 10th Summit!

2023 BPSA International Single-Use Summit Attendees,

On behalf of the BPSA Board of Directors, our sponsors, and the BPSA staff, I want to welcome all of you to the Four Seasons Georgetown and to Washington, DC! This year marks a significant milestone - the 10th edition of the BPSA International Single-Use Summit. BPSA's Mission is built around advancing the worldwide adoption of single-use technologies and the Summit is a key part of that mission. Thank you for joining us this week.

My initial exposure to BPSA activities came at the very first Summit. There were big dreams for single-use technology and a passionate group ready to tackle the challenges. Through the hard work and unrelenting enthusiasm of BPSA volunteers, many of those dreams have become reality. 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 the 10th Summit is "Collaboration, Technology & Innovation: Shaping the Future of Single-Use." The theme reflects many of the trends impacting the single-use industry, customers, and patients. We will delve into key BPSA technical projects that are led by dedicated volunteer committees. We will hear from industry leaders, government officials and partners who will share their insights and expertise. And we will gain valuable knowledge and new connections. Enjoy the program, the social events, and the chance to network with your industry colleagues.

I want to thank all the BPSA members and sponsors for their ongoing support and participation. Special thanks go to the BPSA Program Planning Committee who have organized this event. I also want to acknowledge the exceptional contributions of BPSA immediate past Chair, Jeff Carter of Cytiva, who will be recognized this week for his outstanding leadership and immense contributions to BPSA.

Finally, please remember that BPSA relies on the efforts of individuals. I encourage you to get involved, 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.

Once again, thank you for being here. Enjoy the 10th BPSA International Single-Use Summit!

BPSA 2023 SUMMIT PROGRAM COMMITTEE

A conference of this caliber would not be possible without the support of our sponsors and member volunteers. We thank the 2023 Summit Program Committee for their time and effort on behalf of BPSA and its members.

Ross Acucena
Entegris

James Hathcock
Cytiva

Hélène Pora
Cytiva

Todd Andrews
CPC

Todd Kapp
Entegris

David Radspinner
Vinta Bio

Danielle Arcuri
Qosina

Greg Love
Berkert

Kirsten Strahlendorf
Sanofi

Magali Barbaroux
Sartorius

Duncan Low

Elizabeth Vachette
Sartorius

John Boehm
CPC

Brendan Lucey
Entegris

Jim Vogel
The BioProcess Institute

Jeff Carter
Cytiva

Ravi Narayanan
Nordson Medical

Tom Warf
BARDA

David Chau
3M

Hernán Parma
RENOLIT Healthcare

Adam Goldstein
Thermo Fisher Scientific

Mark Petrich
Krystal Biotech

BPSA is always striving for a better Summit experience. Fresh ideas and perspectives are always welcome. Please consider joining the Summit Program Planning Committee.

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

PROGRAM SPONSORS

BPSA sponsors support BPSA events and sustain BPSA's advocacy of single-use manufacturing technologies. The 10th International Single-Use Summit would not be possible without their generous support. Become a BPSA sponsor by contacting Jeanette McCool at jmccool@socma.org.



2023 BPSA BOARD OF DIRECTORS

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RENOLIT Healthcare

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ILC Dover

Dan Rosen (2023)

Thermo Fisher Scientific

Mark Sitcoske (2024)

High Purity New England

Elisabeth Vachette (2024)

Sartorius Stedim Biotech

PAST CHAIRS

Kenneth L. Bibbo

Wood PLC

John Boehm

CPC

Jeffrey Carter, PhD

Cytiva

Jerold Martin

Richard Sullivan

BPSA TECHNICAL COMMITTEES

Automation Committee

Co-Chairs:

Hernán Parma
RENOLIT Healthcare

Stuart Tindal
Sartorius

Cell & Gene Therapy (CGT) Committee

Brendan Lucey

Entegris

Continuous Bioprocessing Committee

Co-Chairs:

David Chau
3M

Davinder Chawla
Sanofi

Integrity Assurance Committee

Patrick Evrard

Cytiva

Sustainability Committee

Magali Barbaroux

Sartorius

X-Ray Sterilization Committee

Co-Chairs:

James Hathcock
Cytiva

Samuel Dorey
Sartorius

For more information about BPSA's technical committees and how to get engaged, please visit our [website](#) or contact our team.

AGENDA

MONDAY, JULY 10TH

- 9 AM – 5 PM** **SUMMIT REGISTRATION** | Ballroom Foyer - Events Level
- 10 AM – 4 PM**
A & B **BPSA CONCURRENT COMMITTEE MEETINGS (MEMBERS ONLY)** | Ballroom Salons
- 10 – 11:30 AM** **SUSTAINABILITY** | Ballroom A
Magali Barbaroux, Sartorius, *Chair*
INTEGRITY ASSURANCE | Ballroom B
Patrick Evrard, Cytiva, *Chair*
- 11:30 AM** **LUNCH BREAK – GROUP ON OWN**
- 1 – 2:30 PM** **CELL & GENE THERAPY** | Ballroom A
Brendan Lucey, Entegris, *Chair*
AUTOMATION | Ballroom B
Hernan Parma, RENOLIT Healthcare & **Stuart Tindal**,
Sartorius, *Co-Chairs*
- 2:30 – 4 PM** **X-RAY STERILIZATION** | Ballroom A
James Hathcock, Cytiva & **Samuel Dorey**, Sartorius,
Co-Chairs
CONTINUOUS BIOPROCESSING | Ballroom B
David Chau, 3M & **Davinder Chawla**, Sanofi, *Co-Chairs*
- 4 – 5:30 PM** **BPSA ANNUAL MEMBERSHIP MEETING (MEMBERS ONLY)** | Ballroom A
- 5:30 – 7 PM** **WELCOME RECEPTION** | Seasons Restaurant | Mezzanine Level
- GROUP ON OWN FOR DINNER**



AGENDA, CONTINUED

TUESDAY, JULY 11TH

- 8:30 AM – 5 PM** **SUMMIT REGISTRATION** | Ballroom Foyer - Events Level
- 8:30 AM – 5 PM** **ALL SESSIONS BALLROOM AND BALLROOM FOYER, EVENTS LEVEL**
- 8:30 AM** **BREAKFAST BUFFET**
- 9 – 9:15 AM** **CHAIRMAN'S WELCOME & OPENING REMARKS**
Mark Petrich, *Krystal Biotech, BPSA Chair*
- 9:15 – 10:15 AM** **OUTLOOK, TRENDS & FUTURE MARKETS FOR SINGLE-USE**
Eric Langer, *BioPlan Associates, Inc.*
Larry West, *Aspen Media Inc.*
- 10:15 – 11:15 AM** **PER- AND POLY-FLUOROALKYL SUBSTANCES (PFAS) -
A REGULATORY UPDATE**
Moderator: **Brian Chung**, *Solvay, BPSA Board Member*
Monica Cardona, *Millipore Sigma, BPSA Board Member*
Barbara Henry, *W.L. Gore*
Steve Risotto, *American Chemistry Council*
- 11:15 – 11:30 AM** **BREAK**
- 11:30 – NOON** **DEVELOPING BIOPROCESSING TALENT FOR THE FUTURE**
Ken Baker, *AdvantaPure/NewAge Industries*
- 12:00 – 12:30 PM** **2023 BPSA QUALITY TEST MATRICES**
Jim Vogel, *The BioProcess Institute*
- 12:30 – 2 PM** **NETWORKING LUNCHEON** | Ballroom B
- 2:00 – 2:45 PM** **THE DESIGN, CONTROL & MONITORING OF SUS FOR INTEGRITY ASSURANCE**
Moderator: **Patrick Evrard**, *Cytiva, BPSA Board Member & BPSA Integrity Assurance
Committee Chair*
Charlotte Masy, *GSK, BPSA Board Member & BPSA Integrity Assurance Committee
Member*
Scott Patterson, *ILC Dover, BPSA Board Member & BPSA Integrity Assurance
Committee Member*
Charlie Zhang, *Sanofi, BPSA Integrity Assurance Committee Member*

AGENDA, CONTINUED

TUESDAY, JULY 11TH, CONTINUED

- 2:45 – 3:30 PM** **SUSTAINABILITY & SUS: FROM VISION TO ACTION**
Magali Barbaroux, Sartorius, *BPSA Sustainability Committee Chair*
- 3:30 – 3:45 PM** **BREAK**
- 3:45 – 4:15 PM** **BARDA Q&A**
Joe Figlio, *Biomedical Advanced Research & Development Authority (BARDA), U.S. Department of Health & Human Services*
- 4:15 – 5:15 PM** **BPSA SUPPLY CHAIN PANEL DISCUSSION**
Moderator: David Radspinner, *VintaBio*
John Boehm, *CPC, BPSA Past Chair*
Joe Figlio, *Biomedical Advanced Research & Development Authority (BARDA), U.S. Department of Health & Human Services*
Dan Rosen, *Thermo Fisher Scientific, BPSA Board Member*
- 6 – 8 PM** **OFF-SITE NETWORKING RECEPTION** | Sequoia Restaurant on the Potomac
Georgetown Harbour, [3000 K Street NW, Washington, DC](#) (10-minute walk)

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WEDNESDAY, JULY 12TH

- 8:00 AM – 1 PM** **ALL SESSIONS BALLROOM AND BALLROOM FOYER, EVENTS LEVEL**
- 8 AM** **BREAKFAST BUFFET**
- 8:30 – 8:45 AM** **VICE CHAIRMAN'S WELCOME & OPENING REMARKS**
Todd Kapp, *Entegris, BPSA Vice Chair*

AGENDA, CONTINUED

WEDNESDAY, JULY 12TH, CONTINUED

- 8:45 – 9:45 AM** **AUTOMATION/CONTINUOUS BIOPROCESS MANUFACTURING SESSION**
Moderator: Hernan Parma, RENOLIT Healthcare, BPSA Board Member & BPSA Automation Committee Co-Chair
- DIGITIZATION & ITS POTENTIAL INFLUENCE IN BIOPROCESSING**
Sam Svitenko, ConSynSys Technologies, Inc.
Craig Vincze, Alphinity
- FUNDAMENTAL ROLE OF SINGLE-USE SENSORS IN INDUSTRY 4.0**
Nick Troise, PendoTECH
- ADVANCING FACILITY FLEXIBILITY THROUGH SINGLE-USE & AUTOMATION**
Matt Kessler, MSD Switzerland
- 9:45 – 10:30 AM** **PANEL DISCUSSIONS & PRESENTATION OF BPSA'S AUTOMATION COMMITTEE SURVEY**
- IDENTIFYING PAIN POINTS IN SU AUTOMATED MANUFACTURING**
Moderator: Hernan Parma, RENOLIT Healthcare
David Chau, 3M, BPSA Continuous BioProcessing Committee Co-Chair
Jeff Leverton, Wood PLC, BPSA Automation Committee Member
Nick Troise, PendoTECH, BPSA Automation Committee Member
Matt Kessler, MSD Switzerland
Sam Svitenko, ConSynSys Technologies, Inc.
- 10:30 – 10:45 AM** **BREAK AND HOTEL CHECK OUT**
- 10:45 – 11:15 AM** **DIGITILIZATION AND SINGLE-USE-AN END-USER'S PERSPECTIVE**
Charlotte Masy, GSK, BPSA Board Member
- 11:15 – 12:15 PM** **X-RAY STERILIZATION: BPSA UPDATE**
James Hathcock, Cytiva & Samuel Dorey, Sartorius, BPSA X-Ray Committee Co-Chairs
Tom Kroc, Fermi National Accelerator Laboratory
- 12:15 PM** **WRAP UP AND ADJOURNMENT**

**SAVE THE DATE: 2024 BPSA INTERNATIONAL SINGLE-USE SUMMIT
JULY 8-10, 2024, WASHINGTON, DC.**

SAVE THE DATE

2024 BPSA INTERNATIONAL SINGLE-USE SUMMIT

JULY 8-10, 2024 | WASHINGTON, DC

WWW.BPSALLIANCE.ORG

SPEAKERS



KEN BAKER | ADVANTAPURE/NEWAGE INDUSTRIES

Ken Baker is the CEO of NewAge Industries, a plastic, rubber, tubing, hose manufacturer and a RFID tag solutions provider located in Southampton, Pennsylvania and providing service to customers across the country and around the world.

A family-owned business that originated in 1954. Ken Baker joined the business in 1985, as the second generation of his family to carry on its successes of the family business. Since coming on board, Ken has taken NewAge Industries to new heights. The NewAge industries' AdvantaPure division produces platinum-cured silicone tubing, single use systems and more with a mission to become the premiere company for high purity tubing and other fluid flowing products used in the Pharmaceutical, Biomedical, Biopharmaceutical, and Food and Beverages industries globally. Ken Baker has been recognized as a leader in business and NewAge Industries has been a finalist of "Top Small Company Workplace" 2 years running and the winner of the Warton Family Business of the year award.

Committed to being a sustainable company, NewAge Industries has one of the largest solar arrays in Pennsylvania, being landfill free with an extensive recycling program. NewAge Industries was awarded the PennFuture Green Power award in 2011, being now 100% renewable energy company. NewAge is a certified B Corporation. In 2006, Ken established the company's Employee Stock Ownership Plan (ESOP), and its employees now own 100% of the company. Ken is a founding member and Chairman of the Pennsylvania Center for Employee Ownership (PCEO), an organization designed to raise awareness and increase the number of employee-owned companies in Pennsylvania. Ken is also a founding board member of the EOeX. Ken is committed to the success of ESOPs, and he spends time speaking about ESOPs to other CEOs at local and national events.



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 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.



JOHN BOEHM | CPC

John Boehm is the Vice President of Biopharma at CPC. He has over twenty years of experience with single-use technology including roles in new product development, commercial business development and corporate leadership. John has been active in numerous industry groups and workstreams, including being a past chair of BioProcessing Systems Alliance (BPSA). John has a bachelor's degree in mechanical engineering and a master's degree in business.



MONICA CARDONA | MILLIPORE SIGMA

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 Bachelors 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.



DAVID CHAU | 3M

David Chau is a Global Bioprocess Application Specialist in 3M's Separation and Purification Sciences Division. He has over fifteen years of research experience in the biotechnology industry where he earned his Ph.D at the University of Minnesota in Twin Cities and his B.S at the University of Texas.

Currently, he is responsible for developing product application and driving collaborations with key industry leaders around the globe. He drives technology transfers and multiple collaborations for different key accounts in the space of life science purification.



BRIAN CHUNG | SOLVAY

Brian has worked as a bench chemist, in marketing and product management. He is currently a Senior Key Account manager for Solvay. In his free time he likes to Rock climb and design campers.



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 end 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.



JOE FIGLIO | BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY (BARDA), U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Branch Chief, Pandemic Vaccine Preparedness Capabilities and Readiness BARDA
Pharmaceutical Countermeasures Infrastructure Division

Start Date: August 2009

Background/Areas of Expertise:

- BS in Commerce & Engineering Sciences, Drexel University in Philadelphia, PA.
- MBA in Production and Operating Systems, Drexel University in Philadelphia, PA.
- Branch Chief in the PCI Division of BARDA – Responsible for multiple Capacity Expansion projects initiated during the pandemic, including supply chain issues related to vaccine and therapeutic manufacturers. Key role in procurement/distribution of needles/syringes during the pandemic and building of domestic capacity for the future.
- Formerly Project Officer/COR for various infrastructure related contracts (totaling over \$1B), including the first US-licensed cell-based influenza facility in Holly Springs, NC and two of three CIADM contracts.
- 19 years Merck & Co., West Point, PA in Site Engineering Services, Pharmaceutical Planning & Logistics and Vaccine Operations. Positions held included mechanical support for existing vaccine manufacturing facilities for Recombivax, Mumpsvac and Pedvax, start-up team member for a multi-use, large scale bulk vaccine manufacturing facility. Five years at Merck as lead supervisor of the glassware and sterile supply area of a new bulk Rotavirus facility during the engineering lots and licensure.
- 2 years with Mitos Technologies, Inc., Phoenixville, PA as Operations Lead. Responsible for all clean room manufacturing, materials management and warehouse operations. Responsible for moving the facility to a new location including building a new 21,000 sq. ft. manufacturing clean room.



JAMES HATHCOCK | CYTIVA

Dr. James Hathcock is Senior Director of The Regulatory and Validation Consulting Team at Pall BioTech, which includes responsibility for the extractables and leachables characterization strategy to support the safe and successful end-user implementation of technologies enabling pharmaceutical manufacturing. He is an active member of ASTM, PDA, ISPE, and BPSA as well USP <665> panel volunteer. Since joining Pall in 2008, James has led chemical and performance characterization of Medical and BioTech components, as well as relevant technical packages supporting regulatory filings.



BARBARA HENRY | W.L. GORE

Dr. Henry has been a Toxicologist at W.L. Gore & Associates since 2008. Her toxicology experience includes the chemical, petrochemical and agricultural chemical industries (Chevron, PPG, Aventis and Bayer). Dr. Henry received her Ph.D. from the University of Pittsburgh. She has published several peer-reviewed papers, defended new and commercial products to global regulatory authorities, made presentations to many state and federal regulatory authorities including EPA's Scientific Advisory Board, the White House Science Advisor to President George W. Bush and Valentina Bertato of the EC Directorate General Environment. Dr. Henry has experience with numerous trade associations including the International Life Science Institute (ILSI), American National Standards Institute (ANSI), American Chemistry Council (ACC), American Petroleum Institute (API), National Paint & Coatings Association (NPCA), Association for Advancement of Medical Instrumentation (AAMI), and the Advanced Medical Technology Association (ADVAMED). She has been a member of the Society of Toxicology for over 25 years.



TODD KAPP | ENTEGRIS

Todd Kapp currently serves on the BPSA BOD as First Vice Chair. Prior to aiding as the marketing sponsor, Todd was Chairman of the BPSA Cell and Gene Therapy Committee. In total, Todd has been an active member of BPSA since 2006 when it was first allowed to have organizations other than single-use integrators involved. He has also served as Secretary on the Executive Board Committee, member of the Board of Directors and held the position of Marketing Committee Chairman, Election Committee Chair and helped co-chair the inaugural BPSA Summit. During the past decade and a half, Todd has been extremely influential in setting and implementing BPSA strategy to help get it to the point it is today. This has included participating in technical committees on the original quality matrix, sterility assurance, and updating the by-laws to remain relevant and grow as the organization has grown. He was also heavily involved in transitioning the organization from SPI to SOCMA.

Todd is the Global Commercial Development Director for Life Sciences at Entegris, Inc.



MATT KESSLER | MSD SWITZERLAND

Matt is a Senior Director within Process R&D and has been with MSD for over 20 years across roles in Clinical and Commercial Drug Substance and Drug Product production. Matt leads the overall BioNX Facility at MSD Dunboyne in Ireland and leads the Biologics Manufacturing Innovation organization across Switzerland and Ireland. He has previously implemented Drug Product production and Continuous Manufacturing at MSD Schachen in Switzerland. Matt holds a BSc and MSc of Chemical/BioChemical Engineering from Drexel and Villanova University.



TOM KROC | FERMI NATIONAL ACCELERATOR LABORATORY

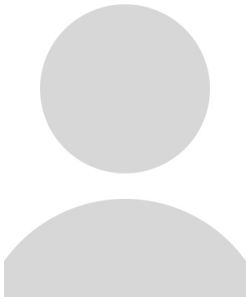
Dr. Thomas Kroc is an Applications Physicist III at the Fermi National Accelerator Laboratory (Fermilab). His present position at IARC at Fermilab emphasizes the application of new accelerators and accelerator technologies to medical applications, and in the present situation, medical device sterilization. This allows him to draw on his educational and professional experience in nuclear engineering, experimental high energy physics, accelerator physics, and medical physics.

He has led the organizing committee for five workshops on Medical Device Sterilization to promote the use of electron beams and x-rays held at Fermilab in 2019 through this year. He was the chair of a committee with the National Academies that published the report - Radioactive Sources: Applications and Alternative Technologies. He was the lead author of a white paper "Accelerator-driven Medical Sterilization to Replace Co-60 Sources" that was written for the NNSA in 2017. For 20 years he worked with the Neutron Therapy Facility at Fermilab which provided external beam radiation therapy for cancer using high-energy neutrons. He assumed leadership of this program from 2008 until its closure in 2013. His interests include development of accelerator technologies, applications of accelerators and accelerator technologies, medical device sterilization, radiation/matter interactions, and medical physics. Dr. Kroc holds a PhD in Physics (1989) from the University of Illinois at Urbana-Champaign. He earned his undergraduate degree in Engineering Physics (1981) from The Ohio State University.



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.



JEFF LEVERTON | WOOD PLC

Jeff Leverton has over 20 years of experience, much of that time with a focus on the topic of Automation. Jeff is currently at Wood as the Life Sciences Sector Lead, and was previously the Automation Manager in Commercial Gene Therapy at Pfizer and Automation Manager at GSK Vaccines.



CHARLOTTE MASY | GSK

Charlotte Masy is a BioEngineer with a PhD in surface chemistry and a postgraduate study in big data and analytics. She has 20 years of experience in cGMP working on materials, investigation, and improvement of process. Currently, she has a position of Senior manager at GSK and is recognized as Fellow in Single Use Technology, integrity tests and data analytics.



HERNAN PARMA | RENOLIT

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.



SCOTT PATTERSON | ILC DOVER

Scott Patterson has been active in a range of processing technologies for over 40 years with the past 25 years specializing in pharmaceutical and biopharmaceutical processing. As a Vice President and Technical Leader with ILC Dover, Scott has specifically focused on technology and expanding the use of single-use systems that are applied for high containment when handling potent compounds or solving large molecule upstream processing challenges. Scott's academic discipline at Youngstown State University in Mechanical Engineering Technology was done in conjunction with technical positions to develop plastics extrusion systems with OEM suppliers. Scott continues the work in applying single-use systems in PharmBio processes advocating the value proposition and sustainability when compared to competing technology. Scott has also participated in multiple industry advocacy organizations including participating in two BPSA committees.



MARK PETRICH | KRYSTAL BIOTECH

Mark A. Petrich is Vice President, Process Development and Validation at Krystal Biotech, Inc. and serves as Chair of the BPSA Board of Directors. Mark's activities in BPSA include over ten years of board and executive board service, End User Committee chair, initiation of the Sustainability Committee, co-authorship of 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 BPSA events and gave the keynote address at the first European Summit (Barcelona 2016).



DAVID RADSPINNER | VINTABIO

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 than fifteen years in Life Science business roles. David holds a PhD in Analytical Chemistry from the University of Arizona.



DAN ROSEN | THERMO FISHER SCIENTIFIC

Thermo Fisher 2017 – present

- Vice President / General Manager, BioProduction Single-Use Technologies (South Jordan, Utah)
- Sr. Director / General Manager, BioProduction Biologicals and Chemicals (Hunt Valley, MD)
- Sr. Director, Integration Management (Waltham, MA)
- Director, Strategy and Corporate Development (Waltham, MA)

Education:

- Dartmouth College MBA – 2016,
- Brown University BA – 2010



SAM SVITENKO | CONSYNSYS

Sam is currently the co-founder and Chief Operating Officer of ConSynSys Technologies, Inc. He has been building and leading global sales, business development, and partner technical and sales development programs for some of the largest technology firms in the world for the past 23 years. He has been both a leader and executive for Amazon Web Services, Palo Alto Networks, Nimble Storage (acquired by HPE), Cisco, McAfee, Platform Computing (acquired by IBM), and Legato Systems (acquired by EMC). In addition, Sam is a retired US Air Force Lieutenant Colonel, a former Lockheed C-5 Galaxy instructor pilot, and a former squadron commander. Finally, Sam is passionate about flying a Pilatus PC-12 NGX for business, and growing and leading teams of diverse talent to pursue the goal of Abundance in Medicine.



NICK TROISE | PENDOTECH

Nick Troise is R&D Engineer from PendoTECH. He has been at PendoTECH since 2017, when he started as an Intern while studying Biomedical Engineering at Rowan University in New Jersey. Nick is an active member of a few BPSA committees, including the groups for X-ray Irradiation and the Quality Test Matrix Update.



CRAIG VINCZE | ALPHINITY

Ph.D. in biomedical engineering – 20 years experience building and leading high-performance engineering, sales, and marketing teams. Expertise in custom solutions engineering, automated liquid handling, biomanufacturing equipment sales and marketing. Passionate about providing innovative drug, cell and gene therapy manufacturing equipment and software to biotechnology, pharmaceutical, and cell and gene therapy companies. President of the Max Vincze Foundation: Funding research to develop treatments for rare young adult cancers – delivering on the promise of modern medicine.



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.



LARRY WEST | ASPEN MEDIA INC

Larry West is the CEO of Aspen Media and Publisher of the Aspen Alert. The Aspen Alert, introduced in 2007, is a digital newsletter distributed daily to an opt-in audience of 50,000+ subscribing biotechnology and bioprocessing professionals. Prior to founding Aspen, he co-founded Finesse Solutions, which was later sold to Thermo Fisher. He has more than 25 years of experience specific to bioprocessing and been awarded ten patents on bioprocess management and control.



CHARLIE ZHANG | SANOFI

Charlie (Changhong) Zhang, Ph.D. is currently serving as Associate Director in MS&T department at Sanofi Bio-campus at Framingham MA site. Zhang has a PhD degree in Bioengineering from Clemson University, and have been working in life science and chemistry fields for over twenty years.

Zhang has supported and led several heavily invested projects in Sanofi for design, qualification, and validation of over two hundred single use assemblies/systems for pharmaceutical production. I have served as co-author for the 2023 publication of BPSA “Design, Control & Monitoring of SUS for Integrity Assurance, Volume 2”.

THANK YOU FOR ATTENDING BPSA'S 10TH INTERNATIONAL SINGLE-USE SUMMIT!



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.

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