THE BIO-PROCESS SYSTEMS ALLIANCE

INTERNATIONAL SINGLE-USE SUMMIT

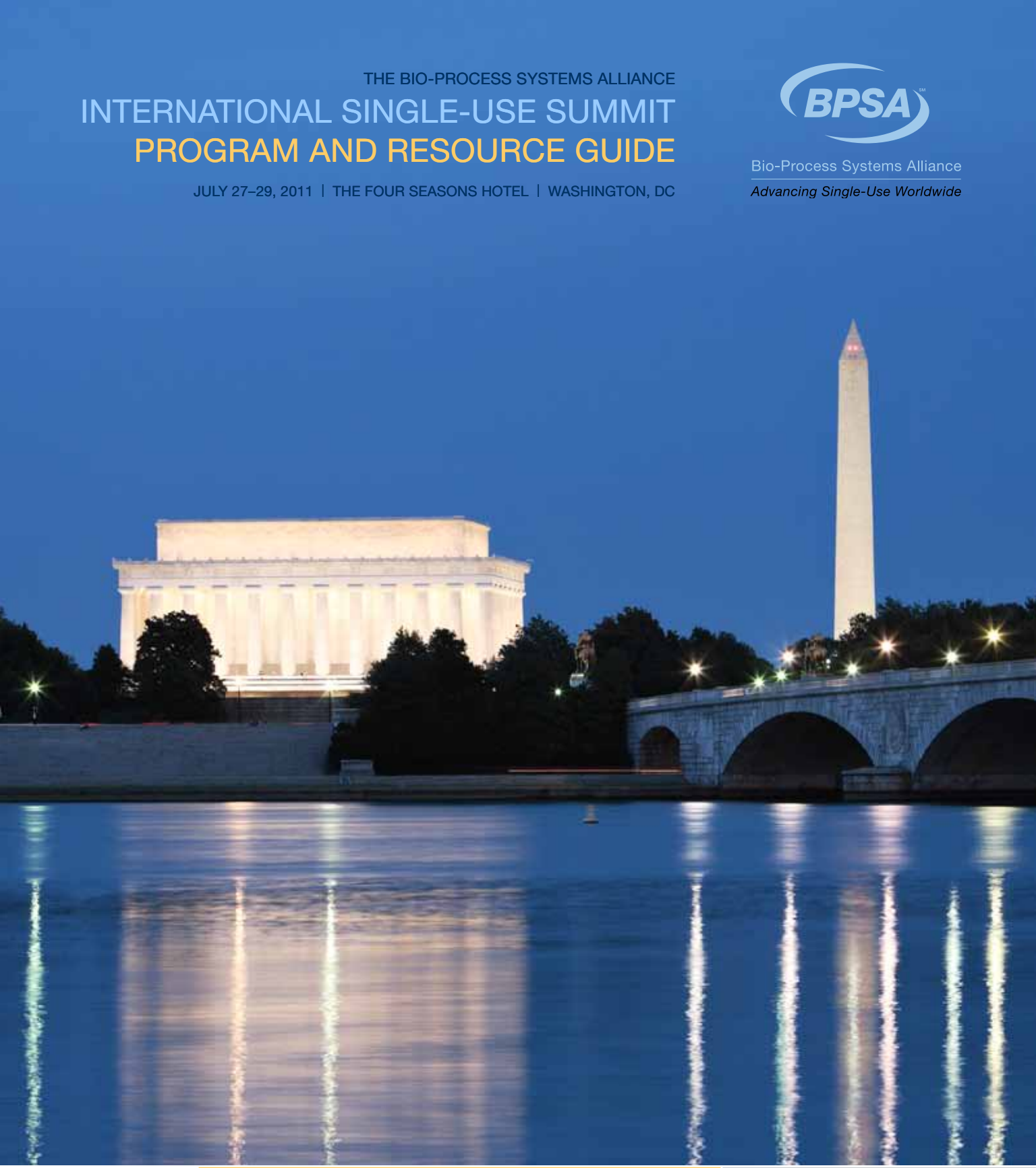
PROGRAM AND RESOURCE GUIDE

JULY 27–29, 2011 | THE FOUR SEASONS HOTEL | WASHINGTON, DC

BPSA℠

Bio-Process Systems Alliance

Advancing Single-Use Worldwide



PLATINUM SPONSOR

ThermoFisher SCIENTIFIC

GOLD SPONSORS

ATMI

EMD MILLIPORE

RENOLIT

PALL Life Sciences

SILVER SPONSORS

BOSCH

DOW CORNING

SPONSORED BY

ThermoFisher SCIENTIFIC

ATMI

EMD MILLIPORE

RENOLIT

PALL Life Sciences

BOSCH

DOW CORNING

ARKEMA

VALUE PLASTICS, INC.
SPECIALISTS IN FLUID CONNECTIONS

MEDIA SPONSOR

BioProcess INTERNATIONAL

BPSA SUMMIT AGENDA COMMITTEE

A summit of this caliber cannot possibly be designed without the support of our generous sponsors and the efforts of the Summit Program Committee member volunteers. Their support and generous time commitment contributed enormously to this endeavor.

Jeff Craig, Co-Chairman
ATMI

Todd Kapp, Co-Chairman
American Renolit

Denise DeTommaso, Speaker Liaison
Atoll-Bio

Jessica Frantz, Speaker Liaison
Bosch

Ken Baker
New Age Industries

Suraj Baloda
Ben Venue

John Boehm
Colder Products Company

Jeff Chase
SaniSure

Ken Davis
Value Plastics

Gary Dennis
Arkema

Mani Krishnan
EMD Millipore

Brian Lee
PBS Biotech

Jerold Martin
Pall Corporation

David Radspinner
Thermo Fisher

Bill Whitford
Thermo Fisher

Steve Wilkowski
Dow Corning

Yanli Zhang
Dow Corning

BPSA has made a donation to the American Chemical Society's ACS Awards scholarship program on behalf of the Summit Agenda Committee as a thank you for their time and effort. The ACS scholarship program offers renewable scholarships to underrepresented minority students who are pursuing a college degree in the chemical sciences or chemical technology fields.

WELCOME

Wireless Internet Access is sponsored by Thermo Fisher Scientific. The pass code for access is **935871**.

ThermoFisher SCIENTIFIC

Dear Attendees:

Welcome to Washington, DC and the BPSA International Single-Use Summit (ISUS).

On behalf of the entire BPSA Executive Committee, we thank you for your commitment to our industry, and for your decision to take part in our first BPSA ISUS event.

BPSA is the one trade association dedicated exclusively to the single-use biopharmaceutical manufacturing industry. We represent both suppliers and users of single-use technology. BPSA was formed in 2006 in response to the increasing demands for technical information, strategies for implementation and the need for a business network surrounding the Single-Use industry. In other words, a business forum for the entire value chain.

Now, a mere 5 years after our formation, we are hosting the first of what we hope will become annual industry networking events in the heart of the nation's capital, Washington, DC. Your participation in this first meeting is very important to us. We have designed this conference a bit differently from others…in addition to presenting issues and providing topical overviews, we have also sought to create opportunities for you to share your thoughts, ideas and concerns in networking sessions. We are looking forward to those productive conversations. We also invite you to provide feedback after the event via our electronic survey, and to share your thoughts, opinions, and constructive inputs to BPSA via our Board Members or our staff during the conference.

This year is special for BPSA – we have grown as a trade group to an all-time high corporate membership level; we have published important technical guides; and, we have launched additional services to our members via our website and our planning and execution of ISUS. Most importantly, though, we are establishing ourselves as a "go-to" resource on single-use, as we all witness its continued aggressive adoption in both biotech and biopharma, from feed to harvest to formulation and fill. The depth of our ISUS program, the quality of the speakers, presentations and topics, the diversity of our audience, speak to the growth and development of BPSA as a trade association that fulfills the business information and networking needs of our growing industry.

We extend our appreciation to all of you, and especially to our event sponsors and our Summit Planning Committee, who worked diligently to put together a business program that is informative, entertaining, and unique. We hope you will take advantage of all that BPSA, ISUS, and the city of Washington have to offer you over the next three days. Thank you for your support.

Jerry Martin
Senior V.P., Global Scientific Affairs
Pall Life Sciences
Chairman of the Board
Bio-Process Systems Alliance (BPSA)

Kevin Ott

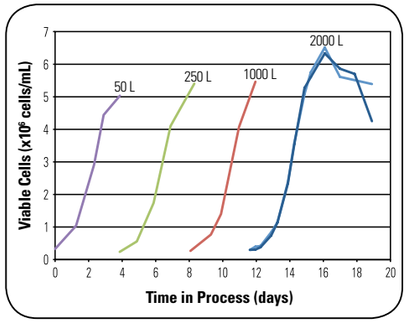
Kevin D. Ott
Executive Director
Bio-Process Systems Alliance (BPSA)
Washington, DC

Since its introduction, the Thermo Scientific HyClone Single-Use Bioreactor (S.U.B.) has become the leading disposable system for cell culture-based bioprocessing, with hundreds of active installations around the world.

HyClone S.U.B. Advantages:

- Industry-tested stirred-tank design
- Qualified animal component free CX5-14 film
- Scalability from 25-2000 L
- Decades of experience optimizing cell culture performance
- System-tested in various bioprocessing configurations
- Fully customizable to your production systems
- Ability to select from a variety of controllers

Visit us at www.thermoscientific.com/hyclone or contact us at 1-800-492-5663 to discuss your single-use bioprocessing needs.



Batch Runs of CHO Cells

CHO cell growth during scale-up and production stage in Thermo Scientific HyClone Single-Use Bioreactors (S.U.B.s) of 50, 250, 1000 and 2000 L volumes.

Moving science forward

Thermo SCIENTIFIC

Part of Thermo Fisher Scientific

BPSA EXECUTIVE BOARD OF DIRECTORS

Jerold Martin, Chairman
Pall Life Sciences, div. Pall Corporation

John Boehm, Vice Chairman/Education Committee Chairman
Colder Products Company

Kenneth L. Bibbo, Treasurer
HyNetics Corporation

Suraj Baloda, End User Committee Chairman
Ben Venue Laboratories, Inc.

Jeffery Lee Craig
ATMI LifeSciences

Kenneth R. Davis
Value Plastics, Inc.

Todd E. Kapp Chairman, Marketing Committee Chairman
American RENOLIT Corporation LA

Mani Krishnan
EMD Millipore

Paul Priebe
Sartorius Stedim

David Radspinner, Ph.D.
Thermo Fisher Scientific, Inc.

Gregory S. Tronto, Membership Committee Chairman
W.L. Gore & Associates, Inc.

Yanli Zhang, Program Committee Chairman
Dow Corning Corporation

Expect a higher level of

service

for validated single-use process solutions

Pall delivers a complete package of single-use customer support

The Allegro™ system platform from Pall is a comprehensive program providing processing solutions, technical support, and validation for single-use systems. The Allegro system platform services all applications from upstream through downstream to formulation and filling.

Our Flexible Solutions approach includes Flexible Support... as Pall's Scientific and Laboratory Services can assist you through the validation studies, regulatory compliance, and Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) processes, to help get your single-use systems operating as quickly as possible. And you can count on our ongoing support to help keep them operating as efficiently as possible. Pall's made-to-order process solutions include:

- Systems validation
- Components validation
- Consultancy services
- Engineering services
- UpScale℠ program
- After-sales support

Put Pall's "global expertise...delivered" to work in your operations today.

Pall Scientific and Laboratory Services assist in the implementation of Allegro single-use processing solutions from drug development to manufacturing.

w: **www.pall.com/allegro**
e: allegro@pall.com

PALL® Life Sciences

Providing Flexible Solutions

EMD MILLIPORE

Your discovery.
Our solutions.
Breakthrough Life Science.

The path from discovery to commercial production is loaded with challenges and opportunities. Which is why having the right Life Science collaboration partner is critical for success. The combined synergies of EMD Millipore can help – with state-of-the-art products and deep know-how – to accelerate your next discovery out of the lab and into the market place. Find out how at www.emdmillipore.com.

EMD Millipore is a division of Merck KGaA, Darmstadt, Germany

BPSA SUMMIT AGENDA

WED | 27

Noon – 6:00 PM — **Summit Registration** | Seasons Foyer, Mezzanine Level

4:00 – 5:30 PM — **BPSA Annual Membership Meeting and End-User Members Forum**
Douglass Room, Meeting Room Level | BPSA members only

6:00 – 7:30 PM — **Summit Welcoming Reception** | Seasons Restaurant, Mezzanine Level

THU | 28

8:00 AM – 5:00 PM — **Summit Registration** | Corcoran Ballroom Foyer, Meeting Room Level

All General Sessions | Corcoran Ballroom, Salon A, Meeting Room Level

8:30 – 9:30 AM — **Continental Breakfast/Opening Keynote**
The Bio-Pharma Supply Chain in 2020: A Critical Lever for Value Creation
Wynn Bailey, Pricewaterhouse Coopers

9:30 – 10:15 AM — Drug Manufacturing in a New Era of Safety
Claudia A. Lewis-Eng, Partner, Venable LLP

10:15 – 10:30 AM — BREAK | Sponsored by Value Plastics, Inc.

10:30 – 11:15 AM — Global Regulatory Scheme and the Adoption of Single-Use Technologies
David Doleski, Consumer Safety Officer, Division of Manufacturing and Product Quality (DMPQ), US FDA

11:15 – Noon — Universal Acceptance and Adoption of Disposable Processing Systems
Sarfaraz K. Niazi, Ph.D., Executive Chairman, Therapeutic Proteins Inc., and President, Pharmaceutical Scientist Inc., Chicago, Illinois

Noon – 1:15 PM — **Luncheon Keynote** | Corcoran Ballroom, Salon B, Meeting Room Level
The Politics of the Ongoing Health Care and Budget Debates 2012
Jonathan Karl, Senior Political Correspondent, ABC News

1:30 – 5:00 PM — **GLOBAL END USERS FORUM: CRITICAL INNOVATIONS AND MARKET DRIVERS TO SINGLE-USE TECHNOLOGIES (SUTS)**
Corcoran Ballroom, Salon A, Meeting Room Level

Personalized Medicines
Michael Ramsay, M.D., President, Baylor University Research Institute

Monoclonal Antibodies and Single-Use Technologies
Brad Wolk, Biopharmaceutical Industry Consultant, Wolk Engineering

Single-Use Technologies for Stem Cell Therapies
Eric Halioua, Chief Executive Officer, Promethera Biosciences

3:00 – 3:15 PM — BREAK | Sponsored by Value Plastics, Inc.

Wireless Internet Access is sponsored by Thermo Fisher Scientific. The pass code for access is **935871**.

ThermoFisher SCIENTIFIC

THU | 28

1:30 – 5:00 PM *continued*

Demands of Biomanufacturing Toward Countermeasure or Pandemic Response and Potential Links to Disposable (Single-Use) Biomanufacturing Systems
Michael P. Angelastro, Project Officer, Biomedical Advanced Research & Development Authority (BARDA)

A Contract Manufacturer's Perspective on the Adaptation (Adoption) of Disposable Manufacturing Technologies: Potential Opportunities, Challenges, Roadblocks
Suraj Baloda, Ph.D., Director, QC Microbiology & Environmental Control, Ben Venue Laboratories, Inc.-U.S.

The Implementation of Single-Use Technologies in China and the Future of Chinese Biomanufacturing
Lei Sun, Ph.D., President, Manufacture, AutekBio, Inc., Beijing, China

6:00 – 9:00 PM — **Networking Dinner Cruise on the Potomac River**
Historic Washington, DC By Night | *See page 21*

FRI | 29

8:30 – 11:00 AM — **Continental Breakfast/Panel Discussion on Single-Use Technologies** | Corcoran Ballroom, Salon A, Meeting Room Level

Qualification/Validation/Best Practices for SUTs (the BPSA Guides)
Jerold Martin, Sr. V.P., Global Scientific Affairs, Pall Life Sciences

Economics of Single Use Technologies
Todd Kapp, Business Development Manager, American RENOLIT Corporation LA

Shared Single-Use Disposables Document Directory
Ken Baker, CEO, New Age Industries/Advantapure

Regulation and Risk Mitigation
David Radspinner, Director, Global Sales, Thermo-Fisher Scientific, Inc.

End-of-Life and Disposal Issues and Challenges
John Boehm, Bioprocessing Business Unit Manager, Colder Products Company and Mani Krishnan, Director, Single-use Processing Systems, EMD Millipore

The Future of Single-Use Technologies
Eric S. Langer, Managing Partner, BioPlan Associates, Inc.

11:00 – 11:45 AM — Creating Ready to Supply Facilities
Steve Attig, Associate Sr. Process Engineer, CRB Consulting Engineers

Noon — **Adjournment**

Steve Attig, Associate Sr. Process Engineer, CRB Consulting Engineers
Steve Attig is an Associate and Senior Process Engineer for CRB Consulting Engineers and has 14 years experience in the pharmaceutical and biotechnology sectors. CRB specializes in consulting, conceptual engineering, detailed design, construction and startup services for high tech industries with 85 percent of their business focused on Life Sciences. At CRB, Steve has been responsible for all phases of engineering design as a Discipline Lead and has experience with large-scale mammalian cell culture, aerobic and anaerobic bacterial fermentation and downstream processing and purification. Steve has worked on numerous projects involving implementation of single-use technologies in both FDA and EU licensed facilities. Prior to his work at CRB, Steve worked in operations for Amgen, CSL and Lyondell Basel in various process engineering roles including project management, process and production engineering. Steve received his B.S. degree in Chemical Engineering from the University of Illinois.

Michael P. Angelastro, Project Officer, Biomedical Advanced Research & Development Authority (BARDA)
Mike Angelastro is a Project Officer for the Manufacturing, Facilities & Engineering (MFE) Division under the Biomedical Advancement Research Development Authority (BARDA) reporting through the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). Mike joined BARDA in October 2007 supporting advanced process development and capacity building contracts within the Pandemic Influenza Program. As a Project Officer, Mike monitors and reviews infrastructure related contracts that will support domestic vaccine or other biopharmaceutical medical countermeasure manufacturing in the event of a public health emergency. These contacts are secured with multiple manufacturers that have deliverables that span several years.

Mike received his BS in Chemical Engineering from Drexel University in Philadelphia, PA and worked for Merck & Co., Inc. for over 8 years as a Senior Engineer in Vial Vaccine Technology and Engineering. He served as direct facility and process support for several viral vaccines including; Measles, Mumps, Rubella, Rotavirus, Varicella at the bulk manufacturing, sterile filling, packaging, and QC testing stages at the West Point, PA plant site. Mike's project management experience and collaborative style allowed him to be the lead engineer on several major process and equipment related issues throughout the vaccine manufacturing area. Mike served as a key contributor during scope development and execution of significant process upgrade projects as well as new facility construction & in-place renovation activities. He also served as the lead downstream support engineer for Rotavirus bulk manufacturing, lead mechanical services engineer for the Varicella franchise, and lead coordinator of improvement efforts for preventive maintenance procedures used by vaccine manufacturing facilities at the West Point site.

Mike is an active member of the ISPE, ASME, PDA, and AIChE.

Wynn Bailey, Pricewaterhouse Coopers
Wynn is a Partner in the Pharmaceuticals & Life Sciences Advisory practice of Pricewaterhouse Coopers, based in Chicago, and leads the firm's Operations and Supply Chain practice for Life Sciences clients. He has more than 20 years' experience consulting to top management and board-level clients across all sectors of the health industry including government, payer, provider, bio-pharma, medical technology, channel partners, service providers and investors. Wynn's work in operations includes strategy and performance improvement initiatives covering the entire operations value stream: planning, procurement, manufacturing, distribution, and customer service. His clients include large global companies as well as small and mid-sized companies, in initiatives ranging from operations strategy, network design, performance improvement, and merger/integration planning and execution. Prior to joining PwC, Wynn led the US Healthcare & Life Sciences practice of A.T. Kearney. His earlier career includes time with the US Senate Special Committee on Aging, ICF Incorporated (healthcare public policy analysis), and APM Incorporated (strategic and operational consulting to hospitals and health systems).

Ken Baker, CEO, New Age Industries/Advantapure
Ken Baker has over 25 years of experience in the plastic tubing and hose industry. His father, Raymond Baker, started NewAge® Industries, Inc. in 1954, and Ken joined the company in 1985. Under Ken's nurturing, NewAge has become one-third employee owned (ESOP) and has twice been recognized as a finalist in Winning Workplaces' Top Small Company Workplaces. In 2001, Ken led the company in the launch of its AdvantaPure® sanitary products division, and this continues to be his primary focus. He is a co-inventor on three patents in RFID tagging technology and a co-founder in the RFID in Healthcare Consortium. Ken is also an active member in ISPE's Community of Practice (COP) on Disposables, member of PDA and NewAge AdvantaPure is a member of BPSA. He invites area high school students to intern at NewAge Industries each summer and is a generous contributor to local and national charities. Ken may be reached at kbaker@advantapure.com or 215.526.2151.

Suraj Baloda, Ph.D., Director, QC Microbiology & Environmental Control, Ben Venue Laboratories, Inc. – U.S.
Dr. Baloda is a leading expert in Microbiology with more than 30 years of experience of managing multinational/multicultural teams of pharmaceutical professionals, cross-functional teams of laboratory scientists and staff from 15 different countries in 3 continents. He is presently Director of QC Microbiology & Environmental Control at Ben Venue Laboratories, Inc., in Ohio.

Ben Venue Laboratories, Inc. develops and manufactures liquid and lyophilized sterile products under contract to its customers, employing Single-Use Systems in its manufacturing processes. It is one of the oldest, largest and most experienced contract manufacturer of lyophilized products in the United States.

Dr. Baloda holds a Ph.D. in Microbiology from Swedish University of Agricultural Sciences in Uppsala, Sweden.

John Boehm, Bioprocessing Business Unit Manager, Colder Products Company
John Boehm is responsible for Colder Products Company's bioprocessing business. John joined Colder Products Company in 2001 and has held leadership positions in engineering, marketing, and business development. John has a B.S. in mechanical engineering and an MBA. John is the vice chair of the BioProcess System Alliance (BPSA).

David Doleski, Consumer Safety Officer, Division of Manufacturing and Product Quality (DMPQ), US FDA
Mr. Doleski is currently an Acting Branch Chief in CDER's Office of Compliance. He leads a branch that: participates in the review and inspection of NDAs and ANDAs; serves as a liaison between the FDA District Offices and the CDER Review Divisions; and, reviews District Office recommendations for drug pre-approval inspections. Mr. Doleski actively participates in various groups that develop policy and guidance involving drug cGMPs.

Mr. Doleski has had a 20 year career with FDA, and previously held positions in CBER and the Office of the Commissioner. During his nine years in CBER, he held positions of increasing technical and management responsibility involving a branch that performs reviews of BLAs and inspections of biologic manufacturing facilities.

Mr. Doleski received his B.S. degree in Biology from Cornell University and a second B.S. degree in Computer Information Systems from University of Maryland University College. Currently, he is pursuing a M.S. degree in Systems Engineering at Johns Hopkins University.

Eric Halioua, MBA: Chief Executive Officer of Promethera Biosciences
Eric Halioua is the CEO of the Belgian Biotechnology company Promethera Biosciences. Promethera® Biosciences' mission is to discover, develop and commercialize cell therapy products to treat liver diseases in an innovative way using stem cell from healthy human livers.
Eric is co-founder of two biotechnology companies called Myosix and Murigenetics.
Myosix is a tissue engineering company specializing in musculoskeletal cells culture used in the regeneration of the heart muscle. The company has signed a strategic partnership with Genzyme mid-2002 to finance the phase 2 of clinical trial.

Murigenetics is a Biotechnology company developing therapies for genetic disorders.
Eric was also a Board Member of a French public biotechnology company called Vivalis, which specializes in the production of avian stem cells lines for the production of vaccines and recombinant proteins.

Eric was as well principal of the international life sciences practice of Arthur D. Little based in Paris and Boston during 11 years. He has led and conducted work in the areas of strategy, M&A and technology & innovation management for biotechnology, pharmaceutical and medical devices companies. Eric also worked as a strategic marketing manager for the "Centre Européen de Bioprospective" and as project leader in the corporate R&D centre of Zeneca in UK.
Eric holds two master degrees (DEA and Magistère) in Pharmacology and Molecular Biology and a MBA from ESSEC business school (Paris, France), with an advanced degree from the Health Care ESSEC chair.

Jonathan Karl, Senior Political Correspondent, ABC News
Jonathan Karl was named ABC News' Senior Political Correspondent in September 2010, broadening his role in ABC News political coverage. In this role, he is responsible for covering national political news, including presidential politics and Congress, for all ABC News broadcasts and platforms including "World News," "Good Morning America," "Nightline," "This Week with Christiane Amanpour" and ABCNews.com.

Karl joined ABC News in January 2003 as the network's Senior Foreign Affairs correspondent covering the State Department. He traveled around the world with Secretaries of State Colin Powell and Condoleezza Rice. In 2004, Jon Karl spent several months on the campaign trail covering the Bush-Cheney campaign and he also co-anchored election night coverage on ABC News Now – anchoring for more than 14 straight hours.

In December 2005 Jonathan Karl was named Senior National Security Correspondent. He has traveled the world for ABC News, reporting from more than two dozen countries on five continents. Karl reported more extensively on the situation in Darfur, Sudan than any other network correspondent, visiting Sudan three times in 2005. He also broke several stories on Iran's nuclear program and covered the 2004 Presidential elections in Russia.

Before joining ABC News, Mr. Karl served as a congressional correspondent for CNN. In his eight years with CNN, he covered Capitol Hill, the White House, and the Pentagon. While there, he reported on two presidential elections, President Clinton's impeachment, the NATO air strikes against Yugoslavia, and congressional reaction to the September 11, 2001 terrorist attacks.

He graduated Phi Beta Kappa from Vassar College in Poughkeepsie, N.Y., in 1990, where he was editor in chief of "The Vassar Spectator."

Mani Krishnan, Director, Single-use Processing Systems, EMD Millipore
Mani has been with the company for over 17 years and has held various positions of increasing responsibility in process development, R&D and in marketing.

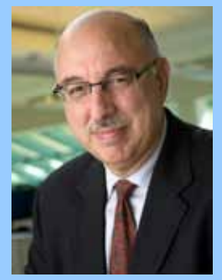
Mani has a Masters' degree in Chemical Engineering. He holds two patents and has published journal articles and text book chapters on topics such as virus filtration, protein concentration/ diafiltration, single-use processing and integrity testing. He is a member of various professional organizations such as PDA, ISPE, BPSA, etc.

Eric S. Langer, Managing Partner, BioPlan Associates, Inc.
Eric Langer has over 20 years experience in biotechnology and life sciences international marketing, management, market assessment, and publishing. He has held senior management and marketing positions at biopharmaceutical supply companies. He is an experienced biotechnology strategist, marketing practitioner, publisher, and researcher. 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 Biopharmaceutical Manufacturing, Biopharmaceuticals in the US Market, cell culture reports, media, sera, tissue engineering, stem cells, diagnostic products, blood products, genetics, DNA/PCR purification, blood components, and many others. He lectures extensively on pricing and channel management topics, and teaches at Johns Hopkins University and American University: Biotechnology Marketing, Marketing Management, Services Marketing, Advertising Strategy, and Bioscience Communication. He has developed numerous courses, classes and seminar programs, including Marketing in a Regulated Environment, Marketing Technical Products, and TechniManagement.™ In 1989 he co-founded BioPlan Associates, Inc. a biotechnology and life sciences marketing company that provides information, market research, pricing, and market analysis to biotechnology and healthcare organizations. He has launched and managed marketing programs for product lines ranging from $500k to $500 million. His company works with both large and small clients at commercial biotechs, non-profit organizations, and governments in assessing and evaluating markets, and marketing strategies and tactics.

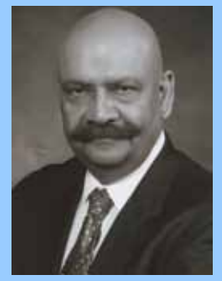
Claudia A. Lewis-Eng, Partner, Venable LLP
Ms. Lewis-Eng represents numerous clients in the areas of FDA regulations governing foods, dietary supplements, over-the-counter drugs, homeopathic preparations, medical foods, medical devices and importation/exportation of FDA regulated goods; FTC regulations governing advertising appearing on the Internet, television, print media and radio; FTC telemarketing regulations; USDA regulations governing the use of the term “organic”; and EPA regulations governing pesticides. Ms. Lewis-Eng also represents scientists, physicians, nutritionists, health care associations, and citizens groups. Furthermore, she has a number of international clients who she has assisted in establishing a U.S. market for their products.

Ms. Lewis-Eng has also appeared and prepared constitutional and administrative law cases before the Food and Drug Administration, the Federal Trade Commission, the Department of Justice, the Bureau of Land Management, and the Environmental Protection Agency.

Ms. Lewis-Eng has been recognized as one of the premier attorneys on dietary supplement label and labeling regulations and has handled complex civil matters from the administrative complaint stage to the Court of Appeals. Her experience in these fields has been in various radio talk shows, where Ms. Lewis-Eng was asked to discuss issues ranging from the impact of *Pearson v. Shalala* (labeling standards for disease or health-related claims of dietary supplements), FTC advertising regulations, and Senate Bill 722 (increased regulatory oversight of dietary supplements) to the proposed cGMPs (industry-wide labeling and manufacturing standards for dietary supplements). She has also been quoted in the *Vegetarian Times, Natural Pharmacy* and the *Tan Sheets*.



Jerold Martin, Sr. V.P., Global Scientific Affairs, Pall Life Sciences
Jerry Martin is Sr. Vice President, Global Scientific Affairs for Pall Life Sciences. He has over 32 years experience in the biopharmaceutical industry and is a frequent speaker and author on filtration, single use manufacturing and aseptic processing topics, including co-authorship of numerous PDA Technical Reports, BPSA Guides and ASTM, ISO and ASME-BPE Standards. He serves on Advisory Boards for BPSA, IBC, PDA and several publications including American Pharmaceutical Review, Pharmaceutical Technology Europe and Genetic Engineering News. He holds an M. Sc. in Microbiology from the University of Toronto.



Sarfaraz K. Niazi, Ph.D., Executive Chairman, Therapeutic Proteins Inc., and President, Pharmaceutical Scientist Inc., Chicago, Illinois
Sarfaraz K. Niazi holds a Ph.D. degree in pharmaceutical sciences and was a tenured professor at the University of Illinois; he has served as Technical Director of Abbott Laboratories and was a Volwiler Fellow; he is currently an adjunct professor at Houston University; Executive Chairman of Therapeutic Proteins Inc., an innovative biological products manufacturing company; and heads the consulting company Pharmaceutical Sciences whose services include turnkey pharmaceutical and biotechnology manufacturing facilities, technology transfer, and patent law. Dr. Niazi has published over 100 research articles, over two dozen major textbooks and handbooks in the field of pharmaceuticals and biotechnology, leads the industry in establishing fully-disposable systems for high-volume biotechnology products manufacturing, and has established the world’s first model disposable facility developed in consultation with the US FDA to meet the future requirements of manufacturing.

David Radspinner, Global Sales Director, BioProcessing, Biosciences Division, Thermo Fisher Scientific
David is the Global Sales Director for Thermo Fisher Scientifics’ Cell Culture and BioProcessing business, Logan, Utah. Previous to this, David spent 13 years developing, manufacturing and characterizing pharmaceuticals for other companies. David holds a Ph.D. in Analytical Chemistry, University of Arizona.

Michael A.E. Ramsay, MD, FRCA, President of Baylor Research Institute
Michael A. E. Ramsay, MD, FRCA, President of Baylor Research Institute (BRI), leads clinically relevant research efforts for Baylor Health Care System (BHCS). Since joining the organization, Dr. Ramsay has developed a successful infrastructure that has increased the number of clinical trials from 250 to more than 800 active trials today. The mission for BRI is expressed in the following statement, "To improve the medical care and well-being of our community – nationally and internationally – through innovative, clinical research that is consistent with the mission, vision and values of BHCS."

Dr. Ramsay has supported and led Baylor Research Institute's investigators in obtaining funding that includes more than $100 million in National Institutes of Health (NIH) grants. To strengthen the position of the institute – and to accelerate the research process – Dr. Ramsay also has developed strategic alliances where a "win-win" agreement can be constructed. For instance, he established collaborative agreements with Mount Sinai Medical School for the further development of cancer vaccines and Benaroya Research Institute for enhancing biomarker and genomic platforms. He also signed a collaborative agreement between Baylor Institute for Immunology Research and the French National Research Institute INSERM to develop vaccine therapies for infectious diseases. That agreement has now resulted in the joint development of a Center for Vaccine Therapy in Paris with ANRS, Baylor Research Institute and a major pharmaceutical company.

Dr. Ramsay also serves as a member of the Baylor University Medical Center Board of Trustees and is the immediate past president of the International Liver Transplantation Society. In addition, Dr. Ramsay is the developer of the Ramsay Sedation Scale, a measurement designed for interpreting the depth of sedation for patients in the critical care unit that has been adopted around the world.

He is currently involved in a number of clinical research projects for which he is the principal investigator. His current research includes the role of nitric oxide in cardiac surgery and lung and liver transplantation. He also is a principal investigator on an NIH-funded clinical trial to improve the outcomes of trauma victims.

Lei Sun, Ph.D., President, Manufacture, AutekBio, Inc., Beijing, China
Dr. Sun is responsible for all manufacturing activities and technology platforms at AutekBio (Beijing), Inc., which is a contract manufacture organization specialized in development and manufacturing of biologics using large scale mammalian cell cultures. In the past few years, Dr. Sun has successfully established technology platforms for manufacturing biologics from cell line development to final large scale product production at AutekBio in China. He has extensive experience in drug discovery and commercialization in US. Dr. Sun has more than ten years of experience in the development of therapeutic biologics and their commercial manufacturing. Prior to joining AutekBio, Dr. Sun held various positions in academic institutions and pharmaceutical companies including DSM/Crucell, Shire Pharmaceutical, UCB Pharma, University of Minnesota, Harvard Medical School, etc.

Brad Wolk, Biopharmaceutical Industry Consultant, Wolk Engineering
Bradley Wolk has nearly 30 years of experience in the bioprocessing industry. Before starting his own company, Wolk Engineering, in late 2010, he spent 20 years at Genentech, Inc. Most recently, he was a Distinguished Engineer and Director of Pharmaceutical and Packaging Engineering at Genentech, Inc., South San Francisco, California. He has also been Director of Process Development Engineering at Genentech with a focus on developing and implementing new technologies. After receiving his B.S. degree in Chemical Engineering from U. C. Davis in 1981, he began his career at Stauffer Chemicals as a Process Engineer. He joined Genencor, Inc. in 1984, holding positions in Process Development and Manufacturing Technical Services. Throughout his career, he has been very active in facility and equipment design, process and technology development, material sciences and technical collaborations with a variety of equipment manufacturers.

Safe and Secure

You've made a commitment to help people live longer, healthier lives. We want to help protect that commitment.

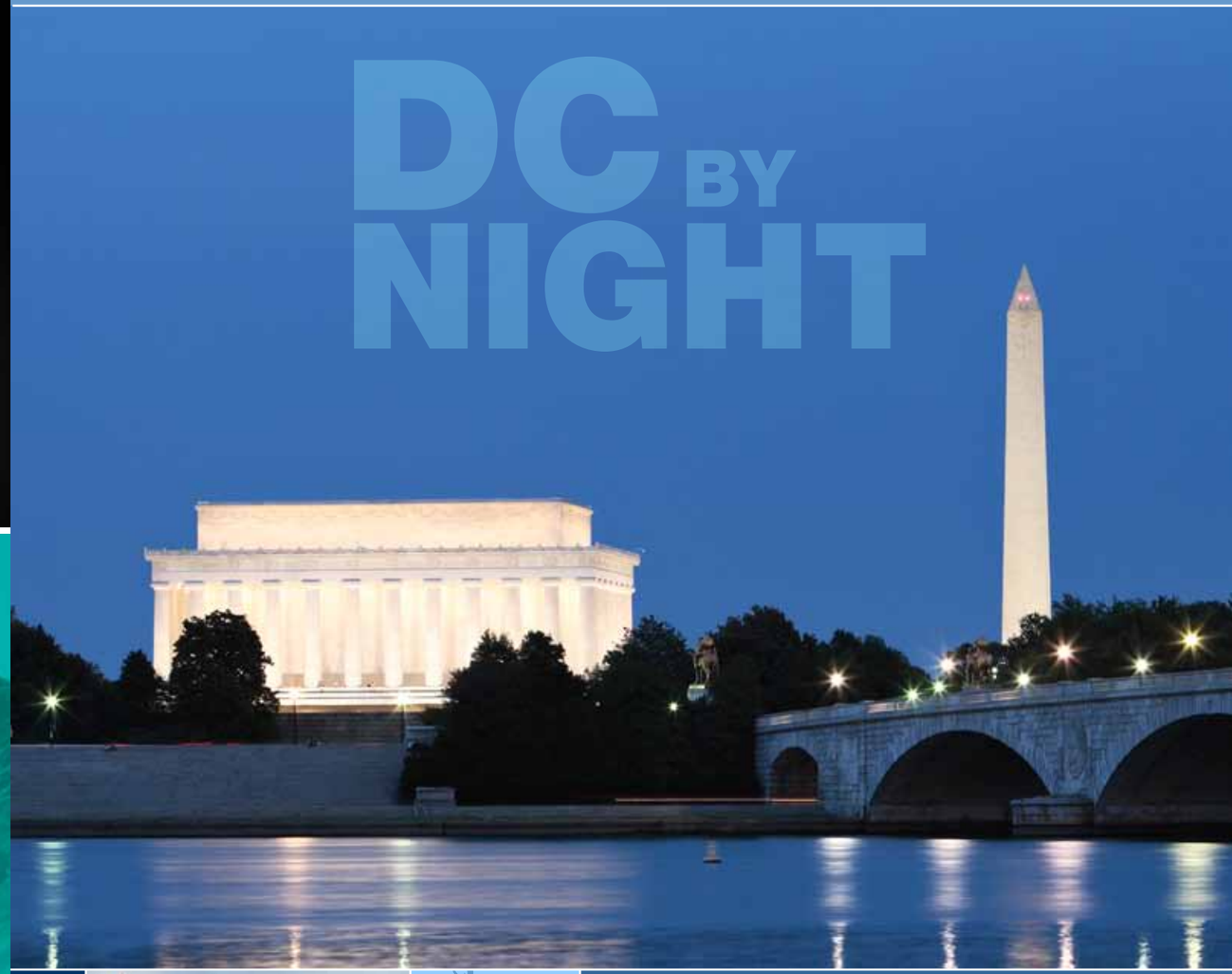
Learn how Dow Corning's products and services are making a difference in biopharmaceutical manufacturing.

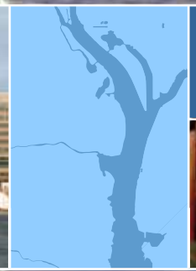
dowcorning.com/healthcare

DOW CORNING Healthcare Solutions

We help you invent the future.™

DC BY NIGHT





Vans will depart promptly at 5:15 PM for the Dinner Cruise. Turn right outside the Lobby entrance to board vans. The cruise will end at approximately 8:30 PM. Vans will return the group to the hotel by 9:00 PM.

CRUISE COCKTAILS SPONSORED BY

BioProcess™ INTERNATIONAL

PreVAS Single-Use Filling System.

125 Years Bosch 1886–2011

BOSCH
Invented for life

PreVAS System provides single-use final fill solution.

PreVAS System by Bosch is set to change the industry.
Using over 30 years of filling system expertise, Bosch Packaging Technology has developed the industry's first single-use positive displacement filling system. The new system combines the advantages and performance of the time tested rolling diaphragm pump with the convenience and cost savings of disposable technology.

PreVAS System
Each PreVAS system can be tailored to meet customer requirements. Each system contains a supply connector, tubing, fittings, disposable rolling diaphragm pumps, a vacuum manifold and filling needles (disposable needles can also be purchased separately). Disposable intermediate product bags, filter, recirculation lines and/or bleed lines are a few other options that can be added to the system. Systems are fully scaleable from single pumps systems for lab use to large multi-head systems for high speed production. PreVAS systems have been tested accurate to over 400,000 cycles and have the same filling performance as the traditional stainless steel rolling diaphragm pumps.

Retrofit
Most machines currently using Bosch or TL Rolling Diaphragm pumps can easily accept the PreVAS system in a matter of minutes with a simple and inexpensive adaptor kit.

Pre V-A-S
- **Pre-Validated:** PreVAS systems come with a validation packet containing detailed component and manufacturing information.
- **Pre-Assembled:** PreVAS systems are preassembled and double bagged in a class 10,000 clean-room by specially trained technicians.
- **Pre-Sterilized:** PreVAS systems are gamma irradiated and include a gamma evident seal ensuring sterility.

Robert Bosch Packaging Technology, Inc.
Phone: +1 763 424 4700
sales@boschpackaging.com
www.boschpharma-us.com

SUMMIT SPONSORS

PLATINUM SPONSOR

ThermoFisher SCIENTIFIC

GOLD SPONSORS

ATMI®

EMD MILLIPORE

RENOLIT

PALL Life Sciences

SILVER SPONSORS

BOSCH

DOW CORNING

COFFEE BREAK SPONSOR

VALUE PLASTICS, INC.
SPECIALISTS IN FLUID CONNECTIONS™

LANYARD SPONSOR

ARKEMA

MEDIA SPONSOR

BioProcess™ INTERNATIONAL

BPSA MISSION

The Bio-Process Systems Alliance (BPSA) was formed in 2006 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**, or call 202.721.4100.

BPSA
Bio-Process Systems Alliance
Advancing Single-Use Worldwide

1850 M St NW, Ste. 700
Washington, DC 20036-5810
www.bpsalliance.org