The Finalists

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Welcome . . .

THE BIOPROCESS INTERNATIONAL 2014 AWARDS:

A CELEBRATION OF THE PEOPLE, ORGANIZATIONS, AND TECHNOLOGY APPLICATIONS THAT ARE MAKING A DIFFERENCE

The mission of the *BioProcess International* publication has always been to deliver valuable industry information to the biotechnology community to continue on the path of scientific advancements, revolutionary technological applications, and strategic partnerships and collaborations. We are honored to cover this market and work with the many talented people sharing their expertise and projects.

Now is the time for us to recognize and honor the outstanding people, organizations, and technologies that have significantly influenced and advanced the efficiency of biotherapeutic development and manufacturing processes, ultimately allowing the industry to deliver better, more effective treatments to a global patient base.

In January 2014, *BioProcess International* opened nominations to the industry through a secure online site. Nominations remained open through 18 July 2014. Each submitted nomination was transferred to an individual ballot form. We consolidated those ballots by category and electronically sent them to the judges we had selected based upon their unique expertise. Each judge scored the separate narratives (answers to four or five questions, depending on the category) in a ballot on a scale from 1 (low) to 5 (high) and then selected an overall score for the entry, which was used to resolve any ties. To confirm impartiality, each judge submitted a signed statement that he or she had scored the nominations fairly and impartially according to the set guidelines.

We would like to thank all of our judges for their time and thorough review. We are especially grateful to have a panel of judges with expertise within their respective fields. This year's judges included those from leading corporations and organizations such as Atheln, Inc., BIOG, BTEC, BioProcess Institute, Complya Asia Co. Ltd., Cleanroom Consulting, Chamow & Associates, Eli Lilly, Johnson & Johnson, Janssen Research & Development, MassBiologics, Primus Consulting, PDA, Pfizer, Roker Technologies, and the University of Birmingham.

Now, *BioProcess International* is proud to formally introduce the 26 *BioProcess International Award* finalists for 2014. This exclusive group represents the very best technologies, applications, collaborations, and thought leaders that the bioprocessing industry has to offer.

On 22 October 2014, *BioProcess International* will host a special dinner and ceremony to honor all those finalists and announce the award winners. We hope you will join us at the awards ceremony taking place at our annual conference at the Hynes Convention Center in Boston, 20–23 October 2014.

Brian J. Caine
Publisher

S. Anne Montgomery
Editor in Chief

The People

EXCELLENCE IN LEADERSHIP

The *Excellence in Leadership* award recognizes any single individual in a company regardless of a company's organizational hierarchy who has shown excellent leadership skills. Achievements of these individual finalists have established them as strong leaders and/or mentors. Their key leadership skills have allowed them to successfully help their businesses achieve operational excellence, demonstrated strong visions to drive their companies to greater commercial success, and motivated their teams for growth and innovation.

Lynn Bottone *Site Leader, Sanford Site*, Pfizer

Lynn Bottone supports the clinical and commercial manufacturing of specialty care biotechnology products, specifically bacterial conjugate vaccines, at the Sanford site, a member of the Pfizer Global Supply organization. She has oversight of all operations. The multiproduct facility employs ~500 colleagues and comprises two manufacturing trains (for clinical and for commercial production), each with two manufacturing suites: one suite dedicated to bacterial fermentation and purification and the other to chemical conjugation of the vaccine polysaccharide to the carrier protein. Since 2012, Lynn Bottone has led the manufacturing department to two years of nearly 100% operational success. In 2013, the bacterial manufacturing department produced 170 fermentation batches, 57 purification batches, and 50 batches of media with no losses. In 2014, quality metrics are the highest that they have been in the site's history. Nearly 85% of all batches produced are right the first time, with no investigations or adverse events. In the first quarter of 2014, the site won 31 mission awards, given out across the Pfizer network for initiatives that bring continuous improvement to the production process.

Olivier Loeillot *General Manager, Enterprise Solutions,* GE Healthcare Life Sciences

Olivier Loeillot has been general manager of the Enterprise Solutions division since joining GE Healthcare in 2010. He has global responsibility for leading the enterprise solutions team, which provides customers with the technologies, services, and support needed to manufacture high-quality biologics at sites of their choosing. The sale of the first KUBio modular biopharmaceutical factory to JHL BioTech in China, announced in September 2013, is the achievement that defines Loellot's leadership. That announcement was the culmination of a concerted period of successfully developing and launching KUBio onto the global market. To reach this point, he established the credibility of the enterprise solutions team both internally and externally to secure the additional internal investment to move the project forward to launch. He equipped a commercial team to take a completely novel concept to customers globally, resulting in multiple sales leads and, ultimately, the agreed purchase by JHL Biotech. In recognition of Loellot's success, he was presented with the President's Award for Globalization by John Dineen, CEO of GE Healthcare, in January 2014.

Robert Preti

Visionary Founder, President and Chief Scientific Officer, **Progenitor Cell Therapy (PCT)**

Dr. Robert Preti is the founder of PCT and a primary driver of the company's successful evolution into a leader in the cell therapy manufacturing industry. As president and CSO, he oversees all PCT business functions as well as scientific, engineering, and technical staff and programs. Under his leadership, PCT's client-focused model addresses key challenges facing developers of cell-based therapeutics who are positioning innovative products for clinical success. Preti serves in a leadership capacity for many professional organizations, including the International Society for Cellular Therapy (ISCT) and the Alliance for Regenerative Medicine (ARM). He recently completed a five-year term as a director for the American Association of Blood Banks (AABB). One of his greatest achievements is building PCT in a way that keeps pace with the industry's explosive growth and evolving needs. A prime example is his vision for the Engineering and Innovation Center at PCT that focuses on development of technological innovations to streamline and automate many cell processing techniques, leading to faster scale up, lower cost of goods, and improved robustness in manufacturing for the industry.

The Organizations

EMERGING COMPANY

The *Emerging Company* award recognizes the companies to watch in the industry. This company has a new technology that is already seeing significant industry adoption; or the company has created a technology through an innovative business or partnering model worthy of emulation. These companies have successfully raised awareness within the scientific community and continue to do so.

BioCision

BioCision is an emerging leader in products that eliminate variability and improve standardization in temperature-sensitive drug and biomaterial handling, storage, and transport. Scientists worldwide in the pharmaceutical, biotechnology, and biobanking industries use the company's products to improve their workflow efficiency and product quality. The company's CoolCell cell-freezing containers are the industry standard for cell cryopreservation in research and clinical applications, including those for cell therapies. The newly marketed BioT temperature stability systems protect temperature-sensitive materials during preanalytical bench-top processes, bioprocessing, and postmanufacturing cold-chain transport. In 2014, a new product line will address unmet needs in controlled cell thawing. Rapid adoption of BioCision products by industry-leading companies has led to double-digit annual sales growth, which speaks to the strong, previously unmet need for the company's solutions. BioCision is leading the drive to implement standardized processes for handling temperature-sensitive biomaterials at a time when the reproducibility of scientific studies has become a major issue in life science research. The BioCision vision is to provide products that provide superior temperature standardization solutions across the R&D spectrum from early research through final product cold-chain logistics.

Horizon Discovery

Horizon is a leading life science company supplying research tools to organizations engaged in genomics research and development of personalized medicines. It seeks to provide science-driven research solutions that advance understanding of the genetic basis of disease and the delivery of better healthcare outcomes. The company is a trusted supplier of genetically defined cell lines, reporter gene assay kits, genomic reference standards, and contract research services to organizations engaged in biopharmaceutical process optimization, drug discovery and development, and clinical diagnostic development. As an emerging leader in the bioproduction field, the company offers a precision cell-line–generation service that modifies host mammalian genomes while maintaining cell-line stability, enabling improvements in selection, yield, and timelines for biopharmaceutical manufacture. Horizon provides technology and business models that support innovation in genomic engineering of bioproduction cell lines, which has until recently been beyond the reach of many companies.

ToleRaM Nanotech, LLC.

ToleRaM Nanotech, LLC.

Nearly half a million people are on dialysis, and more than 100,000 are on the transplant waiting list in the United States alone. Immunosuppressant medications are necessary to keep patients from rejecting newly transplanted organs, but at the cost of harmful and sometimes fatal side effects. Current systemic delivery of immunosuppressive drugs compromises a patient's immune system, a condition analogous to immunodeficiency. Severe side effects range from opportunistic infections to development of cancer. ToleRaM Nanotech proposes a novel delivery device wherein nanocarriers filled with immune modulating drugs are delivered in a targeted fashion to a transplanted organ itself. Through a collaboration of three cofounders spanning the fields of transplant surgery, bioengineering, and immunology, ToleRaM Nanotech was developed as a platform to synthesize and market novel delivery devices wherein antirejection drugs are encapsulated in a biologically inert nanoparticle device and delivered in a focused manner to a transplanted organ with triggered-release. The devices marketed by ToleRaM capitalize on a growing appreciation that immune suppression at the graft level may have more profound effects on rejection than does systemic immunosuppression.

The Organizations

CORPORATE CITIZENSHIP

The *Corporate Citizenship* award recognizes a company that has made significant contributions through activities within a broader urban or regional community. Through the involvement of their employees, these companies are well respected for their significant achievements within their local communities and in that broader context, to the world at large.

Bayer HealthCare

Around the world, Bayer HealthCare applies its expertise in science, business, and innovation to building healthy lives and sustainable communities. Leadership in fields including workforce development, climate protection, and patient support are necessary for its business, while the company concurrently demonstrates commitment to building trust within its communities and among its employees. At all levels of the company, philanthropy and community involvement are a critical part of Bayer's culture. When Bayer chose to move its global biotech headquarters to the Bay Area in 1992, community benefits were written into the company's 30-year development agreement with the city of Berkeley, CA. This groundbreaking agreement went beyond the standard development mitigations to meet broad community needs for resource reduction, recycling plans, auto use reduction, child care, affordable housing, high-quality public education, and an array of other initiatives. This comprehensive strategy represents a high level of commitment from Bayer, including a significant financial investment totaling more than $20 million to date.

Biogen Idec

Biogen Idec is a leader in sustainability, as evidenced by ranking #8 in *Newsweek*'s Top US Green Companies lists. Part of its sustainability leadership is to reduce its carbon footprint. One initiative it achieved in 2012 was a zero waste-to-landfill goal. To further its GHG emission reductions, in 2012, the company participated in a unique pilot program to test the feasibility of recycling the single-use waste from its biopharmaceutical manufacturing processes. Recycling this waste can be a real challenge because it contains a mix of materials that most recycling outlets will not accept. Participation in this pilot program was facilitated by EMD Millipore in partnership with a recycling vendor, Heritage Interactive Services. The ongoing program has been running for 18 months and has greatly increased Biogen Idec's recycling rate.

Sigma-Aldrich

Sigma-Aldrich has made a significant and incremental commitment to environmental stewardship, waste reduction, green chemistry, STEM education (science, technology, engineering and math), and employee engagement in communities around the globe. The company was recognized in January 2014 as one of the "Global 100 Most Sustainable Corporations in the World" at the World Economic Forum in Davos, Switzerland, and for the second consecutive year has been named to The Civic 50, a national ranking that recognizes the most community-minded companies in the United States. It also has been recognized by CDP for leadership in carbon disclosure and by the Dow Jones Sustainability Index for its Corporate Social Responsibility platform. The company's mission focuses on improving the quality of life, and that philosophy extends to its communities, its customers, and its environment.

The Organizations

EXCELLENCE IN FACILITY DESIGN OR RETROFIT

The *Facility Design or Retrofit* award recognizes a facility that is exemplifying innovation through the use of key technologies and/or designs. The results of this innovative facility or retrofit provide a high-quality example of energy efficiency, traffic flow (people and materials), conversion to single-use or flexible operations, increased automation, accommodation to local ordinances and integration with local services and policies, expansion to take on a new product line or convert to a multiproduct facility, creation of better ergonomic conditions, and many other capabilities. The finalists for this award offer a high standard for facility design and sustainability.

Gallus BioPharmaceuticals / GE Healthcare Life Sciences

Gallus BioPharmaceuticals, a mammalian cell culture contract development and manufacturing organization, was established by the purchase of a manufacturing facility in St Louis, MO, in May 2011 by CEO Mark Bamforth. The 27-year-old biopharmaceutical manufacturing facility was previously part of Wyeth, Pfizer, and most recently J&J. Gallus added to existing traditional development and manufacturing capabilities with the "factory of the future" through installation of GE Healthcare Life Sciences' FlexFactory single-use biomanufacturing platform. This new and expanded capability was successfully achieved in just nine months. Gallus began by stripping back the existing office space to a shell before installing all the required elements for a cleanroom environment, including airflow and drainage. FlexFactory was brought in once the construction phase was completed. It gives customers rapid access to CGMP manufacturing capacity for key biologics such as MAbs and vaccines, from cell culture to bulk product formulation. This extensive application of single-use technology provides the flexibility to modify individual processes when production needs to implement a change or to develop a completely new production line for a facility within nine to 12 months.

Vetter

At one of its German production facilities, Vetter operates one of the most effective filling lines currently available on the market. It went online in March 2013. The line's capacity ranges from mid- to large-volume batch sizes (90,000–500,000 units), with a maximum filling speed of 800 presterilized syringes per minute. The line sets new standards in the aseptic handling of presterilized syringes in tubs by applying new solutions and a maximum of automation. The plant offers efficient and reliable conditions for manufacturing parenteral drugs with optimized filling processes to prevent loss of drug substance. It was conceived and designed in collaboration with an equipment manufacturer to meet Vetter's high quality requirements. The filling line features a large number of innovative technologies and flexible solutions to adapt to special product needs. It can process biotechnological and other sensitive substances efficiently, safely, and at high speed.

FUJIFILM Diosynth Biotechnologies

The MCC facility at FUJIFILM Diosynth Biotechnologies' Billingham, UK, site is a strategic investment by the company to grow its cell culture contract manufacturing business. The initial focus for the facility is monoclonal antibodies; however, it has the flexibility to be used for a wider range of customer-specific products. The new facility is the first purpose-built plant in the United Kingdom to use single-use process equipment for the entire manufacturing chain, from the starting cell vials through to packaging the final drug substance. The facility, completed in October 2013, is part of an ambitious 18-month program, which included design, construction, qualification, and start-up of the CGMP manufacturing plant; development of a proprietary mammalian cell line, with innovative expression technologies and process platforms; and design and installation of R&D facilities for multiple customer process development programs and analytical characterization. The MCC facility has been successfully inspected and licensed by the MHRA.

The Organizations

BEST COLLABORATION

The *Best Collaboration* award recognizes a number of promising collaborations that have been formed in the past 18 months and that have proven to result in significant benefits toward accelerating drug development or mitigating risks. The companies or groups have come together and have formed a solid foundation for innovation and a long-term mission for accelerated growth.

Invetech Inc. / Janssen Research & Development, LLC

The challenge was to learn from a phase 2 production project and scale up the processing capacity for equipment and disposables to produce a phase 3 commercial product. Invetech undertook the engineering design for the equipment, automation and disposables, project management, factory acceptance testing, and site acceptance testing. The Janssen R&D team provided the process knowledge and process development testing and performed the IQ, OQ, and PQ testing. The teams collaborated to design multiple processing stations including cell seeding, cell expansion, cell release and harvest, formulation, and precise-dispense bag filling equipment for both the working cell bank product and the cryopreserved drug product. The group also worked together to design the single-use technology sets (disposables) required for the process, liaising with suppliers to set up and qualify the supply chain, thereby allowing production to be an aseptic process and occur in the lowest possible classification production space.

Promosome / GE Healthcare Life Sciences

Promosome was formed to commercialize the discoveries of the late Nobel Laureate Dr. Gerald M. Edelman and his colleague, Dr. Vincent P. Mauro, of The Scripps Research Institute (TSRI) in La Jolla, CA. Their inventions can enable biotechnology and pharmaceutical companies to shorten the time needed for cell line development and improve expression efficiencies of all types of biological products. However, establishing and validating such technologies so that they become widely adopted requires further development as well as a marketing investment that would have been beyond that available to Promosome alone. GE Healthcare has received exclusive use of the technologies in the mammalian cell culture field. Promosome has retained the rights to use the technologies in all other manufacturing platforms as well as the development and manufacture of its own mammalian cell expressed biotherapeutics. Under the terms of this agreement, Promosome will receive milestone payments for technology transfer and subsequent royalties upon commercialization by GE Healthcare.

TAP Biosystems / Merck & Co., Inc.

The objective of this collaboration was to develop a dual use, fully automated, highly parallel bioreactor system capable of enabling a single scientist to execute a statistical DOE design across 24 single use bioreactors. The collaboration between Merck and TAP Biosystems brought together highly knowledgeable teams of people; Merck brought deep understanding of the bioprocessing and biopharmaceutical development, and TAP came with extensive automation and manufacturing experience. Both TAP and Merck worked in true partnership despite the fact that this was a vendor-customer collaboration. This cooperation was based on a fully transparent relationship, highlighting challenges and overcoming them together as a single team. Flexibility, honesty, and communication played a key role in the realization of this project. The project was successfully completed, resulting in a highly functional product that is based on specific customer needs. This is reflected by its wide placement across the industry.

BPI Honors…

Industry Champions

Industry Champions are individuals whose clear vision, tireless efforts, unwavering dedication, and tangible actions have uniquely helped *BioProcess International* effectively educate the industry. In doing so, Industry Champions challenge the industry never to accept the status-quo, never to doubt, give-up, or give-in. They continually strive to rethink, reinvent, and create new ways to improve existing processes, products, and technologies.

In 2014, *BioProcess International* is proud to honor two industry champions: Lee Buckler and James Vogel. Their ongoing work and commitment to excellence exemplify the definition of *Industry Champion*.

Lee Buckler

Founder and Managing Director, **Cell Therapy Group**

There is little doubt of the promise and potential of cell therapies. However, in this business, we all understand how difficult the road from promise to fulfillment can be. Often, the difference between success — or the ability to continue development — and ultimate failure is not having the right training and/or education or not being able to clearly communicate results or the "big picture."

Lee Buckler has made it his personal mission to do exactly this: to educate the industry, communicating the vision of cell therapies and ensuring that these game-changing technologies have the best opportunities to succeed.

In 2009, Lee was instrumental in helping to shape and steer BPI's Cell Therapy supplement and the BPI theater series. He has worked with us closely ever since. As a long-time member of BPI's Editorial Advisory Board, he has written for us frequently and recommends authors for our continued explorations of regenerative medicines. In fact, Lee has worked with over 45 cell therapy and regenerative medicine groups and associations, and in addition to writing for *BioProcess International*, has been published more than 50 times. Lee has worked with and provided guidance to several conference companies to help create, organize, and breathe life into numerous cell therapy industry meetings that may owe their continued existence to his efforts. Lee is on the advisory boards of several organizations. His tireless work in social media also provides the cell therapy industry with much needed information and perspective.

Lee started his career with a degree in BEd, Social Services, from the Canadian University College in 1990 and earned his law degree from The University of British Columbia in 1995. Lee's cell therapy career began as business development manager at Malachite Management, and since then he has held management roles at nonprofit and commercial cell therapy companies. In 2008, Lee founded The Cell Therapy Group to help meet the demands for business-focused services within the cell therapy and regenerative medicine industries.

Throughout his career, Lee has had the unique ability to make that one extra introduction, to connect like-minded organizations and individuals toward achievement of common goals, and to always recognize and champion the "big picture" of cell therapy. BPI is proud to honor Lee Buckler as its 2014 Industry Champion.

James Dean Vogel, P.E.

Founder and Director, **The BioProcess Institute**

In a relatively short period of time, single-use technologies (SUTs) have entered the mainstream as a critical and essential factor in bioprocessing. With their growth in sophistication and maturation come proprietary concerns, technical and regulatory challenges, and conflicting user expectations. What is a standard? Which guidelines should be followed? Who is responsible for setting them? For which product classes and manufacturing stages are such technologies appropriate? Where are innovations still needed, and why?

At this point, no fewer than eight industry associations are creating and publishing their versions of SUT standards, guidelines, and best practices. The results are yielding a significant body of work, but a clearly unanimous industry standard has yet to emerge. This continuing lack of consensus reflects growing confusion and frustration in the industry, which could ultimately slow or hinder adoption of single-use technologies and limit the innovation necessary to secure their continued growth and maturation.

In 2013, Jim Vogel recognized this threat to the continuing adoption of SUTs and made it his personal mission to ensure that the various organizations not continue to work at cross purposes with one another. To bring some clarity and structure to this market and to try to minimize duplication of efforts, Jim challenged all the associations to come together, find common ground, and educate the industry in one unified voice — all while respecting their individual identities and the integrity of their organizational missions.

To pursue this goal, Jim has organized, facilitated, and moderated multiple panel discussions and meetings, including The Town Hall Forums; conducted teleconferences; and published *Single-Use News L-E-T-T-E-R-S*, a monthly industry newsletter dedicated to facilitating coordination of SUS standards-and-practice efforts. Each issue reviews/summarizes each association's progress, reports and establishes agendas, and announces upcoming presentations and public seminars.

Combine all these efforts, and it becomes clear that Jim has uniquely positioned himself as a champion of single-use technologies. For these reasons and more, BPI is proud to honor James Vogel as its 2014 Industry Champion.

Best Technology Application

UPSTREAM

The *Best Technology Application–Upstream* award recognizes a user or supplier of an application that offers much more than hype: It will have shown through adoption and application of an existing technology or development of its own materials and methods that it is paving the way toward a new approach to process design or a new apparatus that shows well-documented improvement over existing equipment.

XDR-50 MO Fermentor System • GE Healthcare Life Sciences

The XDR-50 stirred-tank fermentor is a single-use system, purpose-built for the growth of microbial cultures including bacteria, fungi, and yeast. The XDR-50 includes a two-stage impeller combination that allows for good mixing and exceptional power input, as well as providing the high oxygen transfer required for fast-growing microbial cultures. The system was successfully designed and implemented following extensive user and in-house input. It allows for microbial cultures to be grown using single-use technology in cultures up to 50 L. The XDR-50 includes three main elements: a fermentor vessel with baffles and condenser, an I/O cabinet, and a plug-and-play portable X-Station control ensemble. The XDR-50's jacketed, baffled tank enables fast heat-up and temperature shifts, with cooling, and is a modular turnkey system suitable for GMP production applications.

STX® Scalable Transfection System • MaxCyte

Flow electroporation from MaxCyte enables production of gram-scale, CHO-based production of antibodies uses transient gene expression (TGE). Flow electroporation is a universal, fully scalable transfection technology that achieves multigram CHO antibody production without requiring specific expression constructs, adapted CHO lines, specialized reagents, or media additives. Flow electroporation outperforms other transient transfection methods, the use of which in antibody production has been limited by low antibody yields. The high transfection efficiency and cell viability of flow electroporation typically produce antibody titers >400mg/L before optimization, which can exceed 1.2 gram/L with routine optimization of posttransfection culture conditions. Flow electroporation does not require protocol reoptimization for scaling, enabling rapid scale-up and scale-down to match antibody production needs. Separately or in parallel, flow electroporation can be used to generate stable pools and high-yield, stable CHO cell lines. Thus, flow electroporation offers a single means of CHO cell antibody production throughout biotherapeutic development pipelines.

ambr250 • TAP Biosystems / Merck & Co., Inc.

The ambr250 was codeveloped by TAP Biosystems and Merck & Co., Inc. This instrument is a fully automated, highly parallel bioreactor system capable of enabling a single scientist to execute a statistical DOE design across 24 single-use bioreactors. The ambr250 is unique in that the technology is both single use and capable of supporting both microbial and mammalian cell culture experiments. In addition, the system relies on simple-to-use processes for connecting the disposable vessels to gas, feed, and sensor systems. Finally, a full suite of automated controls and features, including robotics for sample and liquid handling, drive efficient process development. The ambr250 was developed through a collaboration between Merck and TAP Biosystems; Merck brought deep understanding of bioprocessing and biopharmaceutical development, and TAP came with extensive automation and manufacturing experience. Development of the technology was successfully completed, resulting in a highly functional product that is based on specific customer needs. This is reflected by its wide placement across the industry.

Best Technology Application

DOWNSTREAM

The *Best Technology Application–Downstream* award recognizes a user or supplier of an application that is reducing downstream processing steps and their related time and costs. Strides toward achieving continuous processing regimens and greater efficiency at later stages (even into formulation, fill, and finish) are already transforming the industry's ability to approach its work more efficiently. The finalists in this category are companies whose new technologies show, though well-documented applications, that they are indeed game-changers.

BioT Temperature Stability Systems • BioCision

Temperature-sensitive drug sample handling and transport are critical to activities within the pharmaceutical, bioprocessing, and biobanking fields. However, there has historically been a lack of practical and cost-effective solutions for maintaining samples in defined low temperatures during handling and transport. BioCision sought to fill the gap in internal cold chain logistics with BioT temperature stability systems. BioCision recently developed a customized BioT ULT workstation to solve temperature-control challenges for a leading biotechnology company that is packaging an investigational cancer vaccine for patients with metastatic melanoma. To ensure efficacy and viability of the immunotherapeutic drug, the drug product could not be exposed to temperatures above –50 °C for more than a few seconds at any step in the packaging process. The BioT ULT workstation provided a <–60 °C environment for vial transfer, package tray precooling, packaging, transient storage, and local transport. The novel BioCision solution enabled maximum throughput at optimal ultra-low temperature.

Allegro Single-Use Filling Needles • Disposable-Lab SAS/Pall Life Sciences

Disposable-Lab SAS has recognized over the past ten years that an increasing number of injectable biotechnology products are in development. The company also recognizes that single-use components and systems are ideally suited for processing such products. This presents the possibility of creating — from the ground up — the first-ever production facility using entirely disposable process systems for formulation and filling operations. The company has thus embarked on a development program to create a new manufacturing facility exclusively dedicated to single-use processes. This modular "plastic factory" is designed for production of sterile products both for clinical trials and small commercial batches. Disposable-Lab SAS selected two principal partners to assist in this development: a company specializing in single-use isolators; and Pall Life Sciences for single-use needles and for air and product filtration technologies.

Natrix HD Membranes

Natrix Separations, Inc. / Gallus BioPharmaceuticals

The Natrix HD membrane chromatographic separation technology is a revolutionary and patented-three-dimensional macroporous hydrogel structure providing a high density of binding sites, which allows for a larger binding capacity than with traditional resin-based columns. In addition, the Natrix technology does not rely on diffusion, but rather on using advective flow, which improves load distribution and allows up to 25 times higher flow rates than with conventional resin-based columns. The Natrix technology is applied in a similar way as traditional column chromatography and has the capacity for binding and eluting a wide range of molecules. At Gallus Biopharmaceuticals the Natrix technology is used in downstream processing in biomanufacture of a variety of protein molecules.

Best Technology Application

ANALYTICAL

The *Best Technology Application–Analytical* award recognizes a user or supplier of an application of analytical methods, old and new, which form the essential foundation of biopharmaceutical and biotherapeutic development at all phases from preformulation to postmarketing. These methods ensure the consistency and reliability of raw material quality, the safety and efficacy of a drug throughout development and throughout its stages of characterization, consistency of product manufactured in different facilities, worker safety, and comparability to previous lots or of a biosimilar to an innovator product. The finalists in this category have demonstrated increased functionality in novel combinations with other analytical technologies, whether old or new; or they may reveal significant benefit in new applications — including emerging product sectors.

MicroScale Thermophoresis (MST) • NanoTemper Technologies GmbH

MicroScale Thermophoresis (MST) technology represented by the novel instrument Monolith NT.Automated launched in February 2014. Microscale Thermophoresis is an easy, fast and precise way to quantify biomolecular interactions. It measures the motion of molecules along microscopic temperature gradients and detects changes in their hydration shell, charge, or size. Therefore, binding events can be detected even without an increase in size or mass upon complex formation, providing a large application range, from ions and small molecules to high molecular weight and multi-protein complexes. Because MST is performed without any surface immobilization, bulky or sensitive molecule assemblies such as liposomes, nanodiscs or membrane proteins can be investigated. Within the Monolith Series, the Monolith NT.Automated is designed for high-throughput applications because it can measure 96 samples in parallel. Screening projects can be performed in an automated fashion by integrating the instrument into a robot-compatible sample preparation platform.

ImageStreamX® • Enzo Life Sciences / Amnis (part of EMD Millipore)

Characterization of protein aggregates and other subvisible particles within therapeutic formulations is critical to ensure drug safety because of potential immunogenicity of particles, especially in the 1–10 µm range. To overcome limitations of current techniques, the ImageStreamX (ISX) multi-spectral imaging flow cytometer offers conceptual advantages including direct size measurements, differentiation between multiple particle types using fluorescent labeling, quantification of morphometric properties, absolute concentration measurements, and low sample volume requirements. The company demonstrated remarkable sensitivity, dynamic range, and classification for particles using the ISX cytometer compared with alternative platforms. Moreover, it demonstrated that the cytometer enables completely novel assays; for example, investigation of heterogeneous particle interactions. Integration of this approach within the pharmaceutical setting has potential to address emerging questions regarding the mechanisms of particle formation and their impact on patient risk. In studies evaluating the technology based on specificity and sensitivity of particle discrimination and detection limit and linear dynamic range of particle detection, it is shown to be a highly promising analytical platform for particle analysis of parenteral solutions.

SGS M-Scan Services • SGS Life Sciences

The SGS M-Scan services are used for design and execution of shipment excursion studies involving risk-based design using automated temperature and humidity cycling. Correct and timely application of these studies allows drug developers to be proactive rather than reactive to excursion events, allowing informed, timely decisions to be made that may affect human safety. During a drug development life cycle, biologic products are likely to experience a shipping excursion at some point. CGMP-compliant services use fully validated conditioning chambers with inline monitoring. Shipping assessment is performed in accordance with a risk-assessment approach aligned with ICH Q9 guidelines on quality risk management. Data can also be used to support product handling, formulation, forced degradation, and stability studies. The SGS team has facilities to not only plan, design, and execute these studies, but also to perform all associated comprehensive tests on biological and chemical APIs. The Wokingham (UK) site where the services are performed also employs technical troubleshooting experts in case higher order analyses are required to further characterize degradation products.

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PROGRAM SPONSORS

GE Healthcare Life Sciences provides tools and technologies, solutions, and services that enable the biopharmaceutical industry to develop and manufacture biotherapeutic medicines and vaccines cost-effectively. Our products and platform solutions are designed to meet the key challenges posed at every stage in the biomanufacturing process, delivering the desired product at the required purity and safety — all with fast development and integrated solutions in mind. Across the bioprocessing spectrum, our focus is on supporting the industry from idea to result.

Pall Life Sciences provides process, pilot and laboratory filtration, separation, purification, and fluid handling devices, systems, and services, with single-use systems available for all unit operations from cell culture through final formulation and filling. Based on Pall's long history of providing quality equipment for the biopharmaceutical, vaccine, and cell therapy industries, all products — whether standard or customized to match users' exact process needs — are backed up with extensive documentation and experience in extractables, leachables, and particulate validation. Fully automated single-use systems allow process control and data acquisition to meet or exceed the standards expected from traditional fixed equipment. New product highlights include microcarriers, pyrogen-free vials, and a range of pharmaceutical packaging options.

Sartorius Stedim Biotech is one of the world's leading providers of laboratory and process technologies and equipment. Our innovative products and high-quality services help customers implement complex and quality-critical processes in biopharmaceutical production and laboratory environments in a time- and cost-efficient way. Sartorius Stedim Biotech introduced the first single-use bag for biopharmaceutical applications. Demand for these bioprocessing bags has rapidly increased for use in critical applications. We have developed a new polyethylene film and new bioprocessing bags to pave the way toward the single-use manufacturing facility of the future. Flexsafe meets the most stringent customer needs for safe bioprocessing.

Associate Sponsor

Rentschler is an independent, family-owned biopharmaceutical CMO with a long-term track record, high level of flexibility, and tailored project performance. Our full-service concept covers development, production of recombinant proteins in mammalian cell lines, fill–finish and international regulatory expertise. Our state-of-the-art facilities with bioreactors up to 3,500-L total volume and our quality control ensure highest quality.

Industry Partners

PALL Life Sciences

Single Use.
Multiple Solutions.

Consistent materials of construction, market leading sterile connection technology, and smart system designs from small to large scale make Allegro™ single-use solutions ideal for your process. Fully automated Allegro technologies ensure minimal operator intervention, enhanced safety and robustness, high product recoveries and full batch recording. Strong technical support along with a robust and reliable supply chain with our global manufacturing platform meets all the necessary quality requirements.

To learn more please visit booth #217 during BP1 2014 – Boston, October 21-23.

Allegro Single-Use TFF System a compact, easy to use and fully automated system, providing flexibly in manufacturing.

sartorius stedim biotech

New Flexsafe Bag Family.

New PE Film. New Benchmark.

Cell Growth

Sartorius Stedim Biotech is a proud sponsor of the 2014 BPI Awards. We extend our congratulations to all the finalists and commend them on their accomplishments.

Our new Flexsafe bags ensure an excellent and reproducible growth behavior with the most sensitive production cell lines. The optimization of the resin formulation, the complete control of our raw materials, the extrusion process and the bag assembly guarantee a consistent lot-to-lot cell growth performance.

ONE FILM FOR ALL

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