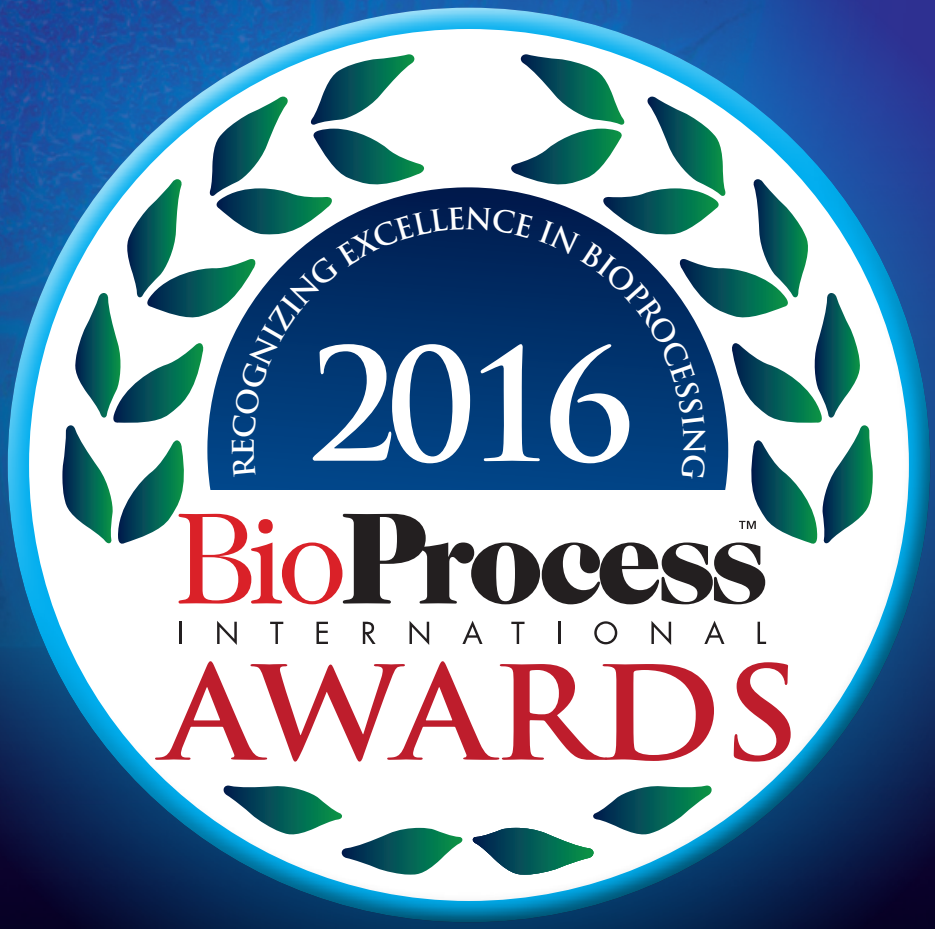

The Finalists

Accelerate your bioprocess journey

Speed and efficiency are crucial aspects of biomanufacturing. The right supplier can contribute to your success. Discover how our pioneering technologies, agile services, and ability to design and construct complete facilities improves speed to market.

Engage with GE to access industry expertise and insights to accelerate your bioprocess journey.

gelifesciences.com/bioprocess

GE Healthcare Bio-Sciences AB, Björkgatan 30, 751 84 Uppsala, Sweden.

29204212 AA 03/2016

WELCOME

THE BIOPROCESS INTERNATIONAL 2016 AWARDS

An evening to recognize and honor the individuals, organizations, and technologies advancing biotherapeutic development and manufacturing.

Since 2003, the mission of *BioProcess International* has been to connect biopharmaceutical scientists and decision makers to the science, technology, and expertise that can positively influence and improve existing bioprocesses.

The *BioProcess International Awards*, created in 2012 to mark *BioProcess International*'s 10-year anniversary, allows us to reflect on and appreciate the time and investment made to research, develop, and launch cutting-edge products, technologies, and services — all designed to support and improve efficiency in existing processes. Simultaneously, the BPI Awards provides a unique glimpse into what drives these advancements: the individuals, collaborations, partnerships, and companies that consistently challenge the biopharmaceutical industry, as a single entity, to never accept what works well as good enough, and to ultimately maintain the pressure necessary to create and deliver better, more efficient treatments and hope to a global patient base.

To date, the biennial *BioProcess International Awards* has recognized more than 50 people and companies that represent excellence in leadership, corporate citizenship and collaborations, innovative facility design, emerging companies to watch, and best application of technologies in upstream and downstream processing and analytical methods. The BPI Awards has also singled out individual industry champions who have personally challenged the biopharmaceutical industry as a whole to rethink, reinvent, and improve itself.

The 2016 *BioProcess International Awards* continues this tradition. This year, *BioProcess International* received a record number of truly inspiring nominations. It made the work for the 16-member independent judging panel very difficult. They took their jobs seriously, evaluating and assigning a value to each nomination based on specific criteria assessing applicability, innovation, results, industry impact, and sustainability. We are indebted to the judging panel and thank them for the time and dedication invested.

Now, after 18 months of work, *BioProcess International* is proud to introduce the 24 *BioProcess International Awards* finalists for 2016 as well as Mark Petrich, *BioProcess International*'s 2016 Industry Champion. This exclusive group represents the very best that the biopharmaceutical industry has to offer.

On the evening of 5 October 2016, at the *BioProcess International* Conference, *BioProcess International* will host a banquet and ceremony to honor all the participants and introduce the 2016 Awards winners to the world. We hope you will join us on our special evening to help us congratulate all the finalists.

Brian J. Caine
Co-Founder and Publisher

S. Anne Montgomery
Co-Founder and Editor in Chief

The People

EXCELLENCE IN LEADERSHIP AWARD

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.

Marcel Bassil

Associate Director, **Benta Pharm Industries**

A Persistent Achiever

Dr. Marcel Bassil serves as the Associate Director for Benta Pharma's biotechnology unit. He is responsible for planning and managing the projects in the production, characterization, and R&D of biological and biotechnology products. He supports top management in evaluating new business opportunities such as in/out licensing, collaborative research and development agreements, joint ventures, and mergers and acquisitions. Dr. Bassil develops, monitors, and evaluates new and existing projects and oversees the scientific and career growth of employees, nurturing their talents. He is responsible for introducing new technology into the research and production areas of Benta Pharma's biotechnology unit.

Dr. Bassil oversaw the establishment of the first biotechnology facility in Lebanon for production of biosimilars as well as of small- and large-scale therapeutic proteins derived from bacterial and mammalian cell lines. Facing the scarcity of biotech professionals in Lebanon, he has been training and guiding a team of experienced biotechnology professionals to ensure the growth of the company's biotech unit. He also assisted in signing a cooperation academic agreement with Lebanon's University of Balamand in the field of therapeutic biotechnology to retain Lebanese talents and ensure creation of a pool of biotech professionals in that country.

Igor Fisch, PhD

Chief Executive Officer, **Selexis**

Innovator, Scientist, Biotechnology Business Leader

Igor Fisch has been the CEO of Selexis since its founding in 2001. He built the company from a start-up based on a technology asset out of the University of Lausanne (Switzerland) into a global leader in mammalian (suspension-adapted CHO-K1) cell line generation.

Igor's greatest single achievement has been to build a culture within Selexis that has fostered development of a suite of recognized world-class, innovative cell line development technologies. He has been able to achieve this by recognizing and hiring talent, supporting them with the tools and time for experimentation, and then having the vision and market savvy to know which of the innovations will have the biggest impact in the field and for Selexis clients. Selexis currrently has 143 patents and more than 65 clinical programs with manufacturing cell lines.

In addition to building his own company, Igor helps other entrepreneurs build their companies. He has worked for eight years as a strategy board member for the Venture Kick Initiative in Switzerland, for which he provides feedback and assessment of start-ups coming out of Swiss universities. His experienced know-how provides valuable direction to entrepreneurs launching new businesses.

Olivier Loeillot

General Manager, **GE Healthcare**

Entrepreneur Turning Vision into Reality

As leader of GE's Enterprise Solutions business within life sciences, Olivier recognized the need to expand local biomanufacturing capacity. The challenge, however, was to find a cost-effective solution that could be implemented quickly regardless of geographical location. Olivier and his team developed the idea of a ready-to-run, modular preengineered facility, fully equipped for MAb production. Such a complete solution would reduce both time and cost and minimize the coordination effort for biomanufacturers. Olivier named this solution *KUBio* and succeeded in turning the concept into reality in spite of numerous challenges.

The basis for Olivier's success is his entrepreneurial thinking. Olivier has an outstanding talent for identifying a customer need, turning that into an opportunity, and developing a solution quickly regardless of potential challenges during the way. When faced with resistance, Olivier persists, trying to find alternative ways to continue moving forward to reach the end goal. He is fast-paced, energetic, and intense and takes on projects with an infectious enthusiasm that motivates and inspires his team to do its best work. He is an excellent team leader who encourages his team to deliver to exceptionally high standards.

The Organizations

EMERGING COMPANY AWARD

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.

Cell and Gene Therapy Catapult

The Cell and Gene Therapy Catapult vision is for the United Kingdom to become a global leader in development, delivery, and commercialisation of cell and gene therapy. In this context, businesses can start, grow, and confidently develop cell and gene therapies, delivering them to patients rapidly, efficiently, and effectively.

The organization's mission is to grow the industry in the United Kingdom to substantial and sustainable levels by taking products into clinical trials; derisking them for further investment; providing clinical expertise and access to NHS clinical partners; providing technical expertise and infrastructure to ensure that products can be made in compliance with GMP and delivered cost effectively; providing regulatory expertise to ensure that products can get to the clinic safely, in the shortest amount of time; providing opportunities for collaboration, both nationally and globally; and providing access to business expertise, grants, and investment finance so that commercially viable products are can progress and generate investable propositions.

NuMedii

NuMedii, Inc., discovers effective new drugs by translating its predictive data intelligence technology into therapies with a higher probability of therapeutic success. The company's exclusive Big Data technology, originally developed at Stanford University, uses large amounts of scientific data together with proprietary biological network-based algorithms to discover drug-disease connections and biomarkers that are predictive of efficacy. NuMedii translates these predictions into novel derisked drug candidates and partners with pharmaceutical companies for development and commercialization. The company's proprietary and dynamic Big Data technology consists of hundreds of millions of raw human, biological, pharmacological, and clinical data points that the company has normalized and annotated. The company integrates those data with proprietary network-based algorithms to find both drug candidates and biomarkers with predictive efficacy for disease treatment.

Quad Technologies

Founded in 2013 to explore the potential of a unique dissolvable hydrogel technology invented at Northeastern University, Quad Technologies is disrupting cell separation and cell therapy workflows by providing cell biologists with a simple, cell-friendly capture and release technology for cell isolation. The company's primary focus is on developing best-in-class cell separation reagents for immunooncology and translational medicine applications.

Quad Technologies' MagCloudz cell separation products use magnetic particles as carriers for its proprietary QuickGel technology, which enables target cell capture by means of a familiar magnetic cell isolation workflow. At the end of the cell separation process, using the Q-Mag or comparable magnetic stand, the MagCloudz particles are dissolved in less than one minute, using a biologically friendly buffer. That releases the target cells from the magnetic carriers, leaving the captured cells behind in their native state after removal of the magnetic particles. Quad Technologies' unique cell release capabilities dramatically increase cell viability compared with conventional magnetic separation products and eliminate retained magnetic labels from isolated cell populations.

The Organizations

CORPORATE LEADERSHIP AWARD

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.

The Baxter International Foundation

The mission of the Baxter International Foundation is to increase access to healthcare for the disadvantaged and underserved in the United States and around the world.
The Baxter International Foundation supports initiatives and organizations that make a positive, lasting impact on increasing access to healthcare for the disadvantaged and underserved in the United States and globally. The Baxter International Foundation is the philanthropic arm of Baxter International Inc. The Foundation's fundamental purpose is to make a positive and lasting impact on healthcare and the health of communities globally, increasing access to high-quality healthcare throughout the world.

Limited government funding for healthcare, growing numbers of uninsured or underinsured individuals, and natural and human-caused disasters converge to increase the need for healthcare services. At the same time, many nonprofit health organizations face budget and staff limitations, struggling to meet daily needs. Commitment to the Foundation's mission is demonstrated in the grant-making, employee, and prize programs. In each of these efforts, the Foundation's fundamental purpose is to make a positive and lasting impact on healthcare and the health of communities in and near where Baxter employees live and work.

Total Impact since 1981:
- Total giving: $108,162,511.60
- Total charities supported: 6,647
- Total countries: 39

Closing the Hemophilia Gap in the Developing World

Life for many hemophilia patients is often associated with severe disability, isolation, and pain. For the doctors, it is full of impossible choices about how to use what little therapy is available — and always wondering when more will come. Biogen Idec was inspired by the call to action issued by the WFH in 2012 and the need to address this treatment gap in the developing world. Even before the company had products commercially available to treat hemophilia, its leadership believed it could help address the challenge in developing countries by joining the existing humanitarian aid effort and applying Biogen Idec's manufacturing capacity and expertise in supplying medicines around the world.

First, along with collaborators at Sobi, the company made a commitment to donate one billion IUs of its factor therapy to humanitarian aid programs in the developing world over the next 10 years, starting with up to 500 million IUs through the WFH's Humanitarian Aid Program. Then they focused on supporting the infrastructure needed to ensure secure, sustainable, and reliable product delivery to those countries.

Biogen and Sobi have been fortunate to collaborate with the WFH, an organization that for the past 20 years has built the largest supply channel of donated hemophilia products in the world. Now, through this unique coalition, the companies have together built a stronger humanitarian aid infrastructure to get more therapy to patients who need it.

The PULSE Partnership Program

The PULSE Partnership Program is GSK's flagship skills-based volunteering initiative in which employees lend their expertise to help nonprofit organizations. Since its launch in 2009, the PULSE Volunteer Partnership has enabled 565 employees from across 57 different countries to work with 103 nonprofit partners in 62 countries. Over the past six years, PULSE has provided nearly £19 million worth of skilled services as calculated by multiplying the average salary and benefits cost of a GSK employee by the amount of time that PULSE volunteers served on their assignments.

The PULSE Volunteer Partnership has a three-fold mission:

Change Communities: Our employees use their professional skills to create positive, sustainable change for nonprofit partners and the communities they serve

Change Employees: Our employees are challenged to think differently, develop leadership skills and heighten cultural agility through their PULSE experience

Change GSK: Our employees bring fresh ideas and new energy back to GSK to activate change in step with global health needs.

The Organizations

FACILITY DESIGN OR RETROFIT AWARD

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.

FUJIFILM Diosynth biotechnologies

Repurposing a Microbial Facility for Multiproduct GMP Manufacturing

Because high potency biologics are becoming an increasingly important class of therapeutics, this project involved repurposing and upgrading an existing microbial GMP facility to provide self-contained cleanrooms with separate HVAC system(s). The facility needed to be GMP ready for biologic production from vial thaw to drug substance bulk fill. Multiproduct capability and versatility was critical. The retrofit also needed to be suitable for manufacture of early/late-phase clinical and commercial products.

The facility design was completed in consultation with the UK regulatory agency (MHRA) to expedite regulatory approval. It took 24 months from initial concept to initiating a customer GMP run. The retrofit facility is suited for microbial expression at the 100-L volume, which supports the high potency manufacturing scale.

Key design considerations included an initial completion of expertly detailed Failure Mode Effects Analysis (FMEA) assessments on existing procedures. From an operating principle, the following design parameters were incorporated: Segregated "once through" HVAC system with HEPA extraction; dedicated personnel and material access routes; dedicated direct product contact equipment; and non-product contact equipment with disposable flow-path. From a process containment perspective, design risk assessments (FMEA) were performed to ensure the minimization of loss of process containment.

GIBRALTAR LABORATORIES

CGMP Independent Lab and Sterilization Services

Gibraltar is a CRO and does not manufacture. It is a 46-year-old scientific service organization specializing in research and development and quality control. It has diversified through integration of an existing CGMP microbiological laboratory with new steam-sterilization and dry-heat depyrogenation services. As a result, Gibraltar is the first to offer certification, terminal sterilization, and ready to use sterile vials that do not compete with CMOs.

The 24,000 ft^2, class 5–8 facility underwent extensive redesign and repurposing of existing and new space. That work incorporated new technologies including air over pressure steam moist heat sterilization, USP water for injection, and ISO classification.

Steam sterilization is a natural, safe, green and sustainable form of terminal sterilization. Renovations are more sustainable than new construction, and in our situation it places the AOP process adjacent to the certification facilities, eliminating transportation costs. One-stop-shopping is a business strategy that is guided by sustainability. Thus, sterilization and certification is efficiently looped into manufacturing to achieve maximium efficiency while providing our customers with significantly faster product turnaround times. Now categorized as a critical vendor, Gibraltar Laboratories supports aseptic manufacturers in bringing new vaccines and drugs to market with known sterilization assurance levels in compliance with the FDA and USP.

喜康 JHL BIOTECH

Installation of KUBio Biomanufacturing Solution

The JHL Wuhan China manufacturing facility has been designed to support the manufacture up to 100 kg of monoclonal antibodies per year in 2,000-L single-use bioreactors. Initially, four 2,000-L bioreactors have been installed. The modules were prebuilt in Germany and transported to China for assembly in eight days. The facility was operational within 18 months.

The JHL Wuhan facility design was optimized to provide efficient use of space and process flow and use the FlexFactory, a single-use manufacturing platform, so it would complement its plant in Taiwan. The standardized nature of the FlexFactory-fitted KUBio will facilitate easy scale-up from process development and early clinical manufacturing in Taiwan, to late-stage clinical manufacturing and commercial production at the new site in Wuhan. Parallel production of the KUBio modules and the FlexFactory processing equipment during site preparations enabled JHL to reduce the overall timeline and begin production as soon as possible.

The Organizations

BEST COLLABORATION AWARD

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.

The PCMM Consortuim

To create the next generation of drug processing technologies and address the rapidly changing requirements of pharmaceutical drug manufacturers, Pfizer, GEA, and G-CON Manufacturing formed a consortium to design and build a portable, autonomous manufacturing environment for continuous oral solid dosage production using GEA's ConsiGma™25 system and G-CON's modular POD system. The result — Portable, Continuous, Miniature and Modular (PCMM) Development and Manufacturing — a platform technology utilized in product development and commercial manufacture for all purposes of medicinal drug product manufacturing.

Throughout the collaborative design process, innovative approaches were incorporated into the project to increase speed, enhance quality and reduce overall project cost. Increased project speed significantly reduced project timelines for facility design and construction; enhanced quality integration of analytical technology sensor systems within the continuous wet granulation and continuous direct compression process equipment; advanced process control capability are able to integrate signals from process and PAT sensors into a real-time monitoring and control system; reduction of overall project costs by lowering upfront investment cost (compared to traditional facility design and build), lowering overall energy costs and depreciating modular PODs as equipment.

Disruptive Cadence Acoustic Separator

Pall Life Sciences and FloDesign Sonics (FDS) began an extremely close collaboration in 2015 to develop their existing acoustic wave separation (AWS) technology for continuous clarification of highly regulated biopharmaceutical products. Within one year time, the teamwork resulted in the commercialization of the Cadence Acoustic Separator, currently the only scalable single-use technology of its kind for cell culture clarification from process development through to large-scale drug manufacturing. This disruptive, scalable technology takes advantage of single-use components with a small footprint and can be applied for continuous clarification from process development through to large scale manufacturing. A drastic (up to 75%) reduction in the filtration area and buffer volume requirements has been noted by users, and process results have proven to be highly reproducible with consistent purity profiles. The platform is flexible for application with various types of biologic products, including recombinant therapeutic proteins and monoclonal antibodies, regardless of the variability in particulate concentrations or cell culture density, turbidity and viability.

FibroSelect for Industrial Use

Puridify Ltd spun out from University College London in 2013 to develop a step-change downstream processing technology for industrial biotherapeutic manufacture. The unique high capacity, high flowrate properties of FibroSelect dramatically reduce unit operation size relative to traditional packed beds. The ready-to-operate units reduce validation burden, improve process robustness and increase facility flexibility. Puridify required industrial quantities of cell harvest material only accessible through industrial collaborations. GSK and Puridifiy have been in a highly complementary collaboration for the past 12 months developing and evaluating the technology from microliter to 50-L pilot scale and in the process have shared knowledge, industrial processing concepts, and novel ideas. This initial collaboration has been successful in proving a 50-fold increase in purification productivity and has been extended for a further 18 months to drive toward full industrial-scale purifying feed from >500-L bioreactors.

In addition to purification productivity, a number of other quantitative and qualitative benefits have been identified and center on processing flexibility, ease of use, speed of processing, reduction of unit operations, and most important, maximizing the productivity of existing and future facilities. FibroSelect offers the potential to address many of the advancements identified as critical to the development of the biopharmaceutical industry but requires in-depth and continuous support from major drug manufacturers to ensure development and market entry with a technology that really makes a difference.

BPI Honors….

2016 INDUSTRY CHAMPIONS AWARD

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.

We are delighted this year to honor **Mark A. Petrich** as our 2016 Industry Champion.

The BPI editors work with many advisors, authors, conference organizers, and industry analysts every day. Although we are continually grateful for the many contributors and other industry contacts who enable us to maintain the high quality of BPI content, we are delighted to honor those who have made an exceptional contribution to the magazine as well to as the industry at large.

Through our biennial awards program, the BioProcess International *editorial staff celebrates this chance to celebrate the accomplishments of an individual whose clear passion, tireless effort, unwavering dedication, and tangible actions have uniquely helped BPI and the industry fulfill their missions. Our industry champion continues to challenge the industry never to accept the status quo and always to look for ways to reinvent and improve development of products and processes.*

Mark A. Petrich

Director of component engineering, **Merck & Co.**

Mark is director of component engineering at Merck & Co. and serves as second vice chair of the Bio-Process Systems Alliance (BPSA). His responsibilities at Merck have included technical support for sterile and solid-dose product manufacturing, clinical supplies production for sterile products and vaccines, process development, and management of laboratory engineering in basic research (Rosetta Inpharmatics). His current role in component engineering involves support for single-use technologies in vaccine and biologics manufacturing and primary packaging components. Before joining Merck, he was assistant professor of chemical engineering at Northwestern University, where he held the M.E. Fine Junior Professor in Materials and Manufacturing chair. He has BS and PhD degrees in chemical engineering from Washington University in St Louis and the University of California, Berkeley.

A key factor in our choice of Mark as our 2017 Industry Champion is his work in promoting single-use technologies — but with a visionary focus beyond the industry's current capabilities. Within the Merck network he is able to promote education and communication regarding single use components to a broad network of end users and clients. With their input and his forward-looking perspectives, he focuses on expanding engagement in disposable materials into a vision of manufacturing processes for the future. Key to single-use manufacturing, especially as more and more companies are exploring continuous processes, is the integrity of component connections as well as compatibility of single-use components with processing materials.

Mark's resume reveals that he has embraced the importance of collaboration and the need to work across what may have been the cross-divisional and -disciplinary divides of the past. His specific contributions include participation in regulatory presentations, regulatory audit response writing, and the Merck Single Use Network: a cross-divisional team promoting single-use technology in manufacturing.

As of 2015, he has served as second vice chair of the Bio-Process Systems Alliance (BPSA, an industry consortium of single use component suppliers and end users). He also is a member of the single-use workstream leadership team of the BioPhorum Operations Group (BPOG) and an editorial advisory board member, *Life Science Leader*.

Through his recognition of the need for communication between suppliers and end-users to help drive single-use advancements into all areas of bioprocessing, and because he is helping to bridge the gaps between the present and the future of biomanufacturing, we are delighted to honor Mark Petrich as our 2016 Industry Champion.

Best Technology

BEST TECHNOLOGY APPLICATION — UPSTREAM AWARD

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.

nova® biomedical

BioProfile FLEX2 Comprehensive Modular Cell Culture Analyzer

Business Application

FLEX2 was developed for all aspects of cell culture. High-throughput design with analysis times as fast as two minutes per sample, coupled with extremely low sample volume requirements as low as 105 uL, provides the industry's only solution for high-throughput screening studies and enables sampling of small volume culture systems. Three unique sampling modes offer the ultimate flexibility for labs running many types of culture systems. Manual syringe mode provides results for all tests while providing the highest accuracy of gas and pH measurements of any available cell culture analyzer. A 24-position external "load and go" carousel provides the most efficient sampling mode for both sequential sampling as well as batch analysis of multiple samples. FLEX2 also can sample directly from 96-well microtiter plates, both deep and shallow well configurations.

Short -and Long-Term Benefits

The technology frees scientists to run their experiments or production using the preconfigured process controller simply by using drop down menus, allowing a scientist to set up recipes at will without needed to have recipes "programmed" to run on the controller. This saves a great amount of time/effort/cost and increases efficiency while empowering scientists and reducing/eliminating the need to rely on software programmers for each new recipe or modification of a recipe.

GLYCOTOPE
The GlycoEngineering Company

Sedimentation in an Automated Microbioreactor (SAM)

Business Application

The SAM model is ideal for selecting clones that will produce product with the desired product quality characteristics. Product produced in the SAM model has highly comparable glycosylation patterns and other product quality attributes to that from the 1-L scale. Furthermore, Glycotope has shown consistent glycosylation profiles between the 12-mL and 1,000-L scales. Glycotope has demonstrated that the SAM model is ideally suited for optimizing cell cultures using a DoE methodology. In one experiment, the 18 perfusion cultures were run in parallel using the ambr 15 systems and were able to identify optimum operating conditions. To perform the equivalent experiment at the 1-L scale would have been costly, time consuming, and labor-intensive.

Short- and Long-Term Benefits

This fully automated, scale-down perfusion method requires minimal operator intervention and therefore has been shown to be highly reproducible and labor-efficient. The technology reduces the significant development costs of cell culture media required to perform perfusion optimization studies. The SAM model reduces the time needed to bring products to the clinic through its capability to operate perfusion experiments in parallel. The ease with which large datasets can be generated using the ambr-based technology is allowing more highly optimized processes to be developed than would otherwise have been possible ,while still ensuring that product quality attributes will be achieved upon scale-up.

STRATOPHASE™
INSIDE KNOWLEDGE

Ranger Service

Business Application

The Ranger service is an innovation in cell culture upstream process development that, for the first time, permits changes in the metabolic rate of cell cultures to be measured in real-time and on-line. This information then allows for process parameter changes to keep the cells in an optimally active and healthy condition. Use of this innovative new approach in cell culture process development has resulted in multiple benefits: more robust processes developed, shorter timelines, and improved productivity. This new approach provides insights into the dynamics of a cell culture process that were not previously available.

Short -and Long-Term Benefits

The Ranger service supports process development scientists in measuring changes in the metabolic rate of a cell culture and allows corresponding process parameter changes (such as feeds) to be automatically triggered to maximize cell metabolic rate. This achieves healthier cells, produces higher product titers, minimizes process risk, and leads to consistent and repeatable product quality. Ranger provides real-time, on-line, automated process parameter control and optimization, such as for cell culture feeding. This leads to many valuable benefits in bioprocess development and a competitive advantage for biopharmaceutical companies. Critically important benefits include speedier process development; more robust processes with less inherent risk; higher product titres, realized earlier on in development; healthier cells producing consistent product; an effective increase in limited process development capacity; and an overall lower cost of goods.

Best Technology

BEST TECHNOLOGY APPLICATION — DOWNSTREAM AWARD

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.

PALL Life Sciences

Cadence Acoustic Separator

The Cadence Acoustic Separator is a scalable single-use technology for cell culture clarification using acoustophoretic separation from process development through to large-scale drug manufacturing. It provides a novel, low-impact method of suspension clarification, separating cells and cell debris from cell culture fluid rapidly and efficiently. And uniquely, the Cadence Acoustic Separator can provide scalable continuous clarification when directly linked to primary downstream capture chromatography.

The Cadence Acoustic Separator features five peristaltic pumps that enable the use of four Cadence Acoustic Chambers that use a low frequency acoustic wave to generate a three-dimensional standing wave across a flow channel. Cell culture from a fed-batch bioreactor enters the flow channel, and as the cells pass through the 3D standing wave, they are trapped by the acoustic forces. The trapped cells migrate to the nodes of the standing wave and begin to clump together until their buoyancy decreases and they settle out of the suspension by gravity. The cells can then be removed. In fact, the Cadence Acoustic Separator allows the cells to be continuously removed in a closed system without centrifugation or primary depth filtration, thus streamlining this challenging step in the biologics manufacturing process within a small operating footprint.

PURIDIFY

FibroSelect

FibroSelect adsorbents from Puridify have the potential to enable disposable product capture purification at industrial scale by vastly improving productivity. The unique high capacity, high flowrate properties of the proprietary adsorbent dramatically reduce unit-operation size relative to traditional packed beds. The ready-to-operate units reduce validation burden, improve process robustness, and increase facility flexibility. Protein A FibroSelect can achieve purification productivities in excess of 450 g of MAb purified/L adsorbent/hr using a single cartridge on standard equipment. This is compared to just 6–15 g/L/h achievable with traditional packed beads. Using a multicycle, single batch mode of operation, FibroSelect units have demonstrated an ability to match process critical quality attributes when cycled over 190 times with three-minute run times (one-second residence times). With dynamic binding capacities of >30 mg/mL and novel housing devices with optimized fluid flow regimes, the buffer-use and product-concentration concerns of high-flowrate chromatography applications are alleviated.

The rapid growth of single-use technologies is driven by various known processing considerations, with the obvious gap in product-capture purification technologies. FibroSelect offers the potential to address many of the advancements identified as critical to the development of the biopharmaceutical industry supported by research and analysis from leading organizations.

SANOFI

Accelerated Seamless Antibody Purification (ASAP)

ASAP (Accelerated Seamless Antibody Purification) is a Sanofi-owned platform for continuous purification of MAbs (patent pending). ASAP was developed in the Bioprocess Science and Technologies department (Sanofi Vitry sur Seine, France), enabling running of three chromatography steps in continuous mode with no holding time nor open phase, including virus inactivation. This means that a cell culture bulk containing MAbs can be fully and continuously processed to obtain a pure MAb batch without human intervention, decreasing process duration, resin, and buffer costs. Dynamic evolution of ASAP already includes use of membrane chromatography instead of conventional resins, leading further improvement of productivity.

The process simplification underlying ASAP has only one goal: Bring the process to higher productivity while keeping the purification simple and independent from complex technologies that could challenge process robustness. A key benefit of the advantages of the ASAP process and the continuous processing is elimination of non–added-value unit operations like adjustment of pH, molarity, and protein concentration and intermediate filtration and storage. The second advantage is a shortened process cycle time to complete the entire purification in less than three hours. For these reasons, processing in a continuous mode with ASAP is an industrial grail.

Best Technology

BEST TECHNOLOGY APPLICATION — ANALYTICAL AWARD

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.

Catalent

BioLayer Interferometry

Business Application

The system defined is, essentially, a toolbox approach for assessing MAb/Fc receptor binding kinetics. The intent is to eventually use the analytical panel both for characterization of biosimilar molecules and comparison to originator molecules, as well as for CMC-related release and stability testing.

Short- and Long-Term Benefits

It is important to test therapeutic MAbs for binding with the complete panel of human IgG-Fc-binding receptors for characterization of original therapeutics and/or testing of biosimilar MAbs. If the MAb is an effector MAb, then it is necessary to show consistency in binding to the high and low affinity receptors CD64, CD32, and CD16. If the MAb is a neutralizing moiety only (no effector function), one might then expect altered binding, if any, to the Fc receptors. However, all antibodies will bind in some fashion to them. More important, all antibodies will bind to FcRN, which despite the name *neonatal,* is present in adult bone marrow–derived cells as well as in other tissue. It is essential that the established Fc Receptor panel test not require derivatization of the MAb (analyte) and be easily adaptable to other MAbs.

OVIZIO IMAGING SYSTEMS

iLine F

Business Application

The iLine F is a smart device for continuous real-time suspension cell monitoring in bioreactors and disposable bags, limiting the number of operations and improving reproducibility of cell culture processes. The automated system combined with the OsOne machine-learning software offers user-independent reproducible quantitative 3D live cell imaging thanks to differential digital holography microscopy.

The Cell Therapy Catapult of the United Kingdom has selected the iLine F in-line monitoring microscope to support development of its multiple cell therapy projects. The center now has a powerful solution to automatically count viable cell density with great accuracy, resulting in improved process insights and reduced production costs.

Short- and Long-Term Benefits

Existing offline manual sampling methods lead to high workload, variability, and contamination risk. Differential Digital Holographic Microscopy is a new quantitative technique allowing automated cell counting as well as cell viability monitoring in a continuous, label-free set-up, eliminating the need of sampling (risk of contamination, workload and variability), staining, and waiting for the results generated by an off-line counter. The iLine F is an innovative and efficient solution to comply with the PAT guidance from regulatory agencies. Cost comparison with traditional counters showed that the iLine system enables a decrease in yearly operational costs by 40% for medium-sized facilities and up to 60% for large facilities. It can be used in R&D, process development, and production.

SCIEX

High Throughput Glycosylation Analysis

Business Application

There is a growing demand in the biopharmaceutical industry for high throughput and large-scale N-glycosylation profiling of therapeutic antibodies in all phases of product development. This is especially true during clone selection, when hundreds of samples should be analyzed in a short period of time to assure their glycosylation-based biological activity. Therefore, development of a novel, fully automatable protocol was necessary. The magnetic-bead–based protocol for N-glycosylation analysis of glycoproteins alleviated the hard-to-automate centrifugation and vacuum-centrifugation steps of the currently used protocols.

Short- and Long-Term Benefits

Automated liquid handling processing offered fast and precise sample preparation, reduced flow-induced shear strain on native biological sample matrices, and minimized contamination risks. Fully automated sample preparation in this instance means no human intervention is needed from the beginning to the end of the sample preparation process. The approach was capable of large-scale sample processing to accommodate rapid glycan analysis of therapeutic antibodies for the biopharmaceutical industry. In addition to the comparison of the glycosylation profile of an innovator drug to its biosimilar counterpart, the biological significance of the differences can also be addressed with the technology. Applying this magnetic-bead–based glycan sample preparation protocol with a laboratory automation workstation, a large number of samples can be processed in 96-well plate format within a couple hours, requiring no centrifugation or vacuum-centrifugation steps.

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