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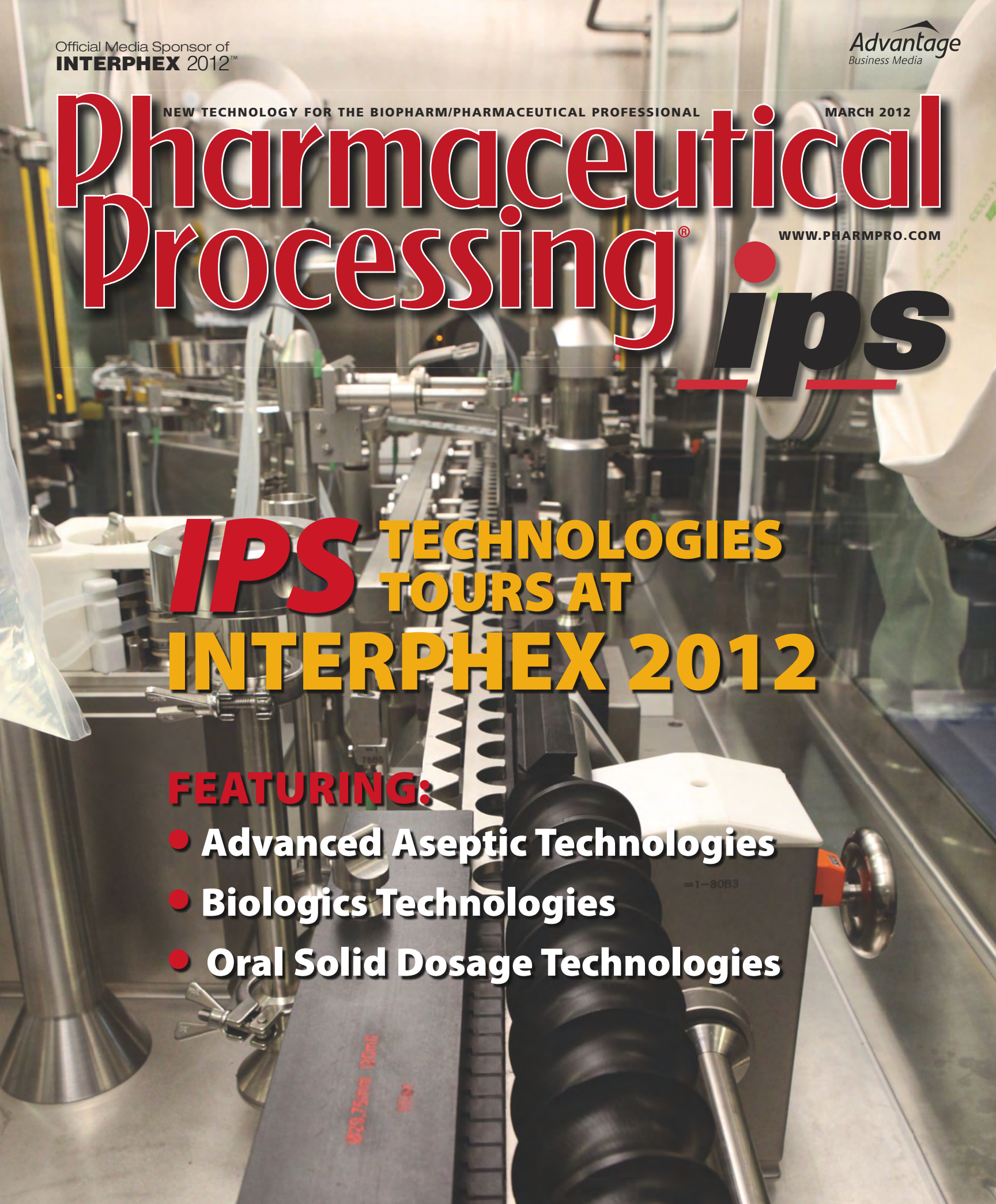

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BIOLOGICS TECHNOLOGIES

Wednesday, May 2: Tour takes place at 10:00 am & 12:30 pm and begins at Room 1E13

Tour features a comprehensive view from leading suppliers of new developments and innovative technologies that can dramatically change the design, construction and operation of biopharmaceutical manufacturing facilities.

Tour Leaders: Jeff Odum, CPIP - Director of Operations/ Biotechnology Lead; Chuck Stock, MBA – Sr. Principal, Senior Consultant; Diana Karnas – Director of Facilities Planning and Design; Gene Martini, PE – Senior Director, Operations, IPS

Tour will kick-off with a brief client presentation.

ORAL SOLID DOSAGE TECHNOLOGIES

Wednesday, May 2: Tour takes place at 10:00 am and 12:30 pm and begins at Room 1E14

On the tour, view efficient processing options, innovation and recent developments in advanced oral solid dosage form technologies from leading suppliers.

Tour Leaders: Russ Somma, PhD, - President, SommaTech Consulting; Mike Vileikis - Lead Process Engineer; Felix Diaz - CAAPPR, NCARB - Director, Process Architecture and Facility Design; and Sam Halaby - Director, Process Technology, IPS

Tour will kick-off with a brief client presentation.

ADVANCED ASEPTIC TECHNOLOGIES

Wednesday, May 2: Tour takes place at 10:00 am and 12:30 pm and begins at Room 1E12

Visit leading aseptic technology suppliers to discuss new technologies, innovation and new strategies.

Tour Leaders: Sterling Kline, RA – Advanced Aseptic Processing Expert; Rob L. Roy, PE – Director of Aseptic Technology; Jason S. Collins, RA, NCARB – Director of Process Architecture, IPS

Tour will kick-off with a brief client presentation.

TECH HIGHLIGHTS

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Please join IPS and INTERPHEX on Wednesday, May 2 for a private reception to be held from 3:00 pm to 5:00 pm in Room 1E21.
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Next Gen Biomanufacturing: Developing the Manufacturing Facility of the Future


Jeff Odum


Chuck Stock


Diana Karnas


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By Jeff Odum, CPIP - Director of Operations/Biotechnology Lead; Chuck Stock, MBA – Sr. Principal, Senior Consultant; Diana Karnas – Director of Facilities Planning and Design; Gene Martini, PE – Senior Director, Operations, IPS

In February of 1985, Ed Bjurstrom's article, "Biotechnology," was published in Chemical Engineering magazine. It was an early survey of the unit operations, from a process engineering viewpoint, that comprised the typical bioprocess manufacturing trains of the time. A look back at this article today is highly informative; it serves as a base point from which the trajectory of the industry emanates at the time of Eli Lilly's Humulin, and in the years before the approval of Epogen and Protropin. Fermentation processes are discussed in great detail, but the term "cell culture" is noticeably absent. Bioreaction systems contain "potential product worth perhaps tens of thousands of dollars" and chromatography column diameters are measured in centimeters, not meters. There is no mention of virus clearance using TFF or any other means. And as one would expect, the article in no way anticipates single-use systems and related technologies like in-line dilution buffer manufacturing.

A read of Bjurstrom's article in today's context provides a single, clear illustration of the degree to which the Biotech Industry has changed and continues to change. But these changes extend far beyond the process technologies that were the focus of the article.

The growing availability of health care around the globe, and improving living standards required to pay for that health care, are driving increases in product demand. Legal and geopolitical changes are creating new drivers to manufacture in different regions, countries, and continents. Consumers are less and less tolerant of product quality failures, and regulators are more willing to take action against the non-compliant. Communities are more sensitive about the use of local resources, such as water. And of course, investors are just as interested in conserving capital and maximizing their returns as they have ever been.

MARKET PRESSURES

The pressures from myriad market forces in the environment of the Biotech Industry have made designing, building, qualifying and operating biopharmaceutical manufacturing facilities a pursuit dramatically different in the twenty-first century from that of Bjurstrom's article. But biopharmaceutical industry scientists and engineers are a resilient, creative lot, and they have risen to the challenge to conceive numerous valuable enabling technologies that can be exploited to address these market pressures. Of all these developments, none shows greater promise than the single use systems currently being implemented by industry visionaries. Single use technologies promise to improve flexibility, reduce energy and water consumption, cut capital investment, minimize Cost of Goods Sold, and increase the capacity per square foot of a biopharmaceutical manufacturing facility.

These improvements will be critical for the industry to continue to grow. Facilities will need to achieve high product quality in the shortest possible time following the decision to build. Flexibility to allow for multiproduct manufacturing, application of continuous improvement in operations, and rapid campaign changeover will be necessary for organizations to respond to the increasing pace of change. Minimization of environmental footprint will be important to drive down costs.

With increasing in-vivo insights into product requirements and improving in-vitro analytical protein characterization methods, the critical path for the development of new products will continue to shift toward the process development and manufacturing phases of the product life cycle, resulting in changes to the focus of equipment and facility design. That is, higher process outputs and better

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characterized products and processes will need facilities that take advantage of these advances. This requirement represents the primary challenge for the future of manufacturing in the Biotechnology Industry.

TECHNOLOGY AS AN ENABLER

The bioprocess technologies that have emerged in recent years, and the technologies that continue to emerge, will be the enablers for the development of facilities that are capable of achieving these cost and flexibility requirements. But the influence of these technologies will span far greater than the design and construction of a new building; the influence will spread through the life cycles of an organization's product portfolio, from capacity planning through product maturity.

Starting with capacity planning, the agile, flexible facility of the future will have a dramatic impact by reducing and organization's dependence on accurate forecasting. It is extremely challenging to estimate, even within an order of magnitude, the capacity requirements for a new product. Between variations in dosage, market penetration, ever-changing competition, and uncertain process performance, the required size of a facility can vary by several orders of magnitude. Although progress is being made, particularly in process performance, determining the size and nature of a manufacturing facility remains a huge challenge.

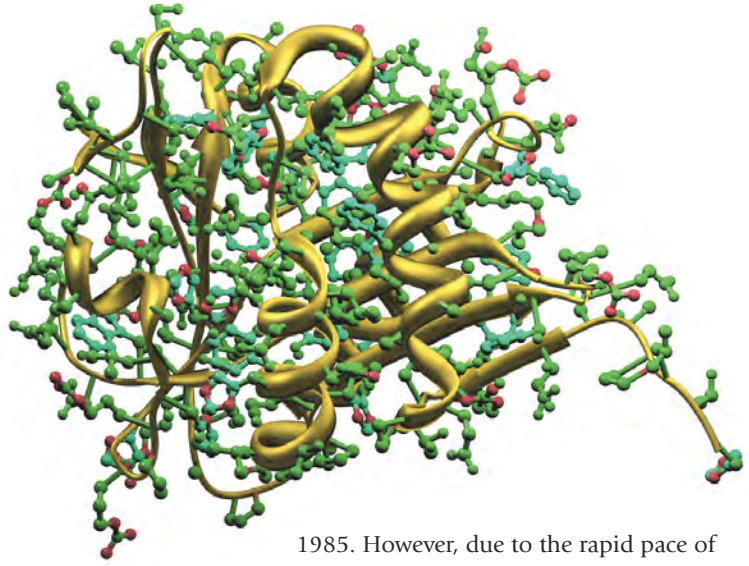
Moving along the product life cycle, it is apparent that the new technologies available to the industry will have a significant impact on late-stage clinical manufacturing. Most biopharmaceutical organizations place a high value on the capability to manufacture Phase III material using the same process and facility that will be used for commercial production. There are significant cost and schedule opportunities to be taken by manufacturing launch material from the same facility that made the clinical material, and regulatory risk is significantly reduced when Phase III material comes from the commercial facility. After Phase III material is manufactured, redeployment of the facility to manufacture other products while maintaining the ability to make new products is another opportunity as the waiting time between Phase III material production and the next step can be significant.

The production of material to support product launch, generally a considerable amount of material depending on market projections, is demanding. After the launch material is produced, turning over a facility to manufacture other products is a significant challenge. Addressing this issue is a key concern for many organizations as they conceive their upcoming factories, and application of the latest bioprocess technologies will support this level of flexibility.

Many of the issues discussed above extend through the life cycle of the product into maturity. But the length of a product's life cycle is another critical factor driving the need for flexibility in biotech facilities. Some products are quickly replaced due to competition, while the life cycles of other products may extend for long periods. Some products need to be relocated for tax or logistical reasons. Demand may suddenly increase in response to the discovery of new indications. These ever-changing requirements are leading manufacturers to solutions employing single-use manufacturing platforms, flexible multiproduct manufacturing units, improved cell culture technologies, and more efficient product purification operations.

TOUR DETAILS

The Biologics Technologies Tour at INTERPHEX 2012 will survey many of the same unit operations described in detail by Bjurstrom in



1985. However, due to the rapid pace of change and development in each of these manufacturing process steps over the past 25 years, many of these unit operations are barely recognizable; they are now designed for single-use and application in multiproduct facilities. Product storage containers are no longer expensive, fixed stainless steel vessels; they are now plastic bags in light-weight portable assemblies. Many of the problems of integrity of bag seams and leaching of polymeric components into product have been resolved, and now this bag technology is being applied to the manufacture of common biotech solutions such as media and buffer.

Key unit operations such as bioreactors are now conducted in similar plastic bags, complete with agitation and feed ports. Disposable instruments, such as pH, conductivity, and dissolved Oxygen sensors, are now readily available and integral to the disposable bioreactor.

In downstream processing, microfiltration and ultrafiltration elements have been disposable for many years. Today, complete MF and UF rigs are available in single use assemblies, and manufacturers have recently introduced disposable depth filtration systems as well.

In addition, the Biologics Technologies Tour will survey the latest advances in the most challenging single use applications: solution manufacturing through in-line dilution and chromatographic separation. As these technologies become mature and are accepted by the industry and its regulators, one can see the shape of the biotechnology facility of the future come into clearer focus.

The organizations that are on the leading edge of these advances will be the focus of the Biologics Technologies Tour at INTERPHEX 2012. The tour will provide attendees the opportunity to learn specifics on how these technologies are changing the face of biologics manufacturing today. Led by noted industry experts, the tour will make stops at selected vendor exhibits and provide an ideal opportunity to obtain information on the latest advances in these technologies and exchange information with commonly-interested attendees. This event has been designed to include the organizations currently making the greatest advances in the enabling technologies that will drive the paradigms for the biotech facility of the future. These organizations include EMD Millipore, Sartorius Stedim, Xcellerex, GE Healthcare, GEA Process, Abec, Inc., Thermo Fisher/Hyclone and Pall Life Sciences.

The Biologics Technologies Tour will be kicked-off by Jeff Odum, CPIP & Director of Operations at IPS. In addition, Mr. Odum will present on how these challenges to our Next Generation Manufacturing Facilities are now being met by the most advanced technologies. If one of your objectives at INTERPHEX is to evaluate the implications of trends in bioprocess technology, and to look into the future of this fascinating industry, you will find that this is not an opportunity to be missed. ■

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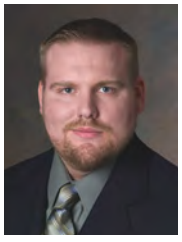
Should it be Scale-Up or Scale Out . . .

Bigger is Not Always Better or Faster

Russ Somma, PhD.



Mike Vileikis

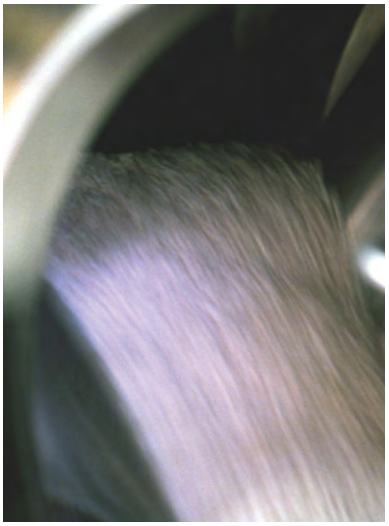
Felix Diaz

Sam Halaby

By Russ Somma, PhD, - President, SommaTech Consulting; Mike Vileikis - Lead Process Engineer; Felix Diaz - CAAPPR, NCARB - Director, Process Architecture and Facility Design; and Sam Halaby - Director, Process Technology, IPS

In the current environment, the pharmaceutical technologist is faced with an ever changing series of regulations, difficult to process drug substances and the time to make market entry and reach maximum product potential. For many drug substance candidates, the inherent physicochemical and pharmacokinetic properties pose unique challenges necessitating the application of advanced solid dosage form technologies. The same is true for innovators as well as generic firms that are manufacturing bioavailable products; which are seamlessly reviewed and reach the market quickly. Imbedded in this technical tapestry is the inevitable question of how large a batch needs to be, or more fundamentally, 'what scale do I need to achieve?'. In many cases, the need for scale-up and the effort to achieve this are looked at as a major technical challenge.

This discussion will provide alternatives to this aspect by considering the risk in scale-up as opposed to the concept of scaling-out using a batch process which is more aligned with that of a 'pilot scale' or carry the pilot/small scale concept through to commercial manufacture. There are many advantages to the use of smaller, more flexible equipment; none the least of which is the reduced risk offered by avoiding scale change and the associated economics of facility requirements and capital equipment cost. The approach requires a fundamental consideration as to the nature of scale or more importantly batch size. It is these concepts which need to be re-considered in the pharmaceutical industry. Based on the literature, it is intuitive that a novel approach to commercialization at smaller scale offers an opportunity for increasing product understanding, product quality, reducing cost, minimizing facility infrastructure and leveraging the early stage knowledge store for not only manufacturing clinical supplies, but to allow this process knowledge to be used to commercialize and launch product. The utilization of early stage knowledge aligns with FDA's Quality by Design approach as well as conforming with the new process validation guidance issued in January 2011.



By following an unencumbered approach when determining scale, processors can realize advantages. If a process can be well-defined at the early stages, then risk is reduced and a successful process introduction will be achieved while avoiding resources needed to develop the new scale. To realize these advantages a firm should look to batch size and manage it by applying supply chain concepts such as a 'just in time' paradigm where the amount of product to be produced will be a function of a number of smaller 'batch units'.

If the pharmaceutical technologist is limited to developing a process which must meet a predetermined 'batch size' requirement, his ability to move efficiently through to commercialization will contend with the risk inherent in scale-up. If, however, an unencumbered approach is taken by the technologist where the process will be at a scale that has been well defined in the early stages, then risk is reduced and a successful process introduction will be achieved while avoiding resources needed to develop the new scale. To get to this situation, a firm should look to batch size and manage it by applying supply chain concepts such as a 'just in time' paradigm where the amount of product to be produced will be a function of the number of smaller 'batch units'. Then the business case will align with the established knowledge store created early in the product development cycle. Time to market will be reduced, capital costs minimized, technical risk mitigated and a path toward product introduction is set. It also allows time for the potential market to dictate the appropriate increase in scale size, if needed.

WHAT ABOUT THE REGULATIONS?

This is a topic which routinely comes up during the discussion about batch size, or more to the point, what is defined as a batch for pharmaceutical firms to address when defining their commercial strategy. The genesis of the discussion has been around for many years in the industry, as evidenced by a section devoted to scaling changes in FDA's Scale-up and Post Approval Changes Guidance and

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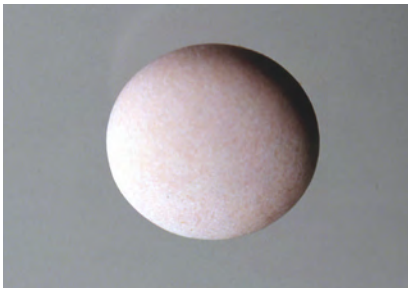
has its roots in the debate surrounding continuous or semi-continuous process designs. A literature search on the topic reveals a significant amount of the current thinking on the subject. This is seen in a recent article published in Pharmaceutical Technology, September 2011. In this article, the discussion centers more on the aspect of the use of innovation by industry when designing processing scenarios. When one considers our current topic as it concerns use of scale-out while employing novel small scale approaches and the guarded attitude of industry, the point made appears to lend itself to placing the implementation of 'batch size' criteria squarely in the laps of industry and their closely held concept of scale-up and the associated area of 'what do we define as a batch?'.

According to the article noted above, Moheb Nasr, at the time director of the Office of New Drug Quality Assessment, Center for Drug Evaluation and Research at FDA, speaking at INTERPHEX March 2011 stated, "There are no regulatory hurdles for implementing innovation in pharmaceutical manufacturing." A key point made by Nasr is that current regulations do not distinguish between batch and continuous manufacturing. "The regulations are silent about the mode that must be used," he said. He emphasized that the term "batch" does not denote a mode of manufacturing, but rather defines a specific quantity of a drug or other material that is intended to have uniform character and quality. The regulations specify: "A batch means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture." Moreover, a "lot" refers to a "batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it having uniform character and quality within specified limits". It would appear that the use of multiple small batches which have been scaled-out at a 'pilot scale', for example, may be managed by the firm using a smaller 'batch unit' approach, which is a hybrid of the continuous process being discussed. That being stated it then becomes a matter of the business model used by a firm to take the scale-out rather than the scale-up approach to bring products quickly down the development path on their way to commercial introduction.



Industry experience shows that small scale behavior is completely different for most unit operations during a scale change so the obvious question that needs to be asked is why scale-up when the option to scale-out at the proven smaller or pilot scale is less of a risk proposition.

WHAT ABOUT THE TECHNOLOGY AND PROCESSING STRATEGY?

The discussion takes a familiar tone, simply stated, we have a long history of events which document scale-up challenges. It is fair to say that failure at scale-up is not so much of a surprise, but rather one of damage control after the fact. Scientists have been trying to gather all the key parameters for decades, but, unfortunately, there are still no exact and well-established rules ensuring an accurate transition for solid dosage forms from one scale to another. Industry experience shows that small scale behavior is completely different for most unit operations during a scale change so the obvious question that needs to be asked is why scale-up when the option to scale-out at the proven smaller or pilot scale is less of a risk proposition. So we need to challenge the batch-wise process and look to a hybrid scale and 'batch unit' application in a pharmaceutical manufacturing plant. We need to consider some additional factors which are collateral advantages to the use of small and inherently more flexible process scenarios.

One thought leader in the area, H. Leuenberger, states this well in his discussion of "scale-up in the 4th dimension" wherein he outlines an approach using multiple smaller batches to achieve commercial introduction. He describes a quasi-continuous production concept which takes advantage of a smaller batch with some aspects of a continuous process. The concept allows a large batch B which would consist of n subunits of sub-batches (b) such that a batch would for example be equal to B=nb.

Several innovator companies have taken the approach wherein they view new products with limited process experience by minimizing scale and taking advantage of a hybrid processing approach such as smaller batches against the backdrop of a semi-continuous process scenario.

The technology to achieve scale-out is best visualized when reading the description given by Tom Chirkot from Patterson-Kelley, "The equipment required for pharmaceutical processing of a directly compressible tablet is just a couple meters long, including feeding devices. The entire system is small enough to be placed over a tablet press". This suggests that the use of a hybrid approach such as scale-out as opposed to scale-up is limited only by a firm's desire to take an innovative step toward product quality and leveraging their knowledge store.

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James Mossop - jmossop@fetteamerica.com
INTERPHEX Booth No. 1524A

GEA Pharma Systems
9165 Rumsey Road,
Columbia, MD 21045
443-766-1136
www.niroinc.com
McCoy Knight, National Sales Manager
mccoy.knight@geagroup.com
INTERPHEX Booth No. 2421

KORSCH America Inc.
18 Bristol Drive
South Easton, MA 02375
www.korschamerica.com
sales@korschamerica.com
508-238-9080; Fax :508-238-9487
INTERPHEX Booth No. 3327

L.B. Bohle LLC
400 Veterans Circle, Suite 100
Warminster, PA 18974
www.bohle-tablet-coater.com
215-957-1240
Martin Hack, Vice President and General Manager
INTERPHEX Booth No. 2253

SKAN US, Inc.
7409 ACC Blvd, Suite 200
Raleigh, NC 27617
www.skan.ch; 866-381 7685
INTERPHEX Booth No.2271

Telstar North America, Inc.
1504 Grundy's Lane, Unit 2
Bristol PA 19007 USA
www.telstar-lifesciences.com
telstar.na@telstar.eu; 215-826-0770
INTERPHEX Booth No. 3337

Case Study: Brazil Fill/Finish

The Role of CMO's in Supporting Global Vaccine Production Needs

Sterling Kline

Rob L. Roy

Jason S. Collins

By Sterling Kline, RA – Advanced Aseptic Processing Expert; Rob L. Roy, PE – Director of Aseptic Technology; Jason S. Collins, RA, NCARB – Director of Process Architecture, IPS

This year's 5th Annual Advanced Aseptic Processing Tour features a case study of an Advanced Aseptic Processing facility for the production of lyophilized and liquid dosage form vaccines and biopharmaceutical products. This state of the art greenfield facility will be located in Brazil, and is slated for completion on or about 2Q 2016. The program is structured to provide an outstanding overview of the pharmaceutical facility design process, featuring the role of top tier equipment vendors in developing and supplying "Best Available Technology" to address technical challenges throughout the project. Persons engaged in a pharmaceutical design activity or supporting role will find the presentation and tour to be of great value.

The tour commences with a brief project overview, provided by Jason Collins (Director of Process Architecture) and Robert Roy (Director of Aseptic Technology) from IPS services. Jason and Rob have been involved with the project since the concept phase, and will speak to IPS's unique project development approach, which focuses on risk mitigation through separation and automation (QbD) to ensure product quality while meeting the projected production capacity requirements.

From the onset, the customer has been committed to sustainable global regulatory compliance for the facility. This is best achieved through a primary reliance on engineering and architectural controls to ensure product quality, or in other words by building quality into the process. Use of Administrative Controls (SOP's) in place of either engineering or architectural controls is strongly discouraged at all design phases.

The role of equipment vendors in achieving the objectives of sustainable compliance + production efficiency can hardly be overstated. Top tier equipment vendors design and fabricate a large number of fill finish lines each year. Their design groups therefore serve as repositories of the "best thinking" in the pharmaceutical industry on how to approach various problems. Their real world experience in manufacturing, testing and operating these systems provides the best possible feedback with respect to which systems and features are cost effective, reliable and user friendly. These systems and features then become, by definition, the "Best Available Technology". Through close collaboration with these equipment vendors, a number of Advance Aseptic Processing technologies have been selected for inclusion in the facility design basis. These include, but are not limited to, the following:

1. Barrier Isolation technology for aseptic formulation and fill/finish operations, including lyophilizer loading and unloading. Barrier isolators are widely regarded as providing the highest level of sterility assurance for the product, while at the same time protecting the operators from exposure to the product. Previous difficulties with isolator validation, turn around, etc. have been overcome as is demonstrated by the large number of successful, approved installations worldwide.
2. Single Use Disposable Systems (SUDS) for selected formulation, filtration/ transfer, buffer storage, and filling applications. Single Use Disposable systems greatly reduce or eliminate product cross contamination and batch-to-batch carryover risk. The design basis for this facility incorporates Single Use Disposable fluid paths for all filling machines, a specification made possible by recent improvements in vendors peristaltic filling systems and development of SUD positive displacement filling systems. Other unit operations are under investigation for application of SUDS, for example stabilizer prep, filtration and storage, vaccine pooling and formulation, bulk product sampling, etc.
3. 100% Non-Destructive Checkweigh systems to ensure vial filling accuracy. This Process Analytical Technology (PAT) has seen recent improvements in accuracy and speed; 100% checkweighing can now be realized at line throughputs of up to 400 vials per minute (vpm). Use of this technology ensures correct dosing for all containers under all processing conditions, including for example filler starting and stopping. This technology also eliminates the need for isolator provisions to segregate vials in the event of a bad checkweigh.
4. In-line automated inspection for liquid products, to ensure product quality and to minimize reject generation. Direct coupling of the inspection machines to the liquid fillers is included in the design basis. Advances in inspection technology allow for automated high speed inspection for a variety of quality attributes including for example absence of visible particulate, cosmetic defects to the vials/

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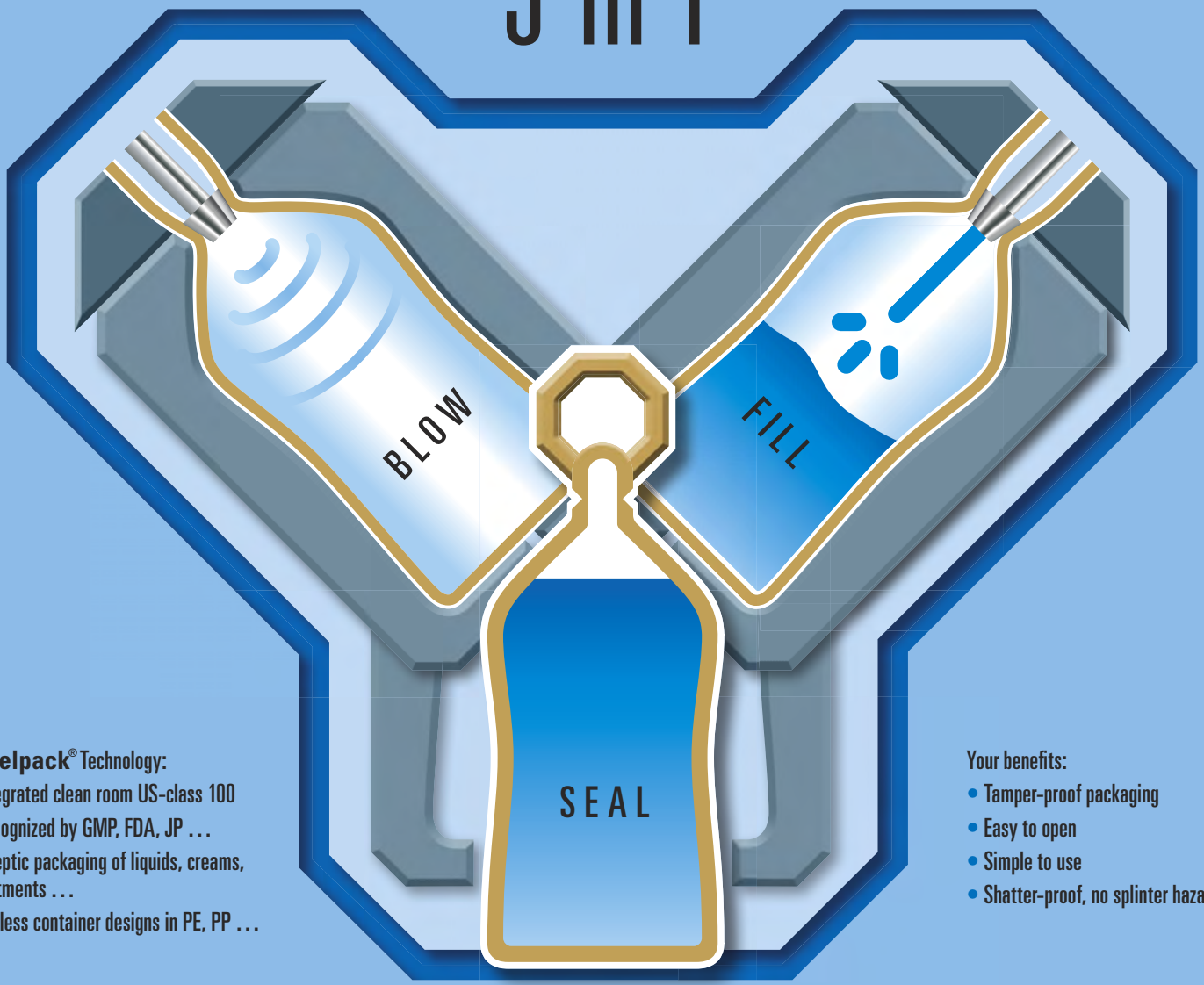

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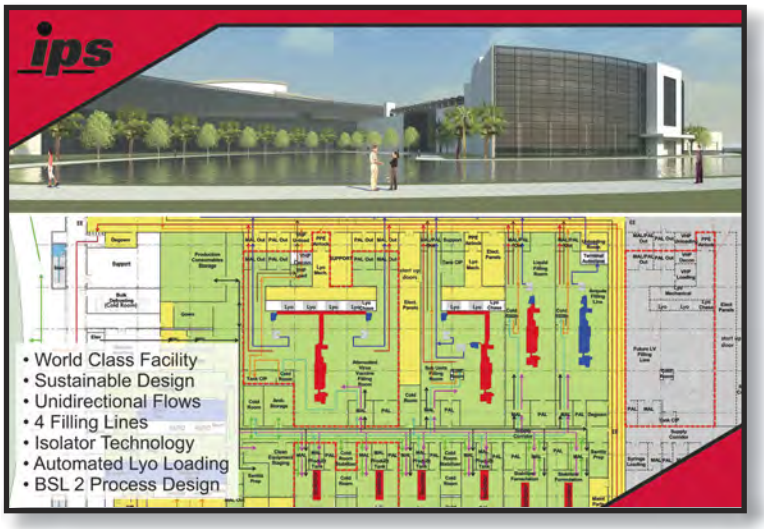

caps, headspace analysis, etc. Direct coupling of the line for liquid filling means that these attributes are inspected in real-time with respect to manufacturing; in the event defect generation rate exceeds pre-established parameters the line can be stopped to investigate and/or correct the root cause.

5. Advanced Stopper Processing Systems, for cost effective in-house processing of serum and lyo stoppers. The stopper processing systems under consideration offer secure and reproducible stopper processing, to include washing, siliconization, sterilization and drying. The delivery systems provide secure storage and transport of stoppers from the component prep area to the isolated filling line, and secure transfer of stoppers into the filling isolator for processing.
6. Raised/missing stopper inspection, monitoring of capping parameters, and post-capping crimp quality inspection – compliance with EU Annex 1 requirements for vial sealing. Recent changes in regulatory requirements for this unit operation have introduced new requirements and considerably design complexity into this once straightforward operation. Questions to be answered now include whether to cap inside the isolator or in a RABS; requirements for a "Grade A Air Supply" when RABS is selected, whether or not to include raised/missing stopper inspect/reject capability, whether to monitor capping parameters (head pressure and vial rotation) during sealing, use of in-process testing to demonstrate Container Closure Integrity (CCI).

The current design basis includes stoppering in a RABS enclosure immediately outside the barrier isolator, with gloveport access at all point upstream of the vial sealing stations. This design avoids having to sterilize overseals during routine processing, but necessitates installation and qualification of raised stopper inspection equipment to comply with FDA expectations. We have also included monitoring of capping parameters during sealing, and use of in-process testing (e.g. Residual Seal Force monitoring) to ensure container closure integrity. Due to the potential impact of this unit operation of overall reject rates and production efficiencies, we are also focusing on component quality, and are investigating the feasibility of post capping crimp quality inspection via camera based systems.

Following the overview presentation, a series of vendor booth visits is planned. These visits will focus on and provide additional detail for the various applied technologies within the project, and will provide an opportunity to meet vendor representatives and exchange contact information.

Vendors were selected based on excellence of equipment and technological design as well as proven project execution capabilities. Due to time constraints on the tour it was necessary to limit the tour to eight (8) vendors. There are a number of other excellent equipment vendors under consideration for this project; a complete listing will be available upon request

.

BOSCH PACKAGING:

Bosch's recent developments in peristaltic filling system technology and single use disposable positive displacement filling systems, and barrier isolation technology will be highlighted during the tour. They will have several machines/processing lines on exhibit, including their new FXS3100 syringe line, and an FLT 30 Intermittent motion vial filler.

GRONINGER:

Groninger's newest peristaltic filling system in conjunction with custom engineered single use disposable systems, and recent innovations in vial capping will be highlighted during the tour.

IMA LIFE

IMA Life is under consideration to provide vial filling and closing equipment, barrier isolators, lyophilization equipment and load/unload systems, and secondary packaging equipment. Recent developments in controlled nucleation (Iyo process), lyo slot door design, vial filling (clinical) and barrier isolators will be discussed on the tour.

SKAN

SKAN is under consideration for barrier isolator systems and ancillary equipment for vial filling, lyo loading and unloading, and aseptic product formulation. Ancillary systems include for example rapid transfer H2O2 airlocks and glove integrity testers.

Recent advances in airflow management, reduced cycle times, material transfer, and isolators for processing of high potency materials will be presented during the tour.

AES

AES's commitment to continuous product improvement has resulted in myriad incremental improvements to the fit and finish of the wall panel system itself, and to innovative accessories such as walkable light fixtures to provide improved maintenance access in interstitial spaces.

During your tour with IPS, AES will have full scale displays of their ½ inch and 2 inch wall panel systems, ceiling panels and other integrated features such as PVC doors, glass doors and windows.

STILMAS

Stilmas is under consideration to provide complete turnkey clean utility generation systems for Water for Injection and Pure Steam, for the cost effective and reliable supply of these critical utilities for pharmaceutical production.

ROMMELAG

Rommelag is under consideration for supply of Blow-Fill-Seal equipment to diluent production, to replace production of these diluents in ampoule format. Their recent efforts in adapting BFS technology for biological products and their product development and support capabilities (BSL2 facility) will be highlighted during the tour.

SARTORIUS STEDIM

Sartorius is under consideration for design and supply of Ready To Use (RTU) Single Use Disposable Systems for filling, filtration, transfer, and buffer storage. ■

Aseptic Technologies Tour Registration

www.interphex.com/Register/

Tour space is limited. To register for the Tours:

1. Visit : **www.interphex.com/Register/**
2. Click on "Attendee Registration" and Complete Information in the "New Registration" Section
3. Enter Priority Code: IPS12
4. Click "Continue" and complete demographics
5. On the next screen view, the Tours page where one can chose which tour and time they are interested in
6. Complete registration process

Aseptic Technologies Tour Participating Companies and Contacts

AES Clean Technology, Inc
422 Stump Road
Montgomeryville, PA 18936
www.aesclean.com
888-AES-CLEAN ext. 103
Fax: 215-393-6819; sales@aesclean.com
INTERPHEX Booth No. 1753

Robert Bosch Packaging Technology, Inc.
Pharmaceutical Operations
8700 Wyoming Avenue N.
Minneapolis, MN 55445
www.boschpackaging.com
763-424-4700; pharm-na@boschpackaging.com
INTERPHEX Booth No. 2227

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2520 Whitehall Park Drive
Suite 800
Charlotte, NC 28273
www.groninger.de;
Lothar Burger; info@groningerusa.com
704-295-9000; Fax: 704-295- 9020
INTERPHEX Booth No. 2705

IMA Life North America Inc.
2175 Military Road
Tonawanda, NY 14150
www.ima.it
716-695-6354; Fax: 716-695-6367
Ernesto Renzi, President, Sales and Marketing
ernesto.renzi@imalife.com
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Evergreen, CO 80437
www.rommelag.com; mail@rommelag.com
303-674 8333; Fax: 03-670 2666
Tim Kram
INTERPHEX Booth No. 2617

Sartorius Stedim Biotech
5 Orville Drive
Bohemia, NY 11716
www.sartorius-stedim.com
631-254-4249; Fax: 631-254-4264
Dan Kopec, Manager, Process Analytics
800-635-2906, Ext. 8504; Mobile: 480-251-9049
Dan.kopec@sartorius-stedim.com
INTERPHEX Booth No. 2805

SKAN US, Inc.
7409 ACC Blvd, Suite 200
Raleigh, NC 27617
www.skan.ch; 866-381 7685
INTERPHEX Booth No.2271

Stilmas USA, LLC,
1361 Lincoln Avenue, Unit 7
Holbrook NY 11741
www.stilmasusa.com
Cristina Testoni; cristinatestoni@stilmasusa.com
631 588-6584; Fax: 631 588-6580; Mobile: 480-285-8200
INTERPHEX Booth No.1675

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EMD Millipore, Billerica MA 01821. www.millipore.com or call 800-Millipore

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Xcellerex, Inc., Marlborough, MA 01752. www.xcellerex.com or call 866-XCELLEREX

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Flexible Biopharmaceutical Production Platforms

Sartorius Stedim Biotech (SSB) and G-Con have agreed to a global collaboration to offer highly advanced and flexible production platforms for the biopharmaceutical manufacturing industry. The new FlexMoSys product line will leverage G-Con's novel, modular, mobile clean-room systems and SSB's well-established broad, single-use and reusable product portfolio to create a totally integrated production process platform.

Sartorius Stedim Biotech, Bohemia, NY 11716. www.sartorius-stedim.com or call 631-254-4249

INTERPHEX Booth No. 2805

Cell Rupture Systems

GEA Process Engineering will feature the advanced Niro Soavi VHP Homogenizer Systems which have become the industry standard for particle size reduction and cell rupture in pharmaceutical and biotech manufacturing. The core of the Niro Soavi VHP System is the GEA Niro Soavi homogenizer, renowned for its robust design, clean-ability, and ease of maintenance.

GEA Process Engineering Inc., Columbia, MD 21045. www.niroinc.com or call 443-766-1136

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Single-Use Bioreactor

The Thermo Scientific HyPerforma® Single-Use Bioreactor Turnkey (TK) system combines the best features from our hundreds of single-use stirred tank bioreactors in use today with a state-of-the-art controller system. This out-of-the-box solution dramatically shortens implementation time and reduces up-front cost, while providing all the advantages of our open-architecture Thermo Scientific Single-Use Bioreactors (S.U.B.)

Thermo Fisher Scientific, Logan, UT 84321. www.thermoscientific.com/bioprocessing or call 435-792-8000

INTERPHEX Booth No. 2753

Custom Single Run Products

ABEC's CSR™ products establish a new paradigm for single use implementation in biopharmaceutical manufacturing. Systems can now be custom-designed to meet exact process needs. In particular, the CSR™ Containers can be of any size or aspect ratio, with custom-designed mixing, aeration, and instrumentation for today's demanding cell culture and fluid preparation processes.

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Top 3 Engineering Firms, *Philadelphia Business Journal*

Top 25 Architectural Firms, *Philadelphia Business Journal*

Top 50 CM Firms, Giants 300, *Building Design & Construction*

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IPS appeared on 21st Century Business, an award winning international television series which aired on CNBC and Fox Business News.

www.ipsdb.com

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- Blending (lab and production scale); and
- Milling (cone mill, hammer mill).

L.B. Bohle LLC, Warminster, PA 18974. www.bohle-tablet-coater.com/us-service-center.html or call 215-957-1240

INTERPHEX Booth No. 2253

Containment Systems

SKAN is the market leader in isolators, barrier systems (including RABS), and hydrogen peroxide-based sterilization technologies. SKAN has the ability to customize interfaces with unique and complex process equipment to provide operator safety and improved process control.

SKAN US, Inc., Raleigh, NC 27617. www.us.skan.ch or call 866-381-7685

INTERPHEX Booth No. 2271

FE55 "Tri.Easy" Tablet Press

The FE55 simplifies the primary aspects of press use – changeover, operation and maintenance. With up to 87 stations requiring less than two square meters of space, it re-defines efficiency and speed. The optional third set of re-designed

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FETTE Compacting America, Inc., Rockaway, NJ 07866. www.fetteamerica.com or call 973-586-8722.

INTERPHEX Booth No. 1524-A

Telstar Life Sciences

Telstar Life Sciences solutions is dedicated to the design, manufacture and sales of equipment-based solutions for life and health sciences applications, including: clean air technology, steam sterilizers, production of WFI and clean steam, laminar-flow solutions for hospitals, containment technology for biologics and potent compounds, vacuum dryers, laboratory lyophilizers and GMP lyophilization systems with automatic load/unload.

Telstar North America, Inc., Bristol PA 19007. www.telstar-lifesciences.com or call 215-826-0770

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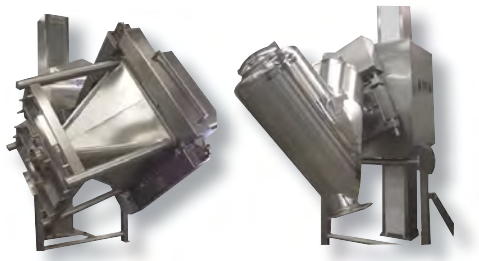
developed with ConsiGma™-1 can be directly transferred to the full ConsiGma™ system.

GEA Process Engineering Inc., Columbia, MD 21045. www.niroinc.com or call 443-766-1136

INTERPHEX Booth No. 2421



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KORSCH America Inc., South Easton, MA 02375. www.korschamerica.com or call 508-238-9080

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Aseptic Filling Systems

Bosch Packaging Technology is the world leader in aseptic filling systems. This year we are showcasing a pre-filled syringe line with automatic bag and tub opener, FXS 3100 filling system, Combi filling station, and check weigh. This complete solution demonstrates the latest in flexible filling solutions for syringes. Also on display is the FLT compact vial filling system. The FLT is the ideal solution for lab or clinical filling. It includes filling, capping and check weigh on a very compact footprint.

- **Robert Bosch Packaging Technology, Inc., Pharmaceutical Operations, Minneapolis, MN 55445. www.boschpackaging.com or call 763-493-6756**
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- **Sartorius Stedim Biotech, Bohemia, NY 11716. www.sartorius-stedim.com or call 631-254-4249**
- **INTERPHEX Booth No. 2805**

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SKAN specializes in the development and integration of isolator systems, RABS and hydrogen peroxide gassing systems for the biopharmaceutical industry. SKAN's most successful aseptic processing products include: fully integrated isolator bio-decontamination systems with accelerated cycle times (under 2 hours) and low residual aeration, 20-minute rapid decon cycles (including 10E6 kill and aeration to <1ppm) for small isolators and transfer systems, SKANFOG™ large area disinfection systems with validatable efficacy and

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- **SKAN US, Inc., Raleigh, NC 27617 866.381.7685 www.us.skan.ch**
- **INTERPHEX Booth No. 2271**

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- **Rommelag USA, Inc., Evergreen, CO 80437. www.rommelag.com or call 303-674-8333.**
- **INTERPHEX Booth No. 2617**

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AES is the leader in turnkey design, manufacturing, construction and commissioning of modular cleanroom facilities for life sciences and technology companies. AES is uniquely qualified to deliver successful projects by leveraging our in-house cleanroom engineering expertise with our advanced modular systems manufacturing capabilities. The net results are precise facilities, executed safely and on-time.

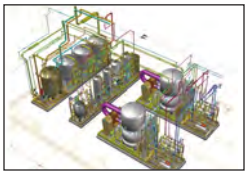
- **AES Clean Technology, Inc., Montgomeryville, PA 18936. www.aesclean.com or call 888-AES-CLEAN**
- **INTERPHEX Booth No. 1753**

Aseptic Processing

IMA Life division offers machines for the washing and sterilizing of pharmaceutical vials, filling and stoppering in aseptic environments of vials, ampoules and syringes, including RABS and isolators, filling and closing of pharmaceuticals and cosmetics, microdosing of aseptic powders as well as industrial, pilot and lab freeze-dryers, which can be combined with a wide range of automated loading/unloading system solutions.

- **IMA Life North America Inc., Tonawanda, NY 14150.www.ima.it or call 716-695-6354**
- **INTERPHEX Booth No. 2553**

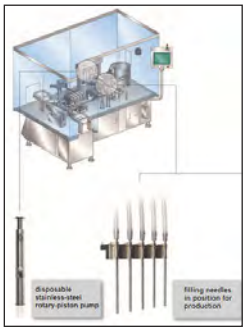
Pharmaceutical Water



Stilmas is an ISO 9001/2000 certified company with a "state of art" manufacturing facility in Milan, Italy. With more than 7,000 installations worldwide, 650 turn-key projects, Stilmas represents a leading company for purified water, WFI (Pharmastill & Vapor Compressor), ultra pure steam generation, storage and distribution systems for the pharmaceutical and biotech industries.

- **Stilmas USA, LLC, Holbrook NY 11741. www.stilmasusa.com or call 631-588-6584**
- **INTERPHEX Booth No. 1675**

Disposable Filling Systems



At INTERPHEX, groninger will focus on the fast growing market for disposable filling systems. Different disposable system-solutions as well as "classic" filling systems are on display. Please visit also the case study "Use of Pre-Sterilized Single-Use Disposable Fluid Paths in Sterile Manufacturing" at the INTERPHEX conference on Tuesday at 4pm.

- **groninger USA L.L.C., Charlotte, NC 28273. www.groninger.de or call 704-919-2782**
- **INTERPHEX Booth No. 2705**

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