

# 2012 editorial calendar

Serving the  
Biopharmaceutical  
development and  
manufacturing  
industry since 1988



## Regulatory Beat—Monthly



Jill Wechsler is a veteran editor based in Washington, DC, where she keeps a close eye on important developments related to biotech manufacturing and research. She gathers first-hand information about issues discussed and decisions made on Capitol Hill, at FDA, and at other US government agencies whose policies affect the biopharmaceutical industry. This direct access allows her to report to *BioPharm* readers every month on significant regulatory decisions, policy developments, and trends.

## Outsourcing Insights—Monthly



Experts offer keen analysis of outsourcing trends and strategies for a wide range of bio/pharmaceutical operations, including research, development, manufacturing, and IT support. Company moves among big and small players are addressed, including analysis of changes and their implications for sponsor companies and contract organizations alike. Jim Miller, president of PharmSource, contributes six times per year. Eric Langer of BioPlan Associates and Gregg Brandyberry of AT Kearney each contribute three times a year.

## The Disposables Advisor—Quarterly



Jerold Martin, senior vice-president, global scientific affairs—biopharmaceuticals at Pall Life Sciences and chair of the Bio-Process Systems Alliance (BPSA) answers your questions about single-use technologies, from extractables and leachables testing to quality standards, environmental issues, and economics. Jerry will draw on extensive experience that he and his BPSA colleagues have gained from working with single-use systems and interacting with end-users, and will also provide updates from worldwide conferences.

## Compliance Notes—Bimonthly



Industry Trades Compliance correspondents share their experience and provide timely advice. Their expert recommendations will help biotech manufacturers avoid unexpected compliance pitfalls and prepare for FDA inspections. They also offer insight into how to build a quality culture, and how to harness the enablers of quality that support and lead to good cGMP compliance. It's a column not to be missed.

## Burrill on Biotech—Quarterly



When you want to know how the industry is performing, you turn to Steven Burrill. In this quarterly column, the renowned industry expert and venture capitalist charts the course of the biotechnology industry by drawing on business metrics and the Burrill Biotechnology Indices to provide readers with an ongoing evaluation of the health of this evolving sector. He assesses the trends in venture capital, M&As, and the overall partnering environment, and looks ahead to the future.

## Final Word—Monthly

In this guest opinion piece, readers, industry leaders, consultants, and regulators share their views about what is going on in biotech. They tell us what should be done about the things that dismay them, how we can draw inspiration from best practices, where the industry should head and the detours to be avoided along the way. It's where the diverse voices in biotech can be heard, for agreement or dissent.

# Content

January - Special Report

## Therapeutic Vaccines

Drug manufacturers are putting a new spin on traditional vaccines, incorporating novel drug classes to treat existing conditions such as cancer and autoimmune diseases. These drugs pose unique challenges for manufacturing process developers and formulators and push the envelope on delivery vehicles. This volume provides an up-to-date review of cutting-edge trends and technologies in the production, formulation, delivery, and preservation of therapeutic DNA, RNA, and protein vaccines.

February - Supplement

## Guide to Bioterminology

The BioPharm Guide to BioTerminology is specific to biopharmaceutical development, manufacturing, and quality control. It covers all the essential terms and acronyms from fields such as chemistry, microbiology, molecular biology, engineering, facility design, cGMPs, and regulatory affairs that are missing from general dictionaries or scattered in multiple specialist sources.

March - Supplement

## Outsourcing

In the new Big Pharma model, clinical materials and commercial products are no longer supplied exclusively by an internal manufacturing organization, but instead through a combined network of in-house and third-party resources. At the same time, the recession and accompanying scarcity of venture capital have stressed both small biotechs and their service providers, permanently altering the CMO landscape and the way contracts are shaped. This special issue will help decipher what these changes mean for drug developers and outsourcing providers alike.

April - Special Report

## Advances in Separation & Purification

With the development of new purification technologies and the revival of older methods, standard approaches to purifying monoclonal antibodies continue to evolve. Meanwhile, other recombinant proteins continue to defy platforming, and progress continues with newer product types, such as MAb fragments and fusions, requiring downstream experts to modify platforms or develop new systems. This supplement will explore the state of the art of separation and purification across a range of product types.

May - Supplement

## Expression Systems

Biopharmaceutical manufacturers are constantly pursuing refinements in upstream processing through methods such as improving clone screening, increasing their understanding of cell metabolism, and studying the effects of media composition and process conditions on yield and product quality. Then, once processes are developed, manufacturers need to implement effective technologies to monitor and control cell growth and metabolism, and to automate processes such as bioreactor feeding. This supplement will provide essential advice for ensuring the robustness of these upstream processes.

July - Special Report

## Cell Therapies

Cells are not just factories for producing protein products; they are the products themselves. This special report focuses on current trends in producing embryonic stem cells, induced pluripotent stem cells, adult stem cells, and genetically modified cells for therapeutic purposes. We review the tools and technologies for optimizing growth surfaces

# Supplements and Special Reports



and culture media for adherent cells, strategies for addressing mass customization of autologous therapeutics, and large-scale manufacture of allogeneic cells, as well as automation, quality control, and cryopreservation of cells used in regenerative medicine and therapeutic cell therapies.

August - Special Report

## Advances in Protein Characterization and Process Analytical Technology

This special issue will explore new developments and best practices in protein characterization, in areas such as biological assays, detecting and monitoring protein aggregation and particulates, characterizing and detecting changes in post-translational modifications, and effective use of orthogonal methods for comparability studies. The strengths and weaknesses of the methods will be examined and case studies showing their practical application will be provided.

September - Supplement

## Biopharmaceutical Trend Report

Read this supplement to learn about the latest industry trends, from quality risk management of raw materials to formulating proteins for patient-friendly drug delivery, and everything in between, such as renewed interest in perfusion cell culture and the adoption of alternative techniques for downstream processing. We also will explore issues such as modular plant design, the development of newer product types like conjugates and antibody fragments, emerging analytics, and manufacturing economics in today's evolving biotech business environment.

October - Special Report

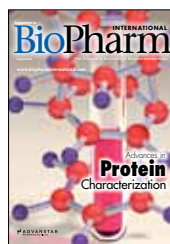
## Prophylactic Vaccines

As vaccine markets grow, methods for vaccine development and manufacturing are maturing. The development of modern vaccine processes involves designing flexible systems and facilities, improving purification platforms and filtration, gaining a better understanding of formulation and stability issues, advancing the transition to cell culture for influenza vaccines, adopting modern approaches to aseptic processing, and establishing production methods for patient-specific therapeutic vaccines. Meanwhile, vaccine characterization is maturing apace: advanced analytical methods and potency assays are being developed, and some firms are beginning to apply quality-by-design principle to vaccines. Here, we explore how far we have come and what remains to be tackled.

November - Supplement

## Single-Use Technologies and the Facility of the Future

Biopharma companies must juggle multiple priorities, including supplying clinical trial materials for growing pipelines, ensuring sufficient commercial-scale manufacturing capacity, and lowering the cost of goods, all while clinical success is more uncertain than ever. As a result, plant flexibility has become an industry mantra. Single-use systems can offer that flexibility, and are considered by many as the building blocks of an ideal "facility of the future." Meanwhile, however, hybrid facilities are becoming the norm, as an interim step or even a long-term approach. Here, we look at industry experience in migrating toward disposables and strategies for the future.



# Content

2012 Editorial Calendar		Q1		
	January	February	March	
<b>Space Deadline</b>	12/8	1/10	2/7	
<b>Material Deadline</b>	12/13	1/16	2/13	
<b>Focus</b>	<b>Downstream Processing</b>	<b>Outsourcing</b>	<b>Upstream Processing</b>	
<b>Monthly Columns</b>	Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word	
<b>Bimonthly Columns</b>	Compliance Notes		Compliance Notes	
<b>Quarterly Columns</b>	Burrill on Biotech	Disposables Advisor		
<b>Special Report</b>	Therapeutic Vaccines			
<b>Supplement</b>		Guide to Bioterminology	Outsourcing	
<b>Value Added Opportunities</b>	Showcase Advertisement Readex Ad Performance Study Advertorial Available	Showcase Advertisement	Showcase Advertisement	
<b>Bonus Distribution</b>	CHI - Pep Talk CMC Strategy Forum CASSS - WCBP IFPAC WTG - Biomanufacturing Summit Phacilitate Cell and Gene Therapy, Vaccine, Protein Therapeutics Forums	Endocrine Disruptors	Pittcon Terrapinn - BioPharma Asia Convention EBD - Bio-Europe Spring 2012 WBR: BioNetwork-East	

*Multimedia Show Packages Available*

To Be Covered Throughout The Year			
Development Strategies	Formulation	CAPA	Fermentation
Early Stage Biotech	Drug Delivery	Cell Line Development	Contract Services and
Fill-Finish	Validation	and Optimization	Manufacturing
Economic Development Zones	Regulatory	Cell Culture	Transfection Tools
Analytical Technologies	QA/QC	Drug-Substance Synthesis	High-Throughput Screening



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2012 Editorial Calendar		Q2	
	April	May	June
<b>Space Deadline</b>	3/7	4/4	5/4
<b>Material Deadline</b>	3/13	4/10	5/9
<b>Focus</b>	<b>Formulation</b>	<b>Downstream Processing</b>	<b>Outsourcing</b>
<b>Monthly Columns</b>	Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word
<b>Bimonthly Columns</b>		Compliance Notes	Disposables Advisor
<b>Quarterly Columns</b>	Burrill on Biotech		25th Anniversary Issue Top Milestones – 25 years.
<b>Special Report</b>	Advances in Separation & Purification		
<b>Supplement</b>		Expression Systems	
<b>Value Added Opportunities</b>	Showcase Advertisement	Showcase Advertisement	Showcase Advertisement Advertorial Available
<b>Bonus Distribution</b>	CMC Strategy Forum - Europe INTERPHEX WTG - Delivery & Formulation America Summit CHI - PEGS BIO Expo Japan	AAPS - National Biotechnology Conference CHI - World Pharmaceutical Conference INTERPHEX Asia & ISPE, Singapore Sartorius - Downstream Forum	World Vaccine Congress Asia DIA Annual Meeting WTG - Global Pharma Manufacturing WTG - Biological Production Forum Bio International

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2012 Editorial Calendar		Q3		
	July	August	September	
<b>Space Deadline</b>	6/6	7/11	8/8	
<b>Material Deadline</b>	6/12	7/17	8/15	
<b>Focus</b>	<b>Upstream</b>	<b>Formulation</b>	<b>Downstream</b>	
<b>Monthly Columns</b>	Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word	
<b>Bimonthly Columns</b>	Compliance Notes		Compliance Notes	
<b>Quarterly Columns</b>	Burrill on Biotech	Disposables Advisor		
<b>Special Report</b>	Cell Therapy	Advances in Protein Characterization and Process Analytical Technology		
<b>Supplement</b>			BioPharmaceutical Trend Report	
<b>Value Added Opportunities</b>	Showcase Advertisement Advertorial Available	Showcase Advertisement	Showcase Advertisement	
<b>Bonus Distribution</b>	Bio Conferences - DNA Vaccines 2012 Bio Process Asia Pacific	ACS Fall CHI - Bioprocessing Summit Sartorius - Downstream Forum	PDA - FDA Singapore and Phacilitate Cell & Gene Therapy Forum International Symposium on Higher Order Structure of Protein Therapeutics Extractables & Leachables for Pharmaceutical Products BioPharm America LogiPharma	

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2012 Editorial Calendar		Q4		
		October	November	December
<b>Space Deadline</b>		9/12	10/10	11/7
<b>Material Deadline</b>		9/18	10/16	11/14
<b>Focus</b>		<b>Outsourcing</b>	<b>Upstream Processing</b>	<b>Formulation</b>
<b>Monthly Columns</b>		Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word	Regulatory Beat Perspectives on Outsourcing Final Word
<b>Bimonthly Columns</b>			Compliance Notes	
<b>Quarterly Columns</b>		Burrill on Biotech		Disposables Advisor
<b>Special Report</b>		Prophylactic Vaccines		
<b>Supplement</b>			Single Use and Modular Systems	
<b>Value Added Opportunities</b>		Showcase Advertisement	Showcase Advertisement	Showcase Advertisement Advertorial Available
<b>Bonus Distribution</b>		PharmaForce CE in the Biotechnology and Pharmaceutical Industries CPHI BioNetwork West CASSS - Bioassays AAPS BIO Europe 2011	World Drug Manufacturing Summit Bio Pharma India	

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