

2011 Editorial Calendar

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The Science & Business of Biopharmaceuticals

Supplements

January

Advances in Vaccine Development and Manufacturing: From Processing to Patient

Vaccine manufacturers are seeking more robust processing methods, and even platforms, along with better vaccine characterization. At the same time, new developments present new opportunities in how and where vaccines are made—such as in small, disposables-based plants in emerging markets or regional facilities in developed countries for autologous therapeutic vaccines—and how they are delivered to patients, including improved stability and formulations that obviate the need for cold-chain storage. This supplement will provide practical examples of how manufacturers are addressing ongoing challenges and taking advantage of new opportunities.

February

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

Guide to Outsourcing: The New World Order of 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

Advances in Separation & Purification: MAbs and Beyond

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.

June

Advances in Fermentation & Cell Culture: Ensuring Process Robustness

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.

August

Advances in Protein Characterization: From Potency Assays to Higher Order Structure

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 weakness of the methods will be examined and case studies showing their practical application will be provided.

September

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

The Maturing of Vaccines

As vaccine markets grow, methods for vaccine development and manufacture 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 to vaccines. Here, we explore how far we have come and what remains to be tackled.

November

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.



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—Bimonthly

(January, March, May, September, October, December)



Jim Miller, president of PharmSource, offers his keen analysis of outsourcing trends and strategies for a wide range of biopharmaceutical operations including research, development, manufacturing, clinical trials, and IT support. He evaluates the moves of the big players and the small, deciphering the reasons behind the changes and their implications for outsourcing providers and biopharmaceutical companies alike.

Perspectives on Outsourcing—Bimonthly

(Feb, April, June, July, August, November)

As a complement to Jim Miller's analysis, this guest column offers a variety of viewpoints and practical, hands-on information for handling outsourcing decision-making and processes such as technology transfer, contract negotiation, conflict resolution, project management, auditing providers, and outsourcing abroad.

The Disposables Advisor—Quarterly

(February, June, August, November)



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

(January, March, May, July, September, November)



Senior experts from Tunnell Consulting and Shadle Consulting rely on their extensive industry experience to provide timely compliance 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

(January, April, July, October)



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, 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.



Editorial Calendar

January

Ad Close: December 3

Material Due: December 16

Editorial Theme:

Downstream Processing

Monthly Columns:

- » Regulatory Beat
- » Outsourcing Insights
- » Final Word

Bimonthly Columns:

Compliance Notes

Quarterly Columns:

Burrill on Biotech

Supplement:

Advances in Vaccine Development & Manufacturing: From Processing to Patient



Special Content:

5th Annual Salary Survey

Product & Services Spotlight:

Disposables

Added Value:

- » Purchase Intelligence Sales Lead Report

Advertising cost includes both print and digital editions

February

Ad Close: January 10

Material Due: January 13

Editorial Theme:

Outsourcing

Monthly Columns:

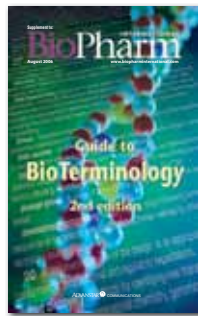
- » Regulatory Beat
- » Perspectives on Outsourcing
- » Final Word

Quarterly Columns:

- » Disposables Advisor

Supplement:

Guide to Bioterminology



Product & Services Spotlight:

Separation & Purification

Added Value:

- » Filtration/Purification User Survey
- » 4/C/Release/Web Page Showcase

Advertising cost includes both print and digital editions

March

Ad Close: February 7

Material Due: February 10

Editorial Theme:

Upstream Processing

Monthly Columns:

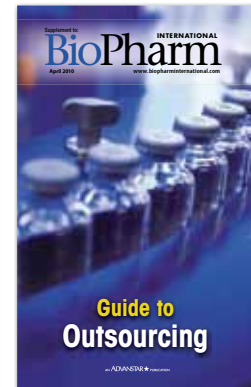
- » Regulatory Beat
- » Outsourcing Insights
- » Final Word

Bimonthly Columns:

Compliance Notes

Supplement:

The New World Order of Outsourcing



Product & Services Spotlight:

Outsourced Services

Added Value:

- » Purchase Intelligence Sales Lead Report
- » 4/C/Release/Web Page Showcase

Advertising cost includes both print and digital editions

Bonus Distribution:

- » INTERPHEX Trade Show Package
- » PITTCON Tradeshow Package
- » BIO Europe

April

Ad Close: March 7

Material Due: March 10

Editorial Theme:

Quality

Monthly Columns:

- » Regulatory Beat
- » Perspectives on Outsourcing
- » Final Word

Quarterly Columns:

Burrill on Biotech

Supplement:

Advances in Separation & Purification: MAbs and Beyond



Product & Services Spotlight:

Fermentation & Cell Culture

Added Value:

- » 4/C Release/Web Page Showcase

Advertising cost includes both print and digital editions

Bonus Distribution:

- » PDA Annual Meeting

May

Ad Close: April 1

Material Due: April 14

Editorial Theme:

Downstream Processing



Monthly Columns:

- » Regulatory Beat
- » Final Word
- » Outsourcing Insights

Bimonthly Columns:

Compliance Notes

Product & Services Spotlight:

Disposables

Added Value:

- » Purchase Intelligence Sales Lead Report
- » 4/C Release/Web Page Showcase

Advertising cost includes both print and digital editions

Bonus Distribution:

- » AAPS National Biotechnology Conference Tradeshow Package

June

Ad Close: May 9

Material Due: May 12

Editorial Theme:

Outsourcing

Monthly Columns:

- » Regulatory Beat
- » Perspectives on Outsourcing
- » Final Word

Quarterly Columns:

- » Disposables Advisor



Supplement:

Advances in Fermentation & Cell Culture: Ensuring Process Robustness

Product & Services Spotlight:

Separation & Purification

Contract Manufacturing User Survey

- » 4/C Release Web Page Showcase

Advertising cost includes both print and digital editions

Bonus Distribution:

- » BIO Annual Meeting Tradeshow Package
- » DIA Annual Meeting

July

Ad Close: June 6
Material Due: June 9

Editorial Theme:
Upstream Processing



Monthly Columns:

- » Regulatory Beat
- » Perspectives on Outsourcing
- » Final Word

Bimonthly Columns:
Compliance Notes

Quarterly Columns:
Burrill on Biotech

Product & Services Spotlight:
Outsourced Services

Added Value:

- » Purchase Intelligence
Sales Lead Report
- » 4/C Release/Web Page Showcase

Advertising cost includes both
print and digital editions

August

Ad Close: July 1
Material Due: July 14

Editorial Theme:
Quality

Monthly Columns:

- » Regulatory Beat
- » Perspectives on Outsourcing
- » Final Word

Quarterly Columns:

- » Disposables Advisor

Supplement:
Advances in Protein
Characterization: From Potency
Assays to Higher Order Structure

Product & Services Spotlight:
Fermentation & Cell Culture

Added Value:

- » Ad Performance Study
- » 4/C Release/Web Page Showcase

Advertising cost includes both
print and digital editions



September

Ad Close: August 8
Material Due: August 11

Editorial Theme:
Downstream Processing

Monthly Columns:

- » Regulatory Beat
- » Outsourcing Insights
- » Final Word

Bimonthly Columns:
Compliance Notes

Supplement:
Biopharmaceutical Trend Report



Product & Services Spotlight:
Disposables

Added Value:

- » Purchase Intelligence
Sales Lead Report
- » 4/C Release/Web Page Showcase

Advertising cost includes both
print and digital editions

Bonus Distribution:

- » PDA/FDA Joint Regulatory
Conference

October

Ad Close: September 12
Material Due: September 15

Editorial Theme:
Outsourcing

Special Content:
Product & Service Innovations

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Monthly Columns:

- » Regulatory Beat
- » Outsourcing Insights
- » Final Word

Quarterly Columns:

Burrill on Biotech

Supplement:

The Maturing of Vaccines



Product & Services Spotlight:
Separation & Purification

Added Value:

- » 4/C Release/Web Page Showcase
- » Advertorial Page

Advertising cost includes both
print and digital editions

Bonus Distribution:

- » AAPS Annual Meeting
Tradeshaw Package

November

Ad Close: October 10
Material Due: October 13

Editorial Theme:
Upstream Processing



Monthly Columns:

- » Regulatory Beat
- » Perspectives on Outsourcing
- » Final Word

Bimonthly Columns:

Compliance Notes

Quarterly Columns:

The Disposables Advisor

Supplement:

Single-Use Technologies and
the Facility of the Future



Product & Services Spotlight:
Outsourced Services

Added Value:

- » Purchase Intelligence
Sales Lead Report
- » 4/C Release/Web Page Showcase

Advertising cost includes both
print and digital editions

December

Ad Close: November 7
Material Due: November 10

Editorial Theme:
Quality

Special Content:
Corporate Capabilities

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Monthly Columns:

- » Regulatory Beat
- » Outsourcing Insights
- » Final Word

Product & Services Spotlight:
Fermentation & Cell Culture

Added Value:

- » Application Notes Page
- » Advertorial Page

Advertising cost includes both
print and digital editions



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