BIOPROCESS ONLINE

BioprocessOnline.com Editorial Themes

- Upstream process operations (APIs, assays, bioreactors, cell culture media, expression, fermentation, outsourced development, perfusion)
- Downstream process operations (chromatography, filtration, outsourced manufacturing, separation/purification, viral clearance)
- Regulatory considerations for early-stage biopharmas
- CMC foundations for the clinic & beyond
- CGMP: FDA quality baselines for biopharma
- Clinical design in a new era of regulatory flexibility
- Process considerations for emerging cell therapies
- Process considerations for emerging gene therapies
- Possibilities and pitfalls of outsourced biologics development
- New therapeutic modalities: where they fall on the biologic spectrum
- Biopharma market dynamics in a post-pandemic world
- Facilities design & bioprocess equipment selection
- Process intensification in practice
- Single use systems trends
- Biopharma supply chain: opportunities and constraints
- Biopharma 4.0: The marriage of computational science and biology
- IP & legal protections for new biopharma entities
- Profiles in biopharma leadership
- Early-stage biopharma financing and finance management
- Organizational development / startup management
- Sustainable sourcing: Ensuring self-sufficiency in APIs, process consumables & equipment
- Navigating government's role in the biologics market: Manufacturing, pricing, & more

MATT PILLAR
Chief Editor
BioprocessOnline.com

BIOSIMILAR DEVELOPMENT

BiosimilarDevelopment.com Editorial Themes

- Cell-line & process development/ formulation
- Analytical & clinical development strategies
- Bioprocessing trends
- Regulatory strategies
- Real-world evidence generation/ collection
- Global regulatory reforms & guidance
- Switching/interchangeability
- Best practices for working with regulators
- Regulatory harmonization
- Global regulatory pathway development
- Government legislation & reimbursement policies
- Market access & commercialization strategies
- Market barriers
- The legal landscape
- Stakeholder education
- Payer policies & formulary management
- Real-world evidence initiatives
- Biosimilar business models

ANNA ROSE WELCH
Chief Editor
BiosimilarDevelopment.com

cell & gene

CellandGene.com Editorial Themes

- Developments in QA / QC
- Enhancements / best practices in process development
- Clinical trial design
- Next steps in “off-the-shelf” therapies
- Advancements in solid tumor medical research clinical trials
- Advancements in blood cancers clinical trials of new therapies or new combinations of therapies
- Scientifically validated and ethically responsible gene editing
- Cell and gene workforce education and training
- Clinical site onboarding for cell and gene clinical trials and for commercial-approved products
- Overall regulatory insights and hurdles
- Emerging platforms and technology
- Supply chain best practices
- Design and scalable production of gene transfer vectors
- Advancements in development of viral and non-viral gene delivery systems
- Financing future development
- Overcoming the biggest hurdles in gene therapy manufacturing (process development, safety testing, vector characterization, regulatory, etc.)
- Key components of the automation and industrialization of manufacturing
- Capacity constraints for current and future cell and gene therapies
- Finding the right contract service support
- Emerging strategies to support commercialization

ERIN HARRIS
Chief Editor
CellandGene.com

Life Science Leader

Life Science Leader Editorial Themes

- AI & machine learning in drug development
- Best practices / strategies for working with regulators
- Market access & commercialization strategies
- Challenges of emerging biopharma
- Clinical trial planning & execution trends
- Corporate culture development
- Diversity & inclusion management strategies
- Finance / funding strategies
- Hot legal-related issues in pharma
- Profiles of top pharma / biopharma executives
- IP / patent protection
- Companies to watch / emerging platforms & technology
- Leadership lessons
- Life science region profiles
- Outsourced manufacturing trends / activities
- Patient diversity in clinical trials
- Pharma / biopharma entrepreneurs
- Startup / emerging biopharma challenges
- Unique business / growth strategies
- Women shaping the life sciences industry

ROB WRIGHT
Chief Editor
Life Science Leader

OUTSOURCED PHARMA

OutsourcedPharma.com Editorial Themes

- How to select CDMOs
- Managing CDMO relationships
- CDMO-drug sponsor business/ relationship models
- Drug development strategies/ challenges
- Scale up and manufacturing strategies/challenges
- Whether or not to use a CDMO (build vs. buy)
- Support services (testing, analytical, regulatory, etc.)
- New drug categories/modalities, new equipment and new facilities
- U.S. domestic resurgence of drug development and manufacturing

LOUIS GARGUILO
Chief Editor
OutsourcedPharma.com

PharmaceuticalOnline.com Editorial Themes

- Implementing advanced manufacturing technology (automation, robotics, AI, Big Data, etc.)
- Designing and constructing next-generation facilities and processes (flexible, modular, decentralized, continuous, etc.)
- Managing and securing a post-COVID supply chain (re/nearshoring, remote audits, resilience, etc.)
- Improving quality systems and culture (data integrity, human performance, risk management, etc.)
- Staying ahead of the regulatory and compliance curve (understanding new US and OUS regulations/standards, learning from enforcement activities, etc.)

JIM POMAGER
Executive Editor
PharmaceuticalOnline.com