2020 Bio/Pharma Virtual Congress

Pharmaceutical Technology® BioPharm INTERNATIONAL

Wednesday, November 11 | 8:30 AM EST – 4:00 PM EST

While the COVID-19 pandemic has disrupted the routine of in-person events, the need for sharing information and building key supplier connections for bio/pharmaceutical development and manufacturing has never been greater.

The 2020 Bio/Pharma Virtual Congress event will connect bio/pharma formulation, development, manufacturing, and quality professionals with a full day of technical presentations, panel discussions, interviews, and vendor meetings, through an interactive portal.

This online event will explore the latest developments in formulation, manufacturing, and innovative drug dosage forms, as well as detailed discussions about crucial topics impacting the industry.

Virtual Congress Agenda

EST	Description
8:30 AM	Registration Opens
9:00 AM – 9:45 AM	**Keynote Panel Discussion: Bio/Pharma Industry—Beyond Politics and the Pandemic** *James Mayne, PhD, Vice President, Science & Regulatory Advocacy, PhRMA* *Phyllis Arthur, Vice President for Infectious Diseases and Diagnostics Policy, Biotechnology Innovation Organization* *Moderator: Rita Peters, Editorial Director, Pharmaceutical Technology and BioPharm International* The bio/pharma industry has demonstrated its R&D capabilities by accelerating development of vaccines and therapeutics to combat COVID-19. At the same time the industry faced intense scrutiny and political pressure. What are the short-, medium-, and long-term implications for bio/pharma development and manufacturing? Representatives of industry organizations will discuss and debate crucial business, regulatory, science-based issues facing the industry.
9:45 AM – 10:00 AM	Networking Break in Exhibit Hall
Session 1	
10:00 AM – 11:00 AM	**Track 1: Formulation** **Improving Patient Outcomes through the Stratum Technology Platform: Revolutionized Injectable Solutions** *Nathan H. Dormer, Ph.D., Director, Drug Product Development, Adare* *Moderator: Rita Peters, Editorial Director, Pharmaceutical Technology and BioPharm International* The presentation will discuss industry formulation challenges associated with current long acting injectables platforms, and how the Stratum Technology Platform can provide the creation of next-generation "pulsatile" release formulations or extended release formulations. These formulations result in increased bioavailability and efficacy for patients, fewer administrations of treatment, targeted delivery and overall an increased compliance option for patients.
10:00 AM – 11:00 AM	**Track 2: Manufacturing** **The Future of Life Sciences Production Automation: Greater Visibility with Audit-Ready Solutions** *Amit Samel, Life Sciences Technical Solution Consultant, Honeywell* *Tiffany Barnes, Life Sciences Technical Solution Consultant, Honeywell* New capabilities offer intuitive process and operational intelligence through real-time visibility and predictive insights. Improve manufacturing operations in a GxP compliant manner with end-to-end data integrity. Learn about technologies such as orchestration, timeline-based batch HMI, modular engineering, OT cybersecurity, and manufacturing intelligence.

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10:00 AM – 11:00 AM	**Track 3: Drug Dosage Form** **Delivering on the Promise: Overcoming Biopharma Development and Manufacturing Challenges** *Eric Langer, Managing Partner, BioPlan Associates, Inc.* *Moderator: Feliza Mirasol, Science Editor, Pharmaceutical Technology and BioPharm International* Discussion topics include the role of biopharma research in combating the COVID-19 pandemic, the impact of the pandemic on manufacturing and development operations and capacity, and lessons learned from bioprocessing operations during the pandemic.
10:00 AM – 11:00 AM	**Track 4: Bio/Pharma Industry Challenges** **Cleanrooms Qualification Vs Cleanroom Monitoring: Annex 1 V12 Requirements** *Gilberto Dalmaso, Technical Science Director for Europe & Asia, Veltek Associates Inc.* *Moderator: Felicity Thomas, European Editor, Pharmaceutical Technology and BioPharm International* Learn the difference between cleanroom qualification and cleanroom monitoring, how to qualify the cleanroom according to Annex 1 and Annex 15, and requirements for cleanroom monitoring.
11:00 AM – 11:30 AM	Networking Break in Exhibit Hall
Session 2	
11:30 AM – 12:30 PM	**Track 1: Formulation** **Data-Driven Strategies to Accelerate Your Molecule's Development Path** *Lisa Caralli, Director of Science and Technology, Pharmaceutics, Catalent Pharma Solutions* *Moderator: Agnes Shanley, Senior Editor, Pharmaceutical Technology and BioPharm International* Catalent expert will introduce a fast and efficient development process that can help deliver the right clinical candidate, best formulation strategy and an optimal dosage form to Phase 1. The presentation will discuss in detail data-driven approaches including PBPK modeling, parallel formulation screening, API sparing techniques and optimal early dosing strategies that will help avoid development pitfalls and de-risk path to clinic.
11:30 AM – 12:30 PM	**Track 2: Manufacturing** **Technology Advances in Process Operations: Using Real-time Monitoring and Artificial Intelligence to Optimize Manufacturing Operations** *Bikash Chatterjee, CEO, Pharmatech Associates* *Pamela Docherty, Life Sciences Industry Manager, Siemens* *Amos Dor, General Manager of the Pharma Team, Automation Products Group, Applied Materials* *Bob Lenich, Global Life Sciences Director, Emerson* Today's technology gives manufacturers the ability to collect and analyze large amounts of process data in real-time. An expert panel will consider key considerations for manufacturers, including: How can artificial intelligence and machine learning can be employed to optimize bio/pharma manufacturing? What is a digital twin and how are early adopters using it? How is predictive maintenance being used in pharmaceutical manufacturing?

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11:30 AM – 12:30 PM	**Track 3: Drug Dosage Form** **Mapping the Transition from Drug Discovery to Development and Beyond** *James Blackwell, Founder and Principal Consultant, The Windshire Group* *Neal Gordon, Managing Director, BPTG (BioProcess Technology Group)* *Andreas Woppmann, PhD, Managing Director and Principal Consultant, BPTG (BioProcess Technology Group)* *Moderator: Rita Peters, Editorial Director, Pharmaceutical Technology and BioPharm International* In this online panel discussion, experts will review key milestones and tasks—as well as potential stumbling blocks—along the drug development pathway and offer strategies to help biopharma companies move drug prospects from the lab to clinic and commercialization.
11:30 AM – 12:30 PM	**Track 4: Bio/Pharma Industry Challenges** **Ensuring Container Closure Integrity of Sterile Vials** *Dr. Derek Duncan, Director Product Line, LIGHTHOUSE Instruments* *Moderator: Felicity Thomas, European Editor, Pharmaceutical Technology and BioPharm International* Recent regulatory revisions have put emphasis on Container Closure Integrity (CCI) testing practices. Increasing attention from regulators and the industry to the sensitivity limits and validation of CCI test methods has raised the importance of appropriately designed CCI studies, robust method validation and generation of data that gives statistical confidence in the process. This presentation will cover approaches that can be used for generating CCI test data in all phases of the product life cycle, from Development, to Manufacturing and Quality Control.
12:30 – 1:30pm	Networking Break in Exhibit Hall

Session 3

1:30 PM – 2:30 PM	**Track 1: Formulation** **Excipients Update: Formulations, Supply, and Quality** *Nigel Langley, Global Technology Director, BASF Corporation Pharma Solutions* *David R, Schoneker, President/Owner/Consultant, Black Diamond Regulatory Consulting, LLC* *Joe Zeleznik, Technical Product Manager, IMCD US* *Moderator: Rita Peters, Editorial Director, Pharmaceutical Technology and BioPharm International* In this panel discussion, experts will discuss pressing topics associated with the identification, selection, acquisition, and testing of these important ingredients. The discussion will include the prospects for preapproval of novel excipients, the global supply of excipients, relationships between buyers and suppliers, impurities in excipients, and effective testing and monitoring programs.
1:30 PM – 2:30 PM	**Track 2: Manufacturing** **End Point Determination and Scale-up of Fluid Bed Coating Through the Use of Process Tools** *Daniel Kuntz, Associate Principal Engineer, Lonza Pharma & Biotech* *Erin Hyde, Scientist II, Product Development, Lonza Pharma & Biotech* *Moderator: Feliza Mirasol, Science Editor, Pharmaceutical Technology and BioPharm International* In the work presented, process analytical technology (PAT) is employed to determine solution endpoints using in-process measurements, aid in process scale-up studies and identify optimal process parameters. A simple, quick, and robust test method utilizing ultraviolet (UV) spectroscopy was developed to determine SLD potency within a GMP manufacturing suite, enabling in-process prediction of endpoints. The method employed is successful in producing consistent product and was a valuable tool for process scale-up. The case study presented details the approach taken for method development, process development, and effective implementation in manufacturing.

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1:30 PM – 2:30 PM	**Track 3: Drug Dosage Form** **Editors' Series: Genotoxic Impurities and Drug Quality: Lessons from the Nitrosamine Contamination Crisis** *David Light, CEO, Valisure* *Ron Najafi, PhD, CEO, Emery Pharma* *Ed Gump, PhD, Vice President, USP Science—Small Molecules* *Moderator: Agnes Shanley, Senior Editor, Pharmaceutical Technology and BioPharm International* The discovery of genotoxic contaminants in commonly used prescription and OTC medicines over the past two years triggered expensive recalls and raised important questions about the safety of drug ingredients, testing procedures, and the supply chain for tracking materials and finished drug products. Public health questions remain unanswered. In this session, experts share best practices for identifying impurities and experiences with testing, and discuss the roles and responsibilities of ingredients suppliers, drug manufacturers, and regulatory authorities.
1:30 PM – 2:30 PM	**Track 4: Bio/Pharma Industry Challenges** **Establishing a "New Normal" for Pharma Quality Practices** *Scott Deckebach, MBA, Director of Compliance, Lachman Consultant Services, Inc.* *Siegfried Schmitt, PhD, Vice President, Parexel* *Marty Lipa, Pharmaceutical Regulatory Science Team member and doctoral student at Technological University Dublin and Executive Director of Knowledge Management at Merck & Co., Inc.* *Moderator: Agnes Shanley, Senior Editor, Pharmaceutical Technology and BioPharm International* A panel of compliance experts will discuss and debate ongoing drug quality topics, regulatory authority response, and how technologies and best practices can help establish, maintain, or even exceed quality demands.
2:30 – 3:00pm	Networking Break in Exhibit Hall
Session 4	
3:00 PM – 4:00 PM	**Track 1: Formulation** **When Drug Meets Device: How to Assess Compatibility** *Lise Vanderkelen, PhD, Pharmaceuticals and Microbiology Expert, Nelson Labs Europe, a Sotera Health Company* *Ruth Verplaetse, PhD, Study Director, Nelson Labs Europe, a Sotera Health Company* *Moderator: Agnes Shanley, Senior Editor, Pharmaceutical Technology and BioPharm International* The compatibility of the drug and device components requires analysis of many different aspects including drug stability, chemical compatibility, and biocompatibility. These aspects need to be in balance to establish a healthy relationship within the combined products and to avoid any danger to the patient. In this session, learn about the necessity of a having good relationship between the drug and the device for the benefit of the patient.

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3:00 PM – 4:00 PM

Track 2: Manufacturing

21CFR part 11 Data Integrity Challenges for Cleanroom Routine Environmental Monitoring Programs

Tony Harrison, Senior Manager, Biotechnology Business Unit, Beckman Coulter Life Sciences

Moderator: Feliza Mirasol, Science Editor, Pharmaceutical Technology and BioPharm International

Routine Environmental Monitoring in GMP cleanrooms is a manual process and is usually complex, involving thousands of sample data points per month, manual data transcription and all too frequently data gaps and data integrity challenges. This presentation discusses the difference between cleanroom classification and routine environmental monitoring, outlines the FDA 21CFR part 11 ALCOA guidance and shows how the new MET ONE 3400+ non-viable air particle counter from Beckman Coulter Life Sciences can automate routine environmental monitoring programs to help manage data integrity challenges.

3:00 PM – 4:00 PM

Track 3: Drug Dosage Form

Demystifying AI in Pharma

Toni Manzano, Co-founder and Chief Science Officer, Aizon

Moderator: Felicity Thomas, European Editor, Pharmaceutical Technology and BioPharm International

Though not yet in widespread use, AI is on deck to become the key for Continuous Manufacturing, where CPV is the best ally for success. Forward-visioned companies that implement it strategically will realize a distinct competitive advantage. There are practical steps that can be done today to implement these technologies safely to bring vaccines and therapies to market safer and faster than ever before.

3:00 PM – 4:00 PM

Track 4: Bio/Pharma Industry Challenges

Expedite Regulated Documents in the Era of COVID-19: From Development to Trials and Manufacturing

Ellen Reilly, VP, Global Partners, IQVIA

Kirsten Schaub, AVP - Commercial Sales, Healthcare and Life Sciences, DocuSign

Christina S. Wong, Marketing – Regulated Industries, DocuSign

Moderator: Rita Peters, Editorial Director, Pharmaceutical Technology and BioPharm International

Learn best practices about how to implement effective technological solutions to digitize aspects the pharmaceutical value chain. A key topic will be how to quickly and efficiently attain internal and external signatures that are compliant with the FDA's 21 *Code of Federal Regulations* Part 11 regulations and allow trial flexibility such as remotely enrolling patients into clinical trials.

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