On 30 & 31 May 2019, New York (USA) will host the BioTech Pharma Summit: Inhalation & Respiratory Drug Delivery 2019 conference. This year’s event is designed for senior industry experts that will showcase new trends in aerosol science and the future directions of inhalation drug delivery research. Further discussion focuses on the regulatory pathways for inhaled therapies and challenges of bringing respiratory products to market. The agenda also features key case studies on the latest trends in inhalation devices, from inhaled insulin to gene therapy.

The global pulmonary drug delivery market is projected to reach USD 52.37 Billion by 2021 from USD 36.10 Billion in 2016, at a CAGR of 6.5% during the forecast period. Growth in this market is mainly driven by increasing preference of pulmonary route of drug delivery, increasing technological developments in the form of smart/digital inhalers and rising incidences of respiratory diseases such as COPD, asthma, and cystic fibrosis.
KEY PRACTICAL LEARNING POINTS

- Novel technologies for pulmonary & nasal delivery
- Innovative development of inhalation devices
- Digital health combination products
- Analytical tools for inhaled medicines
- Challenges of bringing inhalation and respiratory drug delivery products to market
- Regulatory updates in the global respiratory market
- The challenges of developing inhalation devices
- Alternative therapeutic fields
- Dry-powder inhalers (DPIs) and Metered-dose inhalers (MDIs)
- Routes to controlling aerosol response
- Characterizing aerosol dynamics
- Model validation
- Future directions in inhalation and respiratory drug delivery research
- Regulatory pathways for inhaled therapies
- Challenges of developing a generic inhaled product
WHO SHOULD ATTEND

Chief Executives, Executive Directors, Vice Presidents, Heads/Team Leaders and Managers including:

- Respiratory Drug Development
- Generics & Respiratory
- Inhalation Drug Delivery Technologies
- Device Development and Engineering
- Respiratory Pharmacology
- Medical Devices & Injectors
- Inhalation Device Development
- Inhaled Formulation Science
- Inhalation Product Development
- Respiratory Regulations
- Generics & Respiratory
- Inhalation Process Development
- Respiratory Medicine
- Inhalation Drug Delivery
- E-Health
- Inhaled Dosage Forms
- Outsourcing
- Process Development
- Respiratory Pharmacology
- Device Engineering
- Drug Delivery Innovation
- Inhalation Devices
- Metered Dose Inhaler Development
- Scientific Research
- Medical Marketing
- Respiratory R&D
- Particle Characterization
- Business Development
- New Delivery Technologies
- Connective Health
- Respiratory Regulations
- Pulmonary Disease
- Inhalation
12:10 Targeted intransal nose-to-brain delivery of a novel amnion cell-derived biotherapeutic product  
By Larry R. Brown - Executive Vice President, Chief Scientific Officer at Neumoever Biotherapeutics, Inc.

- ST266, a complex, multi-component, neuroprotective and anti-inflammatory cytokine and growth factor mixture
- Targeted intranasal delivery to the cribriform plate bypasses the blood-brain barrier. Measurable delivery to the optic nerve and other brain tissues in rodents and non-human primates
- Demonstrated efficacy in animal models of optic neuritis and optic nerve crush enabling pathway to clinical testing

12:50 Regulatory Success with an Inhalation Digital Combination Product  
By Samir A. Shah - Associate Director - Regulatory Affairs, Combination Products at Teva Pharm

- The inhalation digital combination product was approved by FDA on December 21, 2018. Samir will share his expertise as the regulatory lead for that product.
11:00 Opening Address from the Chairman Wayland Rushin

11:10 Challenges and Future

11:30 Delivery of Therapeutic Aerosols to Critically Ill Patients

11:50 Morning Coffee & Networking Break

12:10 Novel caffeic acid-based oligomer molecules for pulmonary delivery: reversal of emphysema

12:30 Introducing novel platform technology of three phase polymer technology integrated into inhaler packaging to protect drug product from oxygen, moisture, and VOCs

13:00 Business Lunch

14:30 Opportunities, Trends & Possibilities with Capsule Based Inhalation Technology

15:10 Challenges and Limitations with Continuous Administration of Inhaled Prostacyclins

15:50 Inhaled insulin: More compelling than ever!

17:00 Panel Discussion: Alternative therapeutic fields

17:30 Chairman’s Closing Remarks
**BIOGRAPHIES**

**BORIS SHEKUNOV, US**
Director, Sr. Principal Scientist at Shire

Dr. Shekunov’s major scientific interests lie in the areas of particle technology, solid-state chemistry, pharmaceutics of drug delivery and pharmaceutical analysis. His career started in the UK academia. Since 2002, he directed different research groups in the US pharmaceutical industry. At Takeda, he oversees analytical and materials science aspects of the late development and commercial products. He is an author of over 100 publications and 30 patents.

**WAYLAND RUSHING, US**
Director, Scientific Affairs at Eurofins BioPharma Product Testing

Dr. Rushing has 20 years of CMC analytical testing experience, including over 15 years of experience in testing of inhalation drug products. As the Director of Scientific Affairs he is responsible for designing and implementing CMC testing programs for Eurofins clients including programs for pMDI’s, DPI’s. Nebulizers, pre-filled syringes along with a variety of other drug delivery and container/closure systems. He earned his bachelor’s degree from Westminster College and his Ph.D. in Chemistry from the University of Missouri.

**YVONNE CHAN, US**
Director, Center for Digital Health at Icahn Institute for Genomics and Multiscale Biology

Yvonne Yu-Feng Chan, MD, PhD, FACEP is the director of the Center for Digital Health at the Icahn School of Medicine at Mount Sinai. She is a national leader in mobile health and digital health research, and a board-certified Emergency physician. The mission of her Digital Health Center is to rapidly drive large-scale participation of patients and consumers in biomedical research by leveraging the latest mobile/digital technology and advanced analytic techniques to uncover novel insights and actionable results to advance healthcare.

**DRIES CARDOEN, BE**
Sr. Study Director at Nelson Labs

Dries Cardoen received his Ph.D. from the Faculty of Biology at the University of Leuven (Belgium) in 2011. After his academic career as a post-doctoral researcher, he started at Nelson Labs (formerly Tokonox Europe) in 2013 as study director in the Extractables & Leachables Department. He is currently leading the team of study directors that is specialized in E&L testing of inhalation drug products and topical and transdermal drug products.

**JUSTIN KALAFAT, US**
Scientific Business Development at ACG

Justin Kalafat is responsible for collaborating with pharmaceutical industry for capsule business. Prior to joining ACG in 2014, his background includes degrees in chemistry and roles within the generic pharmaceutical industry in quality control and procurement. His experiences enable key strategies to be developed with customers. R&D focused institutions and universities on the technical aspects of capsules as a dosage form solution.

**GÜNTHER HOCHHAUS, US**
Professor at University of Florida

Dr. Hochhaus received his Ph.D. in 1984 at the Institute of Pharmaceutical Chemistry, Westf. Wilhems University (Münster, Germany). He completed a postdoctoral fellowship at the University of California-San Francisco and subsequently joined the University of Florida’s College of Pharmacy. Dr. Hochhaus’ research is interested in evaluating inhalation drugs through in vitro, pharmacokinetic and pharmacodynamics approaches. Dr. Hochhaus is a Fellow of AAPS and the American College of Clinical Pharmacology. He has published more than 200 research papers.

**KRISTEN MERRIMAN, US**
Director of Respiratory Care Services at Stanford University Medical Center

Kristen Merriman has worked in respiratory therapy for over 25-years specializing in adult and pediatric emergency and critical care. While providing for patients at the bedside, she completed her advanced degrees in astrophysics and spent two years analyzing the chemical composition of star clusters around fossil galaxies to understand their evolutionary history. In 2008, she returned to respiratory care to work in an administrative capacity. In 2014, she presented at the California State Society of Respiratory Care conference a novel method for administering Treprostinil to an intubated patient using a vibrating mesh nebulizer.

**BADRE HAMMOND, US**
Director, Corporate Business Integration at Aptar Corp.

Badre Hammond’s background is in Biochemistry and drug development with 15 years’ experience in pharmaceutical product development with focus on nasal and pulmonary drug delivery systems. Mr. Hammond has broad experience in managing development of novel drug product programs from formulation development, pre-clinical, CMC, to market launch. He’s currently responsible for corporate business integration post M&As. His focus continues supporting commercial best practices, strategy, licensing, and business development.

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**JOHN PATTON, US**
Chairman & CEO at Dance Biopharm

Dr. John Patton began Dance Biopharm operations in 2010 with a carefully selected core team. Previously, he was the co-founder of Inhale Therapeutics (now Nektar Therapeutics), where he helped lead the development and FDA approval of the first inhaled insulin product. During his 18-year tenure at Inhale, Patton was a key driver for the company’s business development deals and participated in financings totaling more than $700M. Prior to founding Inhale, Patton led the drug delivery group at Genentech from 1985-1990, before that time, he was a tenure professor at the University of Georgia.

**LARRY R. BROWN, US**
Executive Vice President, Chief Scientific Officer at NovoCare Biotherapeutics, Inc.

Larry Brown, Sc.D. serves as the Executive Vice President of R&D and Chief Scientific Officer of NovoCare Biotherapeutics. He obtained his doctorate in Biochemistry and Bioengineering at the Massachusetts Institute of Technology under Prof. Robert Langer and trained in the late Dr. Judah Folkman’s laboratory in the Surgical Research Department of Children’s Hospital, Boston. He served as Vice President, Research at Baxter Healthcare Corporation and in scientific leadership roles at startup biotech companies. He maintains strong academic collaborations with MIT’s Deshpande Center for technological innovation.

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**NICHOLAS BUCHMANN, DE**
Programme Manager at Vectura Group plc

Dr. Nicolas Buchmann is Programme Manager at Vectura Group plc. He has gained extensive experience as Programme and Project Manager and is leading drug-device combination programmes with pMDIs, development projects with connected inhalation devices, smart nebuliser technology developments and was also deeply involved in the development of novel aerosol generation technologies. At his work at Vectura. His educational background is engineering profession with a Doctor of Philosophy in Mechanical and Biomedical Engineering.

**DONOVAN YATES, US**
CEO at KAER Biotherapeutics

Donovan B. Yates, Ph.D. CEO. KAER Biotherapeutics Corporation, is an internationally recognized authority in aerosol drug delivery and respiratory function. Has developed technologies to deliver aerosols to the lungs, quantify the dose delivered and evaluate the physiological mechanisms whereby they are cleared from the lungs. He is an inventor of aerosol generation and delivery technology to deliver fine particle solid-phase aerosols from viscous solutions at high dose rates. Dr. Yeates is an emeritus professor with over 90 publications and 16 patents. He has a Ph.D. in Medical Biophysics from the University of Toronto.

**KRISTEN MERRIMAN, US**
Director of Respiratory Care Services at Stanford University Medical Center

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Dr. Samir Shah has 17 years of regulatory, clinical, and formulation experience with pMDI’s, DPI’s, Nebulizers, and nasal sprays. In his current role, he leads the regulatory strategy for digital combination products including the regulatory approval of ProAir Digitalhaler, the first FDA approved digital inhaler with built-in sensors which connects to a mobile application. He earned his bachelors degree from Case Western Reserve University in Polymer Science & Engineering and his PhD from Wake Forest University School of Medicine in Biomedical Engineering.

Dr. Barnewall has 25 years of experience in veterinary medicine and biomedical research experience in Inhalation, bacterial pathogenesis, medical countermeasures, and animal model development. Dr. Barnewall has been at Battelle for 19+ years, where he serves as Research Leader and Manager of the Inhalation department, as well as a veterinarian, a scientist, and study director. His duties as a scientist and inhalation leader consist of planning, writing, supervising, and conducting detailed experimental studies with viruses, bacteria, and toxins in laboratory animals under biosafety level 2 and biosafety level 3 conditions.

Dr. De Backer graduated from Delft University of Technology, The Netherlands as aerospace engineer. He attained an MSc degree in aerodynamics and specialised in applied biomedical computational fluid dynamics leading to a PhD from the University of Antwerp, Belgium. He is an alumnus of the MBA programs at London Business School, London and Columbia Business School, New York. Dr. De Backer has received several awards for his innovative research in the field of airway modeling in respiratory and sleep medicine. His work has been published in international journals. Dr. De Backer founded FLUIDDA in 2005 and he holds the position as Chief Executive Officer since 2007.

Dr. Masahiro Sakagami is a Professor in the Department of Pharmaceutics at the Virginia Commonwealth University (VCU) School of Pharmacy in Richmond, Virginia, USA. Dr. Sakagami has extensive experience and expertise of academic and industrial research in the areas of biopharmaceutics and pharmacology for drugs via pulmonary delivery, alongside regulatory assessments of inhaled products. His recent research is focused on novel inhaled drug discovery in emphysema, COPD and pulmonary fibrosis; and dissolution testing for inhaled products. In 2013-2017, he was one of the grant award recipients to develop in vivo-predictive in vitro drug aerosol dissolution testing by the Food and Drug Administration (FDA).
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