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.
Over 200+ delegates representing global pharmaceutical organisations, leading biotech companies and internationally renowned academic institutions will be joining the Inhalation & Respiratory Drug Delivery 2019

**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
SCIENTIFIC
AGENDA
Thursday, May 30, 2019

08:30 Registration and Welcome Coffee
09:00 Opening BioTech Pharma Summit

EVOLUTION AND INNOVATION

09:10 Extractables and leachables: what’s in a name?
By Dries Cardoen - Sr. Study Director, Nalson Labs
- Approach to extractables and leachables testing
- Bridging between extractables and leachables
- Changing FDA requirements

09:50 Speed Networking

10:30 Targeted intranasal nose-to-brain delivery of a novel amnion cell-derived biotherapeutic product
By Larry R. Brown - Executive Vice President, Chief Scientific Officer at Noveome 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

11:10 Morning Coffee and Networking Break

DIGITALIZATION AND REGULATORY LANDSCAPE

11:40 The Mount Sinai Asthma Mobile Health Study powered by Apple’s ResearchKit framework is a remote observation study that enrolled >10,000 participants from 3 countries.
By Yvonne Chan, MD PhD, principal investigator of the study and Director of the Center for Digital Health at Icahn School of Medicine at Mount Sinai, will share lessons learned from this pioneering mobile health research study
- 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

12:20 Regulatory Success with a 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.

13:00 Business Lunch

CHALLENGES, TRENDS AND ANALYSIS

14:30 Regulatory and Logistical Challenges and Complexities in Testing Products for Safety and Efficacy Against Highly Infectious Inhaled Microorganism
By Ray Barnewall - Inhalation Technology at Life Sciences Research and Battelle
- Detail the physical space constraints and safety limitations when conducting tests using infectious organisms
- Detail the regulatory concerns and aspects that can be addressed (equipment calibration, validation, process standardization)
- Provide examples of aerosol concentration/dose data that show successful outcomes and when problems arise

15:10 Analytical Challenges in Implementing Effective QC/Stability Testing of Inhalation Drug Products
By Wayland Rushing - Director, Scientific Affairs at Eurofins BioPharma Product Testing
- Technical challenges of moving from R&D to QC testing for product specific tests (DSD, CU, Spray pattern, etc)
- Automated versus manual testing
- Extractables and Leachables regulatory requirements

15:50 Coffee & Networking Break

16:20 Smart Nebulisers - Opportunities for Development of Drug Products
By Nicolas Buchmann - Programme Manager at Vectura Group plc
- A number of companies (ranging from large to speciality pharma) have strategic initiatives to reposition or repurpose known chemical entities “old drugs” for or within inhalation therapy. Many of these programmes are focussed on developing value-added or differentiated products for “on target” respiratory or “off-target” systemic indications to meet a particular unmet therapeutic need. With lower risk profile compared to New Chemical Entity (NCE) product developments using known drugs offer new opportunities by using new technologies
- Products delivered via smart nebulisation, e.g., via AKITA® JET or FOX® nebulisers, can provide the value propositions that merit their development as repositioned drugs. These nebulisers guide patients achieve the correct inhalation technique and deliver a greater proportion of drug to the lungs with reduced variability, as well as monitor treatment compliance through their connectivity. These attributes may improve patient outcomes and lead to better patient satisfaction and adherence. In both products, a Bluetooth-enabled app records inhalation and adherence data for sharing with the caregiver or physician
- Many poorly treated orphan, rare, or neglected respiratory diseases are benefiting from such repositioned developments providing efficacious licensed products to patients where previously few existed or where off-label drug use is common. Repositioned product developments include anti-infectives for a variety of conditions. CF, NCFB, MAC and tuberculosis, as well as, products to treat niche indications; in lung cancer, severe uncontrolled asthma/COPD, chronic cough, idiopathic pulmonary fibrosis (IPF), pulmonary arterial hypertension (PAH) etc

17:00 Panel Discussion: Future directions in inhalation and respiratory drug delivery research
Moderated by TBA
- Key studies on the latest trends
- New delivery technologies
- Alternative solutions to conventional drug discovery methods
Panelists: Speakers of the day

17:30 Chairman’s Closing Remarks

20:00 Gala Dinner
### Challenges and Future

#### 09:10 Modeling and Characterization of Powder Dispersion in DPIs
- By Boris Shekunov - Director, Sr. Principal Scientist at Shire
- Quantitative mechanisms of particle interactions
- Aerodynamic regimes and inhaler performance
- Analytical aspects, formulation approaches and optimization strategies

#### 09:50 Bringing better-inhaled drugs faster to market through Functional Respiratory Imaging and Artificial Intelligence
- By Jan De Biecker - CEO at FluidDa, Inc.

#### 10:30 Challenges and potential solution for a streamlined development of generic inhalation drugs
- By Günther Hochhaus - Professor at University of Florida
- Approval of generic inhalation drugs remains a challenge. At this time, the FDA is suggesting a weight of evidence approach that compares in vitro characteristics of the generic and innovator formulation, pharmacokinetics to primarily assess systemic safety, as well as biomarker/clinical studies to ensure equivalence of efficacy.
- Biomarker/clinical studies are challenging and represent a large financial risk due to the generally observed flat dose-response relationship, distinct variability, and the large number of patients required for such clinical trials without providing sufficient high resolution in detecting differences in the pulmonary equivalence. A method to assess local equivalence with high resolution and lower costs is therefore urgently needed.
- This talk will review and discuss potential alternative approaches for the development of generic inhalation drugs.

### DAY 2

#### 12:50 Introducing novel platform technology of three phase polymer technology integrated into inhaler packaging to protect drug product from oxygen, moisture, and VOCs
- By Badre Hammond - Director, Corporate at AptarGroup
- Review most recent regulatory combination product guidelines affecting inhalation drug product submission and approval

#### 13:30 Business Lunch

#### 14:30 Opportunities, Trends & Possibilities with Capsule Based Inhalation Technology
- By Justin Kalafat - Scientific Business Development at ACG
- Market trends in dry powder inhalation
- Comparison of capsule based dry powder versus other inhalation delivery systems
- Using Design of Experiments (DOE) to Optimize Inhalation Capsule’s Puncturing. Mapping Performance of Inhalation Based Capsules with Appropriate Puncturing for Optimum Dose Delivery. HPMC Capsules in DPIs
- Evaluation of the Puncturing Force Prepared by Different Manufacturing Methods & Having Different Compositions. Impact of Different Internal Lubricants on Aerodynamic Property from HPMC Dry Powder Inhalation Capsules

#### 15:10 Challenges and Limitations with Continuous Administration of Inhaled Prostacyclins
- By Kristen Merriman - Director of Respiratory Care Services
- Inhaled prostacyclins may prove beneficial in treatment of refractory hypoxemia and pulmonary hypertension. Traditional pneumatic jet nebulizers introduce additional flow that can interfere with microprocessor controlled mechanical ventilators. Vibrating mesh technology provides unreliable nebulization and with no audible alarm systems.
- Wasted medication results from both vibrating mesh and pneumatic jet nebulizers running continuously throughout the patient’s respiratory cycle (inhalation and exhalation).
- Pneumatic jet nebulizers powered by built-in ventilator port results in breath-actuated delivery and consistent alarm features without negatively impacting advanced features provided by microprocessor driven life support systems.

#### 15:50 Coffee & Networking Break

#### 16:20 Inhaled insulin: More compelling than ever!
- By John Patton - Chairman & CSO at Dance Biopharm
- Although inhaled insulin was shown to be feasible almost 100 years ago it was not until 1990, that efforts to commercialize it were started. Since then more than $7B has been spent on development with two dry powder products receiving FDA approval, one in 2006 (Exubera) and another in 2014 (Afrezza).
- Upon launch these products encountered difficult commercial barriers due to poor market preparation, resistance from the established injected insulin businesses and some issues with the first generation technologies. These barriers are understood and addressable. The need for a non-invasive way to deliver insulin remains high.
- Dance is developing a third generation soft mist inhaler that is connected. The company plans to initiate a global phase 3 program next year with 1/3 of the patients coming from China, 1/3 from Europe and 1/3 from the Americas.

#### 17:00 Panel Discussion: Alternative therapeutic fields
- Moderated by TBA
- Inhaled vaccines
- Inhaled insulin
- Inhaled gene therapy
- Inhaled antibiotics

#### 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.

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 Toxikon 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.

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 or 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.

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GÜNTER 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.

JOHN PATTON, US
Chairman & CSO 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 Inhalae Therapeutics (now Nektar Therapeutics), where he helped lead the development and FDA approval of the first inhaled insulin product. During his 18-year tenure there, he was also chairman of the company’s business development deals and participated in financings totaling more than $700M. Prior to founding Inhalae, Patton led the drug delivery group at Genentech from 1985-1990. Before that time, he was a tenured professor at the University of Georgia.

BADRE HAMMOND, US
Director, Corporate Business Integration at AptarGroup

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.

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

Larry Brown, Sc.D. serves as the Executive Vice President of R&D and Chief Scientific Officer at Noveome 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 Childrens 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.
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. 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).

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. Shah is an Associate Director for Regulatory Affairs, Combination Products at Teva. His responsibilities include advancement of regulatory strategies and the development of new in vitro and computational models for drug product development. Dr. Shah has extensive experience in the area of aerosol delivery and pharmaceutical development. His current research is focused on the development of novel delivery technology and inhalation formulation strategies to increase lung deposition and reduce systemic exposure of drugs.
# REGISTRATION FORM

**Title:**

**Name:**

**Position:**

**E-mail:**

**Company:**

**Address:**

**Postcode:**

**City:**

**Phone:**

**Company:**

**VAT No:**

**Signature:**

This booking is invalid without signature

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### ACADEMIC/MED./NPO PACKAGE

- Individual or Group Registration
- 2 days Summit
- Full Access to All Sessions
- Coffee Breaks/Lunches
- Gala Dinner (Extra 50%)
- Unique 1-on-1 meetings
- Airport Pick-Up/Drop-Off
- Accommodation at the Hotel Venue

### INDUSTRY BASIC PACKAGE

- Individual Registration
- 2 days Summit
- Full Access to All Sessions
- Coffee Breaks/Lunches
- Gala Dinner
- Unique 1-on-1 meetings
- Airport Pick-Up/Drop-Off
- Accommodation at the Hotel Venue

### INDUSTRY PREMIUM PACKAGE

- Individual Registration
- 2 days Summit
- Full Access to All Sessions
- Coffee Breaks/Lunches
- Gala Dinner
- Unique 1-on-1 meetings
- Airport Pick-Up/Drop-Off
- Accommodation at the Hotel Venue

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### REGISTRATION FORM

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<th>PACKAGE NAME</th>
<th>Description</th>
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<tr>
<td>SUPER EARLY BIRD</td>
<td><strong>Opportunity to give a speech at the beginning of the conference</strong> (up to 40min)</td>
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<tr>
<td>EARLY BIRD</td>
<td>6m2 exhibition space</td>
</tr>
<tr>
<td>DISCOUNTED TICKET</td>
<td>Full page Ad in conference program</td>
</tr>
<tr>
<td>NORMAL TICKET</td>
<td>Company Banner displayed at the reception desk &amp; Coffee breaks</td>
</tr>
<tr>
<td>DELEGATES</td>
<td>Flyer/promo gifts into congress bags</td>
</tr>
<tr>
<td>IOP AIRPORT PICK-UP/ DROP-OFF</td>
<td>Branding at post-event communication activities</td>
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<tr>
<td>HOTEL ACCOMMODATION</td>
<td>Access to all Sessions</td>
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<tr>
<td>GALA DINNER</td>
<td>Business Lunches &amp; Gala Dinner</td>
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<td>UNIQUE 1-ON-1 MEETINGS</td>
<td>Exclusive One-on-One Meetings</td>
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<tr>
<td>AIRPORT PICK-UP/DROP-OFF</td>
<td>Up to 2 delegates FREE-Admission (25% discount for extra ticket)</td>
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<tr>
<td>ACCOMMODATION</td>
<td>VIP Airport Pick-Up Service</td>
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<td>2 nights accommodation for 5 delegates registered</td>
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### SPEAKER SPONSORSHIP

- **Opportunity to give a speech at the beginning of the conference (up to 40min)**
- 6m2 exhibition space
- Logo on the conference website and main stage
- Flyer/promo gifts into congress bags
- Branding at post-event communication activities
- Access to all Sessions
- Business Lunches & Gala Dinner
- Exclusive One-on-One Meetings
- Up to 3 delegates FREE-Admission (25% discount for extra ticket)
- VIP Airport Pick-Up Service
- 2 nights accommodation for 3 delegates registered

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### KEYNOTE SPEECH PACKAGE

- **Opportunity to give a speech at the beginning of the conference (up to 40min)**
- Logo on the conference website and main stage
- Flyer/promo gifts into congress bags
- Branding at post-event communication activities
- Access to all Sessions
- Business Lunches & Gala Dinner
- Exclusive One-on-One Meetings
- Up to 2 delegates FREE-Admission (25% discount for extra ticket)

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### EXHIBITION PACKAGE

- **Opportunity to give a speech at the beginning of the conference (up to 40min)**
- Logo on the conference website and main stage
- Flyer/promo gifts into congress bags
- Branding at post-event communication activities
- Access to all Sessions
- Business Lunches & Gala Dinner
- Exclusive One-on-One Meetings
- Up to 2 delegates FREE-Admission (25% discount for extra ticket)

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### SECURITY

- All入侵及Respiratory Drug Delivery Summits are an exclusive limited attendance event. Early bird tickets are not non-refundable and subject to availability.

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**By sending this form, I confirm that I have read and accepted the terms and conditions detailed below:**

**Confidentiality:** We will confirm your participation after receiving the signed registration form and the delegate will receive the invoice within 24h of sending the signed form. The hotel details will be sent 2 or 3 weeks before the start of the conference.

**Cancellations:**

- Cancellation made one month prior to the start of the conference will be refunded less 50% administration charge. Refunds will be made after the conference: Cancellations made within one month of the conference start date will receive no refund. Substitutes are accepted up to 3 days before the conference. Any cancellation will be accepted latest one month before the event and should be informed in written form.

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**All Prices displayed include VAT**

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**For More Information Please Visit:**

- [EPM Group](https://www.epmgroup.org)

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**Please send the signed form to this contact:**

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