Global Engage

GLOBAL BIOPROCESSING & BIOANALYTICS CONGRESS

PRAGUE, CZECH REPUBLIC

— 24-25 May 2018 —

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#BioprocessingCongress

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WARM WELCOME

Global Engage

Global Engage is pleased to announce the **2018 Global Bioprocessing and Bioanalytics Congress**, which will be held on 24th–25th May 2018 in Prague, Czech Republic. The event is part of our highly successful series of life science technology congresses including conferences on Biologics & Biosimilars, Pharma R&D Informatics, Medicinal Chemistry, NASH, and Precision Medicine amongst others.

Biopharmaceutical drug production has seen an unparalleled growth in recent years and is now a core element of the pharmaceutical industry, however, their complexity poses challenges for their manufacturing. New technologies and strategies are needed to produce these drugs efficiently whilst maintaining the high quality and standards required for them to enter the market. This makes it the perfect time, therefore, to learn about the latest technologies and methodologies for pharmaceutical bioprocessing and bioanalytics.

Attracting experts working in all areas of bioprocessing and process analytics, including cell line development, single-use technologies, continuous processing, automated systems, monitoring technologies, CMC/GMP practices, QbD strategies, purification optimisation, and protein recovery, the conference will examine the latest developments in the technologies and methods being used for progressing biopharmaceutical manufacturing processes.

The conference will provide an interactive networking forum to both further develop and answer your queries through a vibrant exhibition room full of technology providers showcasing their technologies and other solutions, poster presentation sessions, expert led case study presentations, a high-level panel discussion, and interactive Q&A sessions from a 30-strong speaker faculty examining topics on 4 separate tracks outlined below.

EXPERT SPEAKERS Include:

CHRISTIAN HUNZINGER
Director, Biotech CMC Program Lead, Merck

PAULINE RUDD
Professor and PI, National Institute for Bioprocessing Research, Ireland

JAN SCHÖNING
Head of Global Technology Management, Boehringer Ingelheim

BERTHOLD BOEDEKER
Chief Scientist, Global Biologics-Biotech Development and Project Coordinator, Bayer

LATEST MANUFACTURING STRATEGIES AND TECHNOLOGIES

- Single Use Technologies
- Continuous processing development
  - Technological developments
  - Continuous processing vs batch processing panel discussion
  - High-throughput methods
  - Modular design possibilities
- Automation technologies and their applications
- Process Optimisation and monitoring
- Strategies for implementing risk-balanced innovative technologies
- Change Control/Management

UPSTREAM METHOD DEVELOPMENT

- Cell culture modalities and choosing the right medium
- Microbial vs mammalian expression systems
- Cell line development and optimisation
- Perfusion systems
- Scale-up analysis
- Applications of gene editing and synthetic biology
- Protein characterisation

QUALITY CONTROL, ANALYTICS, AND REGULATION

- Protein characterisation and monitoring
- Real-time quality control methods including multivariate monitoring techniques
- DOE and QbD strategies
- Meeting GMP, PAT and CMC guidelines
- Method validation
- Streamlined process analytics
- Data management and analysis
- System modelling
- Outsourcing challenges

PURIFICATION AND RECOVERY METHODS AND TECHNOLOGIES

- Showing the latest developments in key technologies including:
  - Chromatography
  - Centrifugation
  - Filtration
  - Disposables
  - Automated methods/Continuous processing
- Reducing costs whilst maintaining efficiency
- Tech transfer and scale up
- Troubleshooting key issues in protein purification and recovery

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DYADIC

CONFIRMED SPEAKERS

DIRK REDLICH
VP and Head of Technology, Janssen Vaccines

TAPAN SANGHVI
Senior Director, Vertex Pharmaceuticals

TIM HEISELER
Field Applications Specialist, Pall FortéBio

JAN SCHÖNING
Head of Global Technology Management, Boehringer Ingelheim

JEAN-YVES BAUER
Senior Engineer, GSK Vaccines

JOCHEN SIECK
Head of Perfusion Systems Laboratory, Merck

CHRISTEL AEBISCHER
Principal Scientist, Cell Sciences, Glenmark Pharmaceuticals S.A

KAI TOUW
Process Development Consultant, Sartorius Stedim Biotech

BERNARDO ESTUPINAN-GAISBAUER
Vice President, Business Development, KBI Biopharma

RICHARD KUCIA-TRAN
Head of Purification Research, Biopharm, GSK

RUI RODRIGUES
Principal Scientist, Novartis

BERTHOLD BOEDEKER
Chief Scientist, Global Biologics-Biotech Development and Project Coordinator, Bayer

CECILE BROCARD
Director, Downstream Development, Boehringer Ingelheim

VICKY PIRZAS
Senior Director, Recombinant Protein Production, CSL Behring

GIRIJA KRISHNAMURTHY
Executive Director of Process Development, Amgen

PAUL DENNY-GOULDSON
VP, Strategic Solutions, IDBS

BERTIE CHI
Bioprocessing and Analytics Scientist, MedImmune

VIGNESH RAJAMANICKAM
Post doctorate researcher, Research Division Biochemical Engineering, Institute for Chemical, Environmental and Biological Engineering, TU Wien, Austria

PAULINE RUDD
Professor and PI, National Institute for Bioprocessing Research and Training (NIBRT), Ireland and Visiting Investigator, Bioprocessing Technology Institute, A*Star, Singapore

PAUL DALBY
Professor and Co-Director of EPSRC Centre, University College London, UK

CHRISTIAN HUNZINGER
Director, Biotech CMC Program Lead, Merck

RALPH DAUMKE
Market Manager Biologics, FILTROX AG

JONATHAN BONES
Principal Investigator, National Institute of Bioprocessing Research and Training (NIBRT)

ALISTAIR KIPPEN (Chair)
VP BioPharmaceutical Development, IPSEN

RONEN TCHELET
Head of R&D, Dyadic

RALPH DAUMKE (Chair)
Market Manager LifSciences, FILTROX AG

08:00-08:50 Registration & Refreshments

08:50-09:00 **Global Engage Welcome Address and Morning Chair's Opening Remarks: Ronen Tchelet,** Head of R&D, Dyadic

09:00-09:40

KEYNOTE ADDRESS:
MARK VAN OOIJ

Head of Technical Platform and Implementation, Janssen Vaccines

Novel vaccines addressing today's highest unmet medical need: opportunities and challenges

This presentation will discuss the need and opportunities of matured platforms for the development and commercial production of novel vaccines. The application of robust and scalable platforms, like the Adeno virus vector platform and Per.C6 cell platform, allow to fight unexpected outbreaks of infectious diseases as well as the development of novel approaches to combat HIV, Ebola, Zika and others. The Adeno vector/Per.C6 platform combination allows a fast development approach, where cycle times between target identification/ vector generation and the GMP production of vaccine within less than 12 months can be accomplished. Adeno vector vaccines can not only be developed and produced at large scale within a short time frame but extraordinary characteristics of these vaccines like thermal stability will be discussed in light of the impact on real world examples. Remaining regulatory advantages and challenges will be outlined.

09:40-10:10

TAPAN SANGHVI

Senior Director, Vertex Pharmaceuticals

Process Technology Optimisation – Title TBC

10:10-10:40

SOLUTION PROVIDER PRESENTATION:
TIM HEISELER

Field Applications Specialist, Pall FortéBio

Octet® systems get ready for regulated environments - providing data integrity of biomolecule binding responses in real-time and label-free

Biolayer Interferometry (BLI) technology based Octet® systems have been widely adopted in early research, and development of drug candidates and biotherapeutics. Now, with a comprehensive set of tools for compliance, this label-free technology is gaining traction in process development and quality control (QC) labs for concentration analysis in cell culture and purification, for kinetic and potency analysis of drug-target and drug-Fc receptor interactions, and for stability analysis by assessing changes in activity in stressed and forced degradation samples. Discover the go-to solution providing versatility and flexibility necessary in development combined with rigor and simplicity needed in a QC environment.

10:40-11:50 Morning Refreshments

LATEST MANUFACTURING STRATEGIES AND TECHNOLOGIES

Track Chair: Ronen Tchelet, Head of R&D, Dyadic

11:50-12:20

JAN SCHÖNING

Head of Global Technology Management, Boehringer Ingelheim

Development of biological products – Innovative technologies as prerequisite and opportunity

- Biologics are highly complex molecules and require a sophisticated and yet robust production process
- Developing a manufacturing process is dependent on excellent state-of-the art technologies, development of novel future technologies and excellence in execution by excellent people
- Strategic technology development can break the triple constraint, support the drug development requirements and reduce development timelines and efforts

12:20-12:50

JEAN-YVES BAUER

Senior Engineer, GSK Vaccines

Integrity management of single use systems for critical Bioprocess

- Single use and closed process: pro and cons regarding single use systems for closed processes.
- Implementation of single use system within critical applications: Context for GSK vaccines / Robust implementation process /Drawbacks & Remaining challenges
- Management of integrity: nondestructive pre use tests / validation tests / post use tests.

UPSTREAM METHOD DEVELOPMENT

Track Chair: Alistair Kippen, VP BioPharmaceutical Development, IPSEN

11:50-12:20

JOCHEN SIECK

Head of Perfusion Systems, Cell Culture Media R&D, Merck

Perfusion as a means of increasing productivity and flexibility in biopharmaceutical manufacturing

- Continuous processing is increasingly being adopted to intensify biopharmaceutical manufacturing.
- Perfusion offers great advantages in productivity over fed-batch, which can be further leveraged using perfusion specific cell culture media.
- Strategies like high cell density cryopreservation are emerging to increase flexibility in biopharma manufacturing and process development.

12:20-12:50

CHRISTEL AEBISCHER

Principal Scientist, Cell Sciences, Glenmark Pharmaceuticals S.A

A posteriori monoclonality assessment of production cell lines

Regulatory authorities (ICH Q5D) require that production cell lines are monoclonal, i.e. derived only from a single cell ancestor. Generally two subsequent rounds of limiting dilution are considered acceptable for the generation of clonal cell populations. In case the cloning process is not fully compliant with the authorities' expectations, the homogeneity of the cell bank can be demonstrated a posteriori by the generation of additional data, allowing the use of these cell lines as production cell line. Glenmark has developed a statistical approach based on the detection of cell line specific genetic signatures by NGS and on qPCR analysis of subclones to assess the monoclonality status of a cell line.

12:50-13:20

SOLUTION PROVIDER PRESENTATION:

RONEN TCHELET

Head of R&D, Dyadic

C1: How the C1 platform will change the production approach for therapeutic proteins

For over 30 years, Dyadic has proven itself, both commercially and scientifically, to be a high quality and yield producer of enzymes and proteins for both the specialty chemical and biology applications using its proprietary and patented gene expression system based on the Myceliophthora thermophila fungus, nicknamed C1. C1 produces proteins at very high levels expressing mAbs at levels of 1.71 g/l/d in a 30L fermentation using a fed-batch process that is based on low cost glucose and defined media. The proteins that are produced from C1 are secreted to the media and fold correctly. MAbs produced by C1 have virtually identical binding kinetics to mAbs produced using CHO cells. C1 also has shown to produce FC-fusions at 1.35 g/l/d. Further productivity gains are expected to continue for a growing number of proteins including mAbs, rVaccines, VLP's, bi-specifics, etc. During the presentation data will be presented highlighting the advantages and potential for C1 to be further developed into a safe and efficient expression system that produces high levels of low cost stable and secreted proteins with and without defined human-like glycan structures. To summarize, Dyadic goal is to demonstrate that the C1 platform may improve efficiency of the development, production and performance of biologic vaccines and drugs at flexible commercial scales.

12:50-13:20

SOLUTION PROVIDER PRESENTATION:

KAI TOUW

Process Development Consultant, Sartorius Stedim Biotech

Commercially available intensified upstream platform to triple upstream productivity from 3 to 10 g/L in 12 days of culture

Single Use systems have enabled the biomanufacturing industry to build and operate production facilities in a fraction of the time and at a fraction of the investment costs, while allowing a high degree of flexibility e.g. for multiproduct use. This has allowed early market entry, which is key to achieve market share, at acceptable risks. However, main caveat of the current Single Use facilities is their limited output, typically 500 kg/year for a 6 x 2000 L facility at 3 g/L Fed Batch titer. This substantially limits their usefulness for commercial scale manufacturing. Good news is that this productivity gap can be overcome by process intensification. In this presentation several upstream process intensification examples are shown, including an effective titer boost from 3 to 10 g/L in 12 days of culture, using commercially available platform tools, including cell line, media, process development tools and commercial scale manufacturing tools. With consistent effective titers of 10 g/L and beyond, Single Use facilities become an even more attractive option for commercial manufacturing.

13:20-14:20 Lunch

LATEST MANUFACTURING STRATEGIES AND TECHNOLOGIES

Track Chair: Ronen Tchelet, Head of R&D, Dyadic

14:20-14:50

BERTHOLD BOEDEKER

Chief Scientist, Global Biologics-Biotech Development and Project Coordinator, Bayer

Benefits and challenges of disposable technologies and continuous processing in biomanufacturing and plant design

Disposables, closed system operation and continuous processing as well as less segregated simplified plant design have made significant advances in the past years. This talk will summarize several aspects of these innovative elements on modern bioprocessing and plant design as well as some risks associated with these technologies. In addition, a case study for plant design using a disposables and continuous processing in a ball room facility will be presented and compared to standard fed-batch based plants.

14:50-15:20

VICKY PIRZAS

Senior Director, Recombinant Product Development, CSL Behring

Advantages and challenges of continuous bioprocessing

PURIFICATION AND RECOVERY METHODS AND TECHNOLOGIES

Track Chair: Ralph Daumke, Market Manager LifSciences, FILTROX AG

14:20-14:50

RICHARD KUCIA-TRAN

Head of Purification Research, Biopharma Process Research, GSK

Bioprocess Inc. – Downstream Process Development through GSK's "Onestream" Approach

Increasing pressure to reduce development cycle times, whilst simulataneously facing increasing drug development complexity, means that upstream and downstream processing can no longer be considered as separate disciplines. This talk will outline how, at GSK, a "Onestream" philosophy, involving the integration of upstream process design and downstream process development strategies has enabled a holistic approach to process optimisation. Case studies will be presented illustrating how taking such an approach has enabled, what are traditionally considered downstream processing challenges, to be addressed through strategic combination of both upstream and downstream process optimisation. This has resulted in streamlined cycle times whilst simultaneously maximising productivity, process robustness and product quality, enabling the rapid delivery of GSK's early stage portfolio.

14:50-15:20

RUI RODRIGUES

Principal Scientist, Novartis

Connected-DSP: the next stage of evolution in downstream processes

- Continuous biomanufacturing has the potential to reduce cost and facility size while delivering improved quality and flexible multi-product facilities.
- In a connected-DSP process each individual unit operation is still connected in a familiar sequence, same resins, same buffers, same filters and same chemistry. However, it is in the way they all come together that the enhancement is created.
- Connected-DSP has shown the potential to be the first step forward from the current batch to a fully continuous blue-sky vision process.

15:20-15:50

SOLUTION PROVIDER PRESENTATION

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15:20-15:50

SOLUTION PROVIDER PRESENTATION:
RALPH DAUMKE
Market Manager Biologics, FILTROX AG

Using Alluvial Filtration as an Effective and Economical Solution for Midstream Clarification

- Efficient and economical cell removal
- Midstream application optimization
- Alluvial filtration

15:50-16:40 Afternoon Refreshments

16:40-17:10

CECILE BROCARD
Director of Downstream Development, Boehringer Ingelheim

Downstream Purification Strategies for Microbial Expressed Proteins

We present our holistic approach based on a HTPD toolbox to lever the complexity of manufacturing development for non-platform biotherapeutics. Integration of the whole process chain allows for examination of interdependencies between upstream and downstream development. Our automated screening and optimization unit operations can either be applied as standalone module or in combination as miniaturized process chains.

17:10-18:00

PANEL DISCUSSION:

Continuous processing vs batch processing

Continuous bioprocessing can dramatically speed up biopharmaceutical manufacturing processes but also comes with its own challenges in the need for continuous testing/monitoring and the difficulties of integrating new technologies into established biomanufacturing facilities. In this panel discussion, industry experts will debate the advantages and disadvantages of continuous processing systems and best practices for implementing these technologies in current biopharma facilities.

MARK VAN OOIJ (Chair)
Head of Technical Platform and Implementation, Janssen Vaccines

BERTHOLD BOEDEKER
Chief Scientist, Global Biologics-Biotech Development and Project Coordinator, Bayer

VICKY PIRZAS
Senior Director, Recombinant Product Development, CSL Behring

JOCHEN SIECK
Head of Perfusion Systems, Cell Culture Media R&D, Merck

PAULINE RUDD
Professor and Principle Investigator, National Institute for Bioprocessing Research and Training (NIBRT), Ireland and Visiting Investigator, Bioprocessing Technology Institute, A*Star, Singapore

18:00-19:00 End of Day One / Complimentary Drinks Reception

Interested in sponsoring the drinks reception? Contact Faizel Ismail/Tony Couch at **sponsorship@globalengage.co.uk**

08:30-08:55 Refreshments

08:55-09:00 **Track Chair's Opening Remarks:** **Pauline Rudd,** Professor and Principle Investigator, National Institute for Bioprocessing Research and Training (NIBRT), Ireland and Visiting Investigator, Bioprocessing Technology Institute, A*Star, Singapore

09:00-09:40

KEYNOTE ADDRESS:
GIRIJA KRISHNAMURTHY

Executive Director of Process Development, Amgen

Patient-Centric Approach to Development of Biologics

09:40-10:10

SOLUTION PROVIDER PRESENTATION:
BERNARDO ESTUPINAN-GAISBAUER

Vice President, Business Development, KBI Biopharma

How quickly can we get Biologics into the Clinic

- Early development strategies – everything is not a platform approach
- Analytical development to support process development and manufacturing
- Manufacturing – how quickly can we get Biologics into the Clinic

QUALITY CONTROL, ANALYTICS, AND REGULATION

10:10-10:40

VIGNESH RAJAMANICKAM

Post doctorate researcher, Research Division Biochemical Engineering, Institute for Chemical, Environmental and Biological Engineering, TU Wien, Austria

Enabling continuous biomanufacturing through process characterization tools

The current contribution wants to motivate current needs, prerequisites and solutions of mechanistic model development and its deployment for enabling continuous biomanufacturing. The following elements will be covered for example:

- Regulatory guidelines motivating the use of capturing knowledge in models
- Workflows how goal driven mechanistic models can be developed
- Models as PAT tool: Demonstrations of cases in which models are solutions to measure less
- Observer solutions for real-time parameter optimization
- Multiparametric control and event prediction

10:40-11:50 Morning Refreshments

11:50-12:20

PAULINE RUDD

Professor and Principle Investigator, National Institute for Bioprocessing Research and Training (NIBRT), Ireland and Visiting Investigator, Bioprocessing Technology Institute, A*Star, Singapore

Integrated technologies for glycan analysis: achieving optimal glycosylation processing for drug safety and efficacy

- Integrated approaches to automated glycan analysis and bioinformatics
- Orthogonal technologies to confirm structural assignments
- Applications to defining, monitoring and controlling drug safety and efficacy

12:20-12:50

JONATHAN BONES

Principal Investigator, National Institute of Bioprocessing Research and Training (NIBRT)

Charge Variant Analysis Coupled to High Resolution Native Mass Spectrometry

- Charge variant analysis (CVA) of biopharmaceuticals is required under ICH Q6B. Issues arise when a new peak is identified in the CVA profile.
- Here, the development of high resolution charge variant analysis coupled directly to native high resolution mass spectrometry is described that facilitates the intact mass analysis of minor charge variants with high mass accuracy.
- Application to the characterization of mAbs and other recombinant proteins is described under normal conditions and during forced degradation studies.

12:50-13:20

SOLUTION PROVIDER PRESENTATION:
PAUL DENNY-GOULDSON

VP, Strategic Solutions, IDBS

Title TBC

13:20-14:20 Lunch

14:20-14:50

PAUL DALBY

Professor and Co-Director of the EPSRC Centre, University College London, UK

Analytical challenges and solutions for proteins in bioprocessing

- Wide range of biophysical analyses used to characterise protein aggregation.
- Most biophysical methods are challenging to use during bioprocessing
- Novel analytical tools for proteins in downstream processing will be presented.

14:50-15:20

CHRISTIAN HUNZINGER

Director and CMC Program Lead, Merck

CMC strategies for accelerated submission & approval pathways

- CMC strategies for accelerated submission & approval pathways based on recent experience with Health Authorities
- What are the challenges and opportunities
- Examples from a case study (accelerated product development using QbD elements)

15:20-15:50

BERTIE CHI

Bioprocessing and Analytics Scientist, MedImmune

HTP process analytics for product quality from CM

To be truly able to steer a bioprocess, analytics need to deliver results in a rapid, high throughput manner. This requires a category of analytic methodologies that differ from the traditional QC-type of approach. For instance, one of the bottlenecks lies in the availability of purified material before analysis can be carried out. The capability to monitor potential critical quality attributes directly from the cell culture medium significantly improves the analytical feedback cycle. In this talk I will explore a few of such opportunities using 2D-LC, mass spectrometry and immunodetection-based techniques to support upstream cell line and process development of challenging novel molecules.

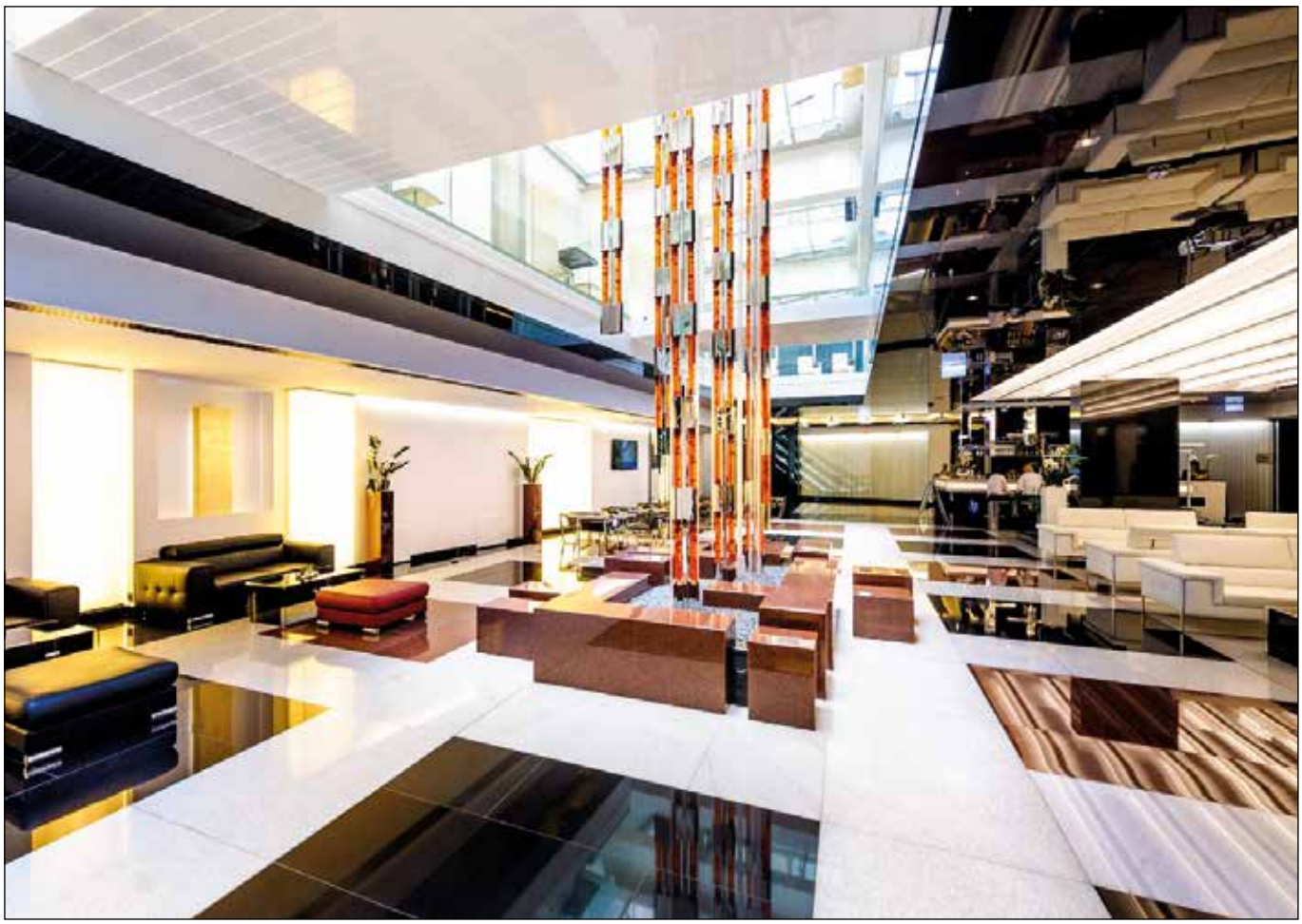
15:50 Conference Close

POSTER PRESENTATIONS

MAKING A POSTER PRESENTATION

Poster presentation sessions will take place in breaks and alongside the other bkout sessions of the conference. Your presentation will be displayed in a dedicated area, with the other accepted posters from industry and academic presenters. We also issue a poster eBook to all attendees with your full abstract in and can share your poster as a PDF after the meeting if you desire (optional). Whether looking for funding, employment opportunities or simply wanting to share your work with a like-minded and focused group, these are an excellent way to join the heart of this congress.

In order to present a poster at the congress you need to be registered as a delegate. Please note that there is limited space available and poster space is assigned on a first come first served basis (subject to checks and successful registration). We charge an admin fee of €100 to industry delegates to present, that goes towards the shared cost of providing the poster presentation area and display boards, guides etc. This fee is waived for those representing academic institutions and not for profit organisations.



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Such attractions of the historic Prague Old Town, like Astronomical Clock on the Old Town Hall, Municipal House on Square of Republic or Charles Bridge, Powder Tower, Music Theatre Karlin and many others are in the immediate walking vicinity, making our hotel a great choice for all travelers.

Our guests enjoy easy access to public transport and the central train station. Subway (Station Florenc, metro line B + C) or tram stops are just around the corner and parking is right in our place.