



DAY 1 – Tuesday, March 5th

08:30	Doors open and event registration begins
09:30-09:40	TEG Welcome Address: Katy Säurich , Head of Production & Operations, TEG The Events Group Chairman's Opening Address: Dr. Louis Boon , CSO & Management Board Member, JJP Biologics & Principal Scientific Advisor, Polpharma Biologics
09:40-10:20	Keynote Opening Presentation: The Future for Microbial Fermentation Based Products <ul style="list-style-type: none"> • What are the key differences between microbial and mammalian cell fermentation products? • What are the key technology differences between these platforms • What is the range of biopharmaceuticals that can be manufactured through microbial fermentation • Opportunities and threats Dr. Erik Bogsch , Head of the Biotechnology R&D Division, Gedeon Richter
10:20-10:40	<i>Networking and Vendor Viewing</i>
10:40-11:20	Case-study Presentations Followed by a Q&A Session: Business Development: How to do it Right from a Small and Mid-sized Biotech Company Perspective <ul style="list-style-type: none"> • Main reasons for initiating business development and partnering activities • Challenges in running business development activities efficiently • Most frequent mistakes made • How to do it right? Paweł Szczepański , COO & Board Member, JJP Biologics Iván Jákó , Senior Business Development Manager, Gedeon Richter
11:20-11:40	<i>Networking and Vendor Viewing</i>
11:40-12:20	Case-study Presentation: New Approach to Antibacterial Therapy: Development of bacteriophage-containing Formulations for Human Use <ul style="list-style-type: none"> • In the European Union, 670,000 people are infected with antibiotic-resistant bacteria every year, 33,000 of whom die. • This number is projected to increase tenfold by 2050. The WHO and EMA are working hard to tackle the problem, and one of the most promising tools is the use of phage therapy. • FLUART Innovative Vaccines Ltd. started developing this technology a few years ago. • The aim of our presentation is to describe the R&D and scale-up experiences and opportunities with this technology. Balázs Kiss , R&D Director, FLUART Innovative Vaccines
12:20-13:20	<i>Lunch in the Restaurant on the Ground Floor of the Hotel</i>
13:20-13:40	<i>Networking and Vendor Viewing</i>
13:40-14:20	Case-study Presentation: Benefits and Pitfalls in Implementation and Application of Machine Learning Methods in Biologics Discovery <ul style="list-style-type: none"> • Data curation • Model development • Orchestration of models • Staying on top of science Paweł Dudzic , Senior Data Engineer, NaturalAntibody
14:20-14:40	<i>Networking and Vendor Viewing</i>
14:40-15:20	Case-study Presentation: AADvac1 lead active tau immunotherapy program for treatment and secondary prevention of Alzheimer's Disease: Recent Phase 2 results <ul style="list-style-type: none"> • AADvac1 is the first-in-man, first-in-kind active tau immunotherapy, stimulating the immune system to produce antibodies specific for all pathological forms of tau; • The completed Phase II study has previously demonstrated an exceptional safety profile of the vaccine and an effect on several plasma and CSF biomarkers (Novak et al, Nature Aging 2021) • The recent post-hoc analysis has revealed significant treatment effects in biomarker-confirmed AD patients on cognitive, functional and neurodegeneration-related biomarker endpoints. The response to treatment was directly related to the levels of AADvac1-induced anti-tau antibodies. Dr. Branislav Kovacech , Deputy CSO, AXON Neuroscience
15:20-15:40	<i>Networking and Vendor Viewing</i>



15:40-16:20	<p>Case-study Presentation: Development of Biosimilars: From Streamlined Development to Increased Access to Affordable Biologicals</p> <ul style="list-style-type: none"> Streamlining biosimilar development: do we really need biosimilar efficacy trials? Real-world evidence for biosimilars: impact on interchangeability Policy impact on sustainability of the biosimilar market Influence of biosimilar competition on access to affordable biologicals <p>Dr. Zsolt Holló, Alliance Management Head, Polpharma Biologics</p>
16:30	Cocktail Reception in the Foyer of the Budapest Ballroom
DAY 2 – Wednesday, March 6th	
08:30	Door opening
09:30-09:40	Chairperson's Opening Address: Dr. Mahwash Mukhtar , Research Fellow at the Faculty of Pharmacy, Institute of Pharmaceutical Technology and Regulatory Affairs, University of Szeged
09:40-10:20	<p>Case-study Presentation: Implementation of eBatch Record System - Lessons learnt</p> <ul style="list-style-type: none"> Project summary Why to do it - Pro's and Con's GMP implications Do's and Don't Conclusions <p>István Király, Site Director of Körmend, EGIS Pharmaceuticals</p>
10:20-10:40	<i>Networking and Vendor Viewing</i>
10:40-11:20	<p>Case-study Presentation: Understanding the Manufacturing Process – From Development to Ongoing Verification</p> <ul style="list-style-type: none"> Manufacturing process development – establishing control strategies for CPPs Do the same control strategies apply for process validation and ongoing verification? Bringing ongoing process verification into life Two years later and after Regulatory inspection <p>Ivana Kovač Lovrenčić, Head of R&D Pharmaceutical Technology Department & Small-Scale GMP Solid Dosage Forms Manufacturing & Lenka Franciško, Head of Processes and Products Quality, Belupo</p>
11:20-11:40	<i>Networking and Vendor Viewing</i>
11:40-12:20	<p>Case-study Presentation: Cooperation between Quality and Production as a Road to Success in the Pharmaceutical World</p> <ul style="list-style-type: none"> What Production and Quality can learn from each other? Necessary areas of cooperation The right way of thinking, openness, transparency and respect as the path to success <p>Dr. Piotr Lipiński, Global Quality Auditor GMP, Sandoz</p>
12:20-13:20	<i>Lunch in the Restaurant on the Ground Floor of the Hotel</i>
13:20-13:40	<i>Networking and Vendor Viewing</i>
13:40-14:20	<p>Case-study Presentation: Risk Management and Business Continuity in Alkaloid Skopje</p> <p>Nada Popstefanova, Quality Compliance and Audit/ Inspection Readiness Manager, Alkaloid Skopje Sonja Spirovska Burcevska, Ecology Coordinator, Alkaloid Skopje Verce Jovanovska Jankovska, Qualified Person, Alkaloid Skopje</p>
14:20-14:40	<i>Networking and Vendor Viewing</i>
14:40-15:20	<p>Panel Discussion: Overcoming Supply Chain Challenges in Pharma Manufacturing</p> <ul style="list-style-type: none"> Overcoming challenges regarding raw materials supply and increased lead time Re-shoring to Europe and chances for CEE New approaches to planning and controlling supply chains and their resilience <p>Erika Dobos, Supply Chain Director, Kedrion Biopharma István Király, Site Director of Körmend, EGIS Pharmaceuticals Dr. Piotr Lipiński, Global Quality Auditor GMP, Sandoz</p>
15:20-15:30	Chairperson's Closing Remarks: Dr. Mahwash Mukhtar , Research Fellow at the Faculty of Pharmacy, Institute of Pharmaceutical Technology and Regulatory Affairs, University of Szeged

PRE - EVENT PROGRAMME

4th MARCH 15:00

SITE VISIT TO THE GEDEON RICHTER Biotechnology plant in Debrecen



The congress also provides an opportunity to visit the Gedeon Richter Biotechnology plant in Debrecen limited for 40 delegates and available on a first come first serve complimentary basis at 15:00 on 4th March and will last for approximately 2 hours.

Gedeon Richter Plc. embarked on establishing biotechnology development and manufacturing capabilities over a decade ago. As a result, the company today has established sites and teams covering R&D and production activities to enable the creation of a biologics product pipeline in addition to offering CDMO activities in the biopharmaceuticals field.

The company has state-of-the-art manufacturing facilities covering microbial fermentation-based products at its Richter-Helm Biologics sites in the north of Germany, and mammalian cell fermentation-based manufacturing capacities, in addition to fill and finish capabilities at its plants on the Gedeon Richter site in Debrecen, Hungary.

The Debrecen GR site covers production, development, analytical testing and releasing activities on a greenfield site that has expanded continuously over past years, providing a workplace for nearly 400 highly skilled associates, benefiting from the growth momentum and strong higher education credentials of the city of Debrecen.

Your visit to the Gedeon Richter site will provide you with a good overview of the unique capabilities and assets of the facilities covering manufacturing, development and analytical areas. This will be followed by a site tour including the viewing corridor of the drug substance manufacturing upstream fermentation area and the visit of a laboratory. The tour will finish with a brief outdoor walk around of the site and a wrap-up meeting with refreshments. The 40 participants will be split into 2 groups for the site tour.

TRANSFER: The bus will leave from the front entrance of the Budapest Marriott Hotel on 4th March at 12:00 and will return after the visit at approximately 19:30.