DAY 1 – Tuesday, May 23rd

09:00	**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. Christoph Herwig**, Former Professor for Biochemical Engineering, **Vienna University of Technology, Austria**
09:40-10:20	**Chairman's Opening Presentation: Holistic Data Management & Digital Twins for Accelerated Product Life Cycle** • The product life cycle aims for efficient experimental design to obtain process knowledge and to make sure that process knowledge is transferable to manufacturing via smooth process validation. • Digital Twins are a key enabler to capture and deploy process knowledge. We show cases and scientific approaches to develop and deploy digital twins for multiple applications in biopharmaceutical processes. • Prerequisite for the shown approach is the holistic management of data of different frequencies and dimensionalities to obtain a contextualized data source. **Dr. Christoph Herwig**, Former Professor for Biochemical Engineering, **Vienna University of Technology, Austria**
10:20-10:40	*Networking and Vendor Viewing*
10:40-11:20	**Case-study Presentation: What makes a good Strategy for Outsourcing?** • How to shape outsourcing strategies and manage the transition using the example of a larger outsourcing project • Resource-based view (RBV): Creating competitive advantage, risk management, efficiency gains, and change management strategies • Importance of defining processes which avoid problems during the transfer of activities **Dr. Moritz Perscheid**, Senior CMC Scientist, **LGC Standards**
11:20-11:40	*Networking and Vendor Viewing*
11:40-12:20	**Case-study Presentation: Belupo's Experience of Introducing a New Dosage Form into the Portfolio – How to become a Medicated Foams Manufacturer** Preview of requirements a pharma company needs to take in mind when planning to become a manufacturer of a specific type of aerosol product, medicated foams: • design of production area and liquid petroleum gas storage, • procuration of specific manufacturing and process control equipment, • setting up of critical safety measures, and • establishing processes in line with GMP and Aerosol Directive requirements. **Ivana Kovač Lovrenčić**, Head of R&D Pharmaceutical Technology Department & Small-Scale GMP Solid Dosage Forms Manufacturing, **Belupo**
12:20-13:20	*Lunch and Vendor Viewing*
13:20-14:00	**Case-study Presentation: Drug Manufacturing during One Year of War – Impact on HR, Logistics, QA & RA** • Influence on Ukrainian pharmaceutical market: customer decrease & changing needs, reduced healthcare infrastructure, decrease in orders for local products due humanitarian aid, partial blackouts, stoppage of work during air alarms - consequences for manufacturers, distributors, pharmacies and customers • Staff is a main value for company's sustainability during the war: corporative program for staff support • Interaction & cooperation with DRA during the war • Main results of 2022 and prospects for 2023 and beyond **Dr. Sergii Sur**, Director, **Arterium**
14:00-14:20	*Networking and Vendor Viewing*
14:20-15:00	**Case-study Presentation: Continues Processes in the Pharmaceutical Industry** • What is Continuous Manufacturing? • Parallel granulation • Continuous coater • Multilotting • Benefits of continuous processes **Sylwia Latoszewska,** Process Support Unit Lead in Bulk Production, **SANDOZ - A Novartis Division** **Łukasz Lipiński**, Process & OPEX Expert, **SANDOZ - A Novartis Division**
15:00-15:20	*Networking and Vendor Viewing*
15:20-16:00	**Case-study Presentation: Evolution of Real Time Monitoring** • What to look for in Real Time Monitoring Systems • The Tive Solution including Proactive intervention in case of excursions • Data Integration: The gain of partnering. **Alex Guillen**, Global SME Life Science and Pharma, **Tive**

16:00-16:20	*Networking and Vendor Viewing*
16:20-17:00	**Closing Case-study Presentation: Increase Analytical Throughput with Laboratory Workflow Automation** • Challenge of multi-platform analytical laboratories • How to generate high throughput analytics by improving processes and combining assets • Impact of process changes and improved analytical hardware • Challenges of multi-attribute analysis on large sample sizes • Difficulties of cell based bioanalytical method automation • Accelerated small scale technology optimization **László Csuhaj**, Head of Small Scale Biotechnology Development Laboratory, Biotechnology Business Unit, **Gedeon Richter**
17:00	**Cocktail Reception**

DAY 2 – Wednesday, May 24th

09:00	Door opening
09:30-09:40	**Chairman's Opening Address:** **Dr. Louis Boon**, CSO & Management Board Member, **JJP Biologics** & Principal Scientific Advisor, **Polpharma Biologics**
09:40-10:20	**Chairman's Opening Keynote Presentation: Discovery & Development of JJP-1212, the first Polish Developed Biological with Orphan Drug Designation** • Smart target selection • Personalized medicine • Preclinical package • First-Human strategy **Dr. Louis Boon**, CSO & Management Board Member, **JJP Biologics** & Principal Scientific Advisor, **Polpharma Biologics**
10:20-10:40	*Networking and Vendor Viewing*
10:40-11:20	**Panel Discussion: CEE Innovation Panel - Academic-Science – Industry Collaboration in drug development** • How can collaboration between academia & the pharmaceutical industry be enhanced to drive innovation in CEE? • In the context of the emerging role of science managers & specialized postgraduate studies, such as a Master's in Science Administration: How can we effectively navigate the evolving landscape of cutting-edge pharmaceutical discoveries? • How do we determine whether these breakthroughs are best suited for the business sector, academia, or at the intersection of both? **Introduction talk by: Dr. Magda Kordon**, CEO & Founder, **intoDNA** **Marta Winiarska**, President of the Board, **Polish Union of Innovative Medical Biotech Companies BioInMed** **Konrad Zawadzki**, Deputy Director of the Biological and Chemical Research Center, **University of Warsaw** **Dr. Karolina Maria Nowak,** Director of Innovation & Biotechnology Development Department, **Medical Research Agency**
11:20-11:40	*Networking and Vendor Viewing*
11:40-12:20	**Case-study Presentation: Molecure, a pioneering clinical-stage biotech company striving to become a global leader in the discovery and development of groundbreaking small molecule drugs targeting unexplored protein and novel mRNA targets, with a focus on OATD-01 as a case study.** • Molecure, DNA, pipeline and key events • Value generating programs • OATD-01 history • OATD-01 future **Dr. Marcin Szumowski**, CEO, **Molecure**
12:20-13:20	*Lunch and Vendor Viewing*
13:20-14:00	**Case-study Presentation: Targeting Apoptosis for Anticancer Therapy: Updates from Adamed's Pipeline** • Apoptosis as a target for anticancer therapy • Novel apoptosis inducing molecules in Adamed pipeline • Proapoptotic fusion protein at a Pre-IND stage • IND-ready MDM2 small molecule inhibitor program **Dr. Katarzyna Jastrzębska-Mazur,** Scientific Program Manager, Preclinical Department, **Adamed**
14:00-14:20	*Networking and Vendor Viewing*

14:20-15:00	**Case-study Presentation: Unlocking the Therapeutic Potential of Synthetic Lethality in Cancer Precision Medicine** • Overview of synthetic lethality and its relevance to cancer precision medicine • Case studies of successful applications of synthetic lethality in preclinical and clinical settings, highlighting therapeutic benefits and potential limitations • Presentation of projects from Ryvu pipeline in the area of synthetic lethality • Future directions for synthetic lethality research, including the identification of novel discovery models, new biomarkers and therapeutic targets using 2D Prime platform **Dr. Krzysztof Brzozka**, Chief Scientific Officer & Executive Vice President, **Ryvu Therapeutics**
15:00-15:20	*Networking and Vendor Viewing*
15:20-16:00	**Case-study Presentation: Me better and Me smart in IO Drug Development** • 'me-better' approach as a risk mitigation of project attrition • 'smart clinical trial design' to create value infliction point in early clinical development **Dr. Pieter Spee,** Chief Scientific Officer & Vice President of the Board of Directors, **Pure Biologics**
16:00	**Chairman's Closing Remarks** **Dr. Louis Boon**, CSO & Management Board Member, **JJP Biologics** & Principal Scientific Advisor, **Polpharma Biologics**

Pre - Event Programme

Plant Excursion to the Novartis Plant & Packaging Centre in Stryków

22nd May 2023

SANDOZ A Novartis Division

The congress also provides an opportunity to visit the Novartis Plant & Packaging Centre in Stryków, limited for 40 delegates and available on a first come first serve complimentary basis at 14:00 in the afternoon on 22nd May. This will last for approximately 2 hours and delegates will be split into two groups, 20 people joining a section focusing on production and quality and a further 20 comprising a group focusing on warehousing and packaging.

TRANSFER: The bus will leave from the front entrance of the Warsaw Marriott Hotel on 22nd May at 12:30 in the morning and will return after the visit at approximately 17:30.
Bulk – production:

Bulk unit in Strykow (BCS) is a modern, big scale facility production Centre focused on manufacturing of generic solid dosages drugs.
Facility opened in 2004 and originally planned for around 1billion tablets. Today, in the same foot print has an impressive capacity of over 10 billion.
BCS plays significant role in Novartis Technical Operations and supply two packaging facilities in Poland as well as customers in Canada, Slovenia, Germany and Asia market.
Innovative approach to mature generic products and fit to purpose and standardized equipment allows efficient manufacturing processes and as consequence very competitive costing for our customers and eventually for patients around the world.
Current product portfolio concentrates around alimentary tract and metabolism (mostly metformin) and cardiovascular (bisoprolol, ramipril, torasemide, atorvastatin, rosuvastatin) and in the near future Combo Products sitagliptin+metformin.
Growing product portfolio and market demand for our products urges us to optimize current processes and target the continuous processes.

Quality:

Quality Unit consists of Quality Assurance and Quality Control. Quality Assurance teams are located according to main responsibilities – close to Production Unit for Operational QA and in the main office building for Quality Systems and Compliance.
Quality Control has QC laboratories in two locations. All our laboratories (chemical, microbiological and packaging material lab) are well equipped with modern techniques fulfilling data integrity requirements. In QC labs we test raw materials, API, finished products and packaging materials as well as environment. Central Testing Laboratory provides analytical testing services for other manufacturers in the scope of EU re-testing, stability testing and stability management. QC Lab is certified for Lean Lab management, supported with planning tools and continuous improvement. Next to QC team we have well-developed Analytical Science & Technology team responsible for analytical methods development, transfer, validation and equipment service. The design of the laboratories is compliant with GMP and HSE requirements.

Warehouse Management:

In Stryków we operate two automated warehouses dedicated to: bulk and packaging operations. The first one with a capacity of 8,2 k pallets supports bulk operations and is used for handling and storage of APIs, excipients and bulk manufactured locally prior it is shipped to Packaging Centres. The second one, with 50% bigger capacity (13,5 k pallets), started its operations only in 2015, is dedicated to packaging and used as a distribution warehouse for all products packed in Polish sites. Majority of its capacity is utilized by FDFs, the rest is consumed by primary and secondary packaging materials and bulk (both locally manufactured and imported from other suppliers). The warehouse and packaging operations are equipped with AGVs which ensure fully automated material between both operations. AGVs are also used on the production floor.

Key numbers (2021):

1. Total pallets shipped to customers (Finished Dosage Form) ~ 72 k, over 1300 trucks
2. Total pallets received ~ 27 k
3. Total number of pallet on stock ~19 k

Packaging Center Stryków:

Packaging Center in Strykow has been operating since 2015.
We are one of the largest Pharmaceutical packaging site in Poland.
At our plant, we put operations safety first and the highest products quality.

We operate on 15 highly automated packaging lines with potential to increase our capacity additionally up to 24 lines. We are growing 25% volumes every year. Our current production capacity is more than 9 billion tablets per year.

We have innovative solutions in areas:

- robotization
- automatic material flow
- paperless production
- integrated support systems: MES, ERP, WMS, SCADA
- automatic washing and storage for format parts

We invite you to visit our plant!