DAY 1 – Tuesday, May 17th

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. Marten Ritz**, Head of Global Projects | Operational Excellence, Production Networks, Smart Manufacturing at the Institute of Technology Management, **University of St.Gallen, Switzerland**
09:40-10:20	**Keynote Opening Presentation: From Quality Metrics to Quality Management Maturity – Insights from the St.Gallen/ US FDA collaboration** • How to operationalise Plant Performance and Maturity • Linking OPEX Implementation to Performance • Sustaining OPEX programmes over time • An outlook on the future of regulatory surveillance **Dr. Marten Ritz**, Head of Global Projects | Operational Excellence, Production Networks, Smart Manufacturing at the Institute of Technology Management, **University of St.Gallen, Switzerland**
10:20-10:40	*Networking and Vendor Viewing*
10:40-11:20	**Case-study Presentation: Smart PAT – Shifting Quality Control to the Shop-Floor** • New real-time measurement technologies that overcome the challenges of durability, specificity, and speed to measure PAT Critical Process Parameters and Key Performance Indicators during the process • Progressing digitalization to enable innovative process analytics (soft sensors), advanced process control (e.g. digital twin simulation), preventative maintenance, and asset management **Giovanni Campologno,** eMBA, Biopharma Segment Manager, **Hamilton Bonaduz AG**
11:20-11:40	*Networking and Vendor Viewing*
11:40-12:20	**Case-study Presentation: The Road to Industry 4.0 in Novartis Technical Operations Poland** • Novartis's path towards Industry 4.0 • Cultural aspects: commitment, curiosity and process of continuous improvement • Long-term strategy in different areas of our company • Example of tools for automation and digitalization in our factory **Przemyslaw Wierzbicki**, Project Engineer & Head of Continuous Improvement at Packaging Plant, **Novartis**
12:20-13:20	*Lunch and Vendor Viewing*
13:20-14:00	**Case-study Presentation: Live Processes Around Electronic Batch Records (EBR)** • Implementation of EBR and the surrounding processes in the production area • Key conclusions from the implementation - expectations versus reality • Quality assurance expectations and the production area perspective - stuck in the middle • The batch release challenges caused by the implementation of EBR - laziness is the key to success **Błażej Różański**, Senior Production Systems Specialist, Department of Manufacturing Science & Technology, **Polpharma**
14:00-14:20	*Networking and Vendor Viewing*
14:20-15:00	**Case-study Presentation: Factory-of-the-Future: How Digital Shapes the New Ways of Working at Takeda** • Usage of automation, data and digital tools to reduce bottlenecks, increase capacity and improve the quality of our manufacturing network • Impact of use of digital tools and robots on people capabilities and how they can shift their focus on value adding tasks **Roland Straub**, Global Head of Digital Supply Chain, **Takeda Pharmaceuticals International**
15:00-15:20	*Networking and Vendor Viewing*
15:20-16:00	**Panel Discussion: How to Increase the Flexibility & Reliability of the Supply Chain** • Lessons learned from COVID-19 and how to react in the future - Are we prepared for future outbreaks? • Be ready for fast & flexible solutions - Manage disruptions – Ready for constant change • Impact on Supply Chains due to Russian war against Ukraine, following global sanction against Russia and Belarus, and voluntary exodus of many international companies from Russia • Remote working – Ways of working in the future, esp. which pharma roles can be done remotely in the future and how? • Chance for CEE pharma manufacturers to fill the existing vacuum / gap **István Király**, Managing Director, **HUMAN BioPlazma, Kedrion Biopharma** **Roland Straub**, Global Head of Digital Supply Chain, **Takeda Pharmaceuticals International** **Ana Dzaleva**, Sourcing Manager, **ALKALOID**
16:00-16:20	*Networking and Vendor Viewing*

16:20-17:00	**Closing Keynote Presentation: Bringing the Real Value from Digital Solutions for Industrial Operations & Quality in Polpharma** • Polpharma's journey to embed digital solutions in business processes – from hype to rational • Usage of Internet of Things, Virtual & Augmented Reality to support business processes and bring real value to the organization **Łukasz Krause**, Group CIO, **Polpharma Group**
17:15	**Award Ceremony of the 7th CEE Pharmaceutical Manufacturing Excellence Award & Cocktail Reception** **Welcome Speech** by **Dr. habil. Tamás Sovány**, associate professor, Institute of Pharmaceutical Technology and Regulatory Affairs and Vice Dean for Education, Faculty of Pharmacy at the **University of Szeged, Hungary**

DAY 2 – Wednesday, May 18th

09:00	Door opening
09:30-10:10	**Chairman's Keynote Opening Presentation: Strategies & Benefits to Deploy Digital Twins along the Product Life Cycle** • Generic workflows to generate and adapt hybrid digital twins for biopharmaceutical processes • Deployment of digital twins at different unit operations but also along the integrated process chain • The benefits of this approach are: Robust control strategies for accelerated stage 1 and stage 3 process validation as well as prediction of process event to optimise productivity at consistent product quality **Prof. Dr. Christoph Herwig**, Head of Research Group: Bioprocess Technology, Institute of Chemical Engineering, **Vienna University of Technology, Austria**
10:10-10:30	*Networking and Vendor Viewing*
10:30-11:10	**Case-study Presentation: Smart Target Selection to Enable a Personalized Medicine Approach & Optimise Clinical Development** • Personalized medicine and companion diagnostics • Treatment of IgA-mediated autoimmune diseases • Selection of antagonist anti-CD89 • IgA Rheumatoid Arthritis as new disease **Dr. Louis Boon**, CSO & Management Board Member, **JJP Biologics** & Principal Scientific Advisor, **Polpharma Biologics**
11:10-11:30	*Networking and Vendor Viewing*
11:30-11:50 11:50-12:10	**Presentations of Award Winners of the 7th CEE Pharmaceutical Manufacturing Excellence Award** 1. Winner in the manufacturer category 2. Winner in the solution provider category
12:10-13:10	*Lunch and Vendor Viewing*
13:10-13:50	**Case-study Presentation: ICH M7 Assessment & Control of Mutagenic Impurities in Pharmaceuticals to Limit Risks** • ICH QM7 guideline content, purpose and applicability • Impurities assessment, risk characterization with special focus on nitrosamines impurities • Ways of mutagenic impurities control • Lessons learned from 'sartans case' **Dr. Piotr Lipiński**, Global Quality Auditor, Audit & Compliance, Europe II, **Novartis Technical Operations Quality**
13:50-14:10	*Networking and Vendor Viewing*
14:10-14:50	**Panel Discussion: Nitrosamines & Mutagenic Impurities – Challenges & Lessons learned from the Valsartan Case** **Lenka Franciškoviċ**, Head of Processes and Products Quality, **Belupo** **Izabela Majić**, European Commission Expert, **European Commission** **Dr. Piotr Lipiński**, Global Quality Auditor, Audit & Compliance, Europe II, **Novartis Technical Operations Quality**
14:50-15:10	*Networking and Vendor Viewing*
15:10-15:50	**Case-study Presentation: Product Life Cycle Management – Change Production Gx Mainset** • New challenges ahead of the production of generic drugs • OPEX cost reduction – Opportunities • Campaign production – Changing batch mindset • Continuous process • Industry 4.0 **Przemysław Młynarczyk**, Senior Process & OPEX Expert & **Łukasz Lipiński**, Junior Process Expert, **Novartis**
15:50-16:00	**Chairman's Closing Remarks - Prof. Dr. Christoph Herwig**, Head of Research Group: Bioprocess Technology, Institute of Chemical Engineering, **Vienna University of Technology, Austria**

Pre - Event Programme

Plant Excursion to the Novartis Plant & Packaging Centre in Stryków

16th May 2022

NOVARTIS

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 16th 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 16th May at 12:30 in the morning and will return after the visit at approximately 17:30.

Bulk – production:

Bulk unit in Styków (BCS) is 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 + 10 billion.
BCS plays significant role in Novartis Technical Operations network supplying over 8 billion tablets (from around 5000 batches) on yearly basis serving two packaging facilities in Poland as well as customers in Canada, Slovenia and Germany.
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 and torademide).

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:

PCS started operation in 2015 and it is one of the newest site in Novartis.
We are operating on 13 highly automated packaging lines with potential to increase our capacity additionally up to 24 lines.
Each year we are growing and our products are supplied to over 80 markets.
We have automated process:

- flow of material (on production and on warehouse)
- digital flow of production documentation
- online monitoring production execution system which allow to us trace online results and problems on each line using laptop or even cell phone what ensures fast reaction
- format parts washer that help us to reduce time of cleaning and drying.