DAY 1 – Wednesday, 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** **Chairperson's Opening Address: Dr. Louis Boon**, CSO & Management Board Member, **JJP Biologics** & Principal Scientific Advisor, **Polpharma Biologics**
09:40-10:20	**Keynote Opening Presentation: How the big WHY supported the fast Development of JJP-1212** • Precision medicine • Autoimmune and fibrotic diseases • JJP-1212 in phase I clinical testing **Dr. Louis Boon**, CSO & Management Board Member, **JJP Biologics, Netherlands**
10:20-10:40	*Networking and Vendor Viewing*
10:40-11:20	**Presentation: Increasing Efficiency by Modularity and Standardization in Continuous Manufacturing** • Current challenges and hurdles in Continuous Direct Compression • How seven cutting-edge solutions result into game changer • FE CPS – Continuous Manufacturing re-invented **Sven Hems**, Global Manager Continuous Manufacturing, Global Sales, **Fette Compacting GmbH, Germany**
11:20-11:40	*Networking and Vendor Viewing*
11:40-12:20	**Case-study Presentation: Drug Development and Project Management** • Project management is a key methodology to address the unique quality, regulatory and compliance requirements of the (bio)pharmaceutical industry. • This presentation will provide an overview about planning the needs, scope, resources to create a roadmap for a successful project planning and delivery. • It will address the challenge how organizations can combine various project life cycles and embed innovation as a key capability in a structured project process. **Zsolt Holló**, Alliance Management Head, **Polpharma Biologics, Poland**
12:20-13:20	*Lunch and Vendor Viewing*
13:20-13:40	*Networking and Vendor Viewing*
13:40-14:20	**Case-study Presentation: Harnessing Data in Biopharmaceutical Development and Manufacturing** • What are the core concepts in modern data-driven bioprocessing? • Why is data integration so important in biopharmaceuticals? • How do data science and advanced technologies transform the biomanufacturing landscape? **Eszter Varga**, Senior Biostatistics SME, **Gedeon Richter, Hungary**
14:20-14:40	*Networking and Vendor Viewing*
14:40-15:20	**Case-study Presentation: Successful Transfer of Finished Product from Contractual Partner - Technological & Quality Perspective** • Choosing the contractual partner and preparing the commercial agreement • Product transfer • Changes from regulatory point of view **Ivana Kovač Lovrenčić,** Head of R&D Pharmaceutical Technology Department & Small-Scale GMP Solid Dosage Forms Manufacturing & **Lenka Franciškovič**, Head of Compliance, **Belupo, Croatia**
15:20-15:40	*Networking and Vendor Viewing*

15:40-16:20	**Keynote Presentation: Streamlining Biosimilar Development - The Next Step in the Evolution of the Biosimilar Regulatory Pathway** • Developing and manufacturing biosimilar medicines is a complex process, requiring significant expertise and investment over long period of times. There are many different factors impacting the feasibility of biosimilar development: scientific, technological, intellectual property, regulatory, market access, etc. • For many biologicals (70%) losing exclusivity over the next decade, do not have corresponding biosimilar medicines in development, resulting compromised opportunities for HC systems and patients across Europe. The 'Void' impacts BOTH blockbuster medicines and medicines intended for smaller population. • One of the ways of mitigating this 'Void', without compromising safety or efficacy, is the implementation of streamlined biosimilar development. Streamlining aims to eliminate comparable efficacy studies (or CES, so called 'Phase III') by relying on advanced analytical and clinical pharmacokinetic data. Under the current requirements, CES constitute an absolute barrier to biosimilar development. • Ensuring a brighter future for the biosimilar industry requires, but is not limited to: o evolving the biosimilar regulatory standard based on biologic regulatory-science progress, o engaging stakeholders, o promoting global regulatory convergence to support a balanced and functioning biosimilar ecosystem. **Mina Grguri,** Biosimilar Policy & Science Officer, **Medicines for Europe, Belgium**
16:30	**Cocktail Reception**

DAY 2 – Thursday, March 6th

08:30	Door opening
09:30-09:40	**Chairman's Opening Address: Prof. Dr. Stane Srčič, former Head of Pharmaceutical Technology Department, Faculty of Pharmacy, University of Ljubljana, Slovenia**
09:40-10:20	**Case-study Presentation: Employee Retention in Pharma Industry by Offering New Ways of Self-Motivation** • Description of specific features of pharmaceutical continuous education • Employees motivation approaches during career development • List of motivation incentives for employees for self-improvements • Development of educational concept based on the needs for different pharma companies **Petra Miketová**, Managing Director, **Cayman Pharma, Czech Republic**
10:20-10:40	*Networking and Vendor Viewing*
10:40-11:20	**Client Case-study Presentation: Applied Industrial Big Data Analytics to Optimise Fermentation in TAPI** • TAPI introduction • Fermentation process • Solution detail • Results **Dr. Zoltán Németh**, Technologist, **TAPI** **Gergő Kertész**, Director, **MaxFlow Ltd.**
11:20-11:40	*Networking and Vendor Viewing*
11:40-12:20	**Case-study Presentation: Fundamental Principles of Continuous Coating with Using of O'Hara FCC 75** **Dr. Gábor Kossa**, Plant Manager, **MEDITOP Pharmaceutical, Hungary**
12:20-13:20	*Lunch and Vendor Viewing*
13:20-13:40	*Networking and Vendor Viewing*
13:40-14:20	**Case-study Presentation: Audits and Inspections – Variety in Approach and Current Trends in Observations** • Variety in inspections approach (EU, US FDA, Rest of World) • Current "hot topics" and observations trends • Some "tips & tricks" for auditee **Dr. Piotr Lipiński**, Global Quality Auditor GMP, **Sandoz, Germany**
14:20-14:40	*Networking and Vendor Viewing*
14:40-15:20	**Panel Discussion: Cost of Quality** **Dr. Piotr Lipiński,** Global Quality Auditor GMP**, Sandoz, Germany** **Lenka Franciškoviċ**, Head of Compliance, **Belupo, Croatia** **Petra Miketová**, Managing Director, **Cayman Pharma, Czech Republic**
15:20-15:30	**Chairman's Closing Remarks: Prof. Dr. Stane Srčič, former Head of Pharmaceutical Technology Department, Faculty of Pharmacy, University of Ljubljana, Slovenia**

PRE - EVENT PROGRAMME

4th MARCH 15:00

SITE VISIT TO THE Meditop Pharmaceutical plant near Budapest

Participants of PHARM Connect can visit the MEDITOP Pharmaceutical plant near Budapest. It is limited for 35 delegates only and available on a complimentary, first-come, first-served basis at 15:00 on 4th March.

MEDITOP Pharmaceutical Ltd. as a middle size company provides a range of pharmaceutical services, including contract manufacturing of solid dosage forms (tablets, capsules, granules) using state-of-the-art facilities. They offer regulatory support for obtaining product registrations globally and R&D collaboration for developing generic, super-generic, and originator drugs, from formulation to clinical trial samples. Additionally, MEDITOP Ltd. is licensed for clinical trial manufacturing and packaging, ensuring compliance with GMP standards.
MEDITOP Pharmaceutical developed an innovative approach to improve film coating efficiency with developing and applying of a continuous film coater for which they received the 3rd CEE Pharmaceutical Manufacturing Excellence Award. With the innovation they successfully developed a method to coat soft tablets with high quality, managed to coat heat sensitive actives without degradation, saved considerable time and energy, and obtained flexible and fast change-over and batch size change.

TRANSFER: The bus will leave from the front entrance of the CROWNE PLAZA on 4th March at 14:00 and will return after the visit at approximately 19:30.