PROGRAMME | DAY 1 | TUESDAY, MARCH 12th

09:00 **DOOR OPENING AND EVENT REGISTRATION**

09:30-09:40 **TEG Welcome Address** - Katy Säurich, Head of Operations & Production, **TEG The Events Group**
CHAIRPERSONS OPENING ADDRESS:
BIOTECH AND R&D: **Dr András Ballagi**, Chief Technology Officer, **Diagon**
REGULATORY: **Assoc. Prof. Dr Ildikó Csóka**, Director of the Institute of Pharmaceutical Technology and Regulatory Affairs, **University of Szeged**

09:40-10:20 **OPENING KEYNOTE PRESENTATION:**
Personalized Medicines - Current Impacts on the Pharma Industry and Future Scientific Possibilities
Personalized medicine is the key factor of today's changes in healthcare. The uptake of PM has been initiated by different reasons. One of them is a medical pressure: the improvement of benefit/risk ratio, the other is an economic pressure: the improvement of price/value ratio. New technologies, the genomic and digital medicine offer/provide widening possibilities for the above listed.

Translational and personalized medicine takes into consideration all the three aspects. Its uptake was evolutional, recently, however, it has become disruptive. Health-related decision making has moved from a budget-approach towards a cost-efficient approach. On a scientific level the more precise understanding of the pathophysiology of diseases initiate the spread of target therapy rather than the therapeutic reductionism.

The regulatory background of all these shifts from a passive to an active regulation. With the use of diagnostic tools predicting safety and efficacy there is a possibility to select the adequate medicine and to monitor the illness/disease. We should not underestimate the methodological challenges and the previously unrecognized ethical issues. The lecture concentrates on the events and trends of the recent past from the viewpoint of pharmacology considering the possible dangers and the future potentials derived from our present knowledge/experience.
Dr György Németh, Chief Medical Officer, **Gedeon Richter** & President of **Hungarian Society of Personalized Medicine**

10:20-10:40 Networking Coffee Break and Vendor Viewing

10:40-11:20 **CASE-STUDY PRESENTATION:**
End-to-End Solutions from Pall Biotech – An Innovative Approach to Design Bioprocesses for Optimal Performance
• End-to-End Biotech Solutions
• Full process capability
• Traditional (Stainless Steel), Single Use or Continuous processing
• Optimized Bioprocess Design
Dr Christian Hetzel, Integrated Solutions Manager, **PALL Biotech**

11:20-11:40 Networking Coffee Break and Vendor Viewing

11:40-12:20 **CASE-STUDY PRESENTATION:**
Reserved for Sponsor Presentation

12:20-13:20 Lunch & Vendor Viewing

13:20-14:00 **CASE-STUDY PRESENTATION:**
Data Integrity - How to Interpret the Guidelines into Procedures and to Reduce "Grey Zones"
• Data integrity guidelines • Data integrity aspects in paper records
• Audit trails • Data backup and restore
• Data Integrity in Quality Control Laboratory
• Data integrity self inspections
Dr Piotr Lipiński, Global Quality Auditor, Audit & Compliance, Europe II, **Novartis Technical Operations Quality**

14:00-14:20 Networking Coffee Break and Vendor Viewing

14:20-15:00 **CASE-STUDY PRESENTATION:**
Industrial Scale Precision Separation by Centrifugal Partition Chromatography
RotaChrom Technologies has developed the world's first industrial scale Centrifugal Partition Chromatographic (iCPC) technology platform.
The company's instruments have revolutionized the purification industry by providing cost effective commercial scale chromatography solutions to customers all over the world.
Sándor Polányi, CEO, **RotaChrom**

15:00-15:20 Networking Coffee Break and Vendor Viewing

15:20-16:00 **CASE-STUDY PRESENTATION:**
Data Integrity Assurance & Investigations of Data
• Data Integrity -- Risk-Based Approach to Preventing & Detecting
• Data Life Cycle Design and Controls
• Validation for Data Integrity
• CGXP Requirements for Data Integrity, including Current Health Authority Data Integrity Guidances
• Techniques to Identify and Investigate Aberrant Data Patterns
• Reviewing electronic data and metadata -- such as audit trails
• Case study of hands-on live system audit to detect data integrity issues
Izabela Majić, Head of Inspectorate, **Agency for Medicinal Products & Medical Devices of Croatia, HALMED**
Dr Ivan Bašic, GMP Inspector Expert, **Agency for Medicinal Products & Medical Devices of Croatia, HALMED**

16:00-16:20 Networking Coffee Break and Vendor Viewing

16:20-17:00 **PANEL DISCUSSION:**
Data Integrity - How to Interpret the Guidelines into Procedures and to Reduce "Grey Zones"
Dr Piotr Lipiński, Global Quality Auditor, Audit & Compliance, Europe II, **Novartis Technical Operations Quality**
Izabela Majić, Head of Inspectorate, **Agency for Medicinal Products & Medical Devices of Croatia, HALMED**
Dr Ivan Bašic, GMP Inspector Expert, **Agency for Medicinal Products & Medical Devices of Croatia, HALMED**
Lenka Francišković, Head of Processes and Products Quality, **BELUPO**

17:15 Cocktail Reception & Award Ceremony of the 5th CEE Pharmaceutical Manufacturing Excellence Award

Welcome Speech by **Prof. Dr Stane Srčič**, Head of Pharmaceutical Technology Department,
Faculty of Pharmacy, University of Ljubljana

PROGRAMME | DAY 2 | WEDNESDAY, MARCH 13th

09:00 **DOOR OPENING AND EVENT REGISTRATION**

09:20-09:30 **CHAIRPERSONS OPENING ADDRESS:**
TECHNOLOGICAL: **Prof. Dr Stane Srčič**, Head of Pharmaceutical Technology Department,
Faculty of Pharmacy, University of Ljubljana
INDUSTRIAL: **Prof. Dr Romána Zelkó,** Dean Faculty of Pharmacy, **Semmelweis University**

09:30-10:10 **CASE-STUDY PRESENTATION:**
Introduction of Lean Management Tools & Principles in the Biotech Pharma Industry
It is always a challenge to introduce and implement the phylosophy of lean in the highly regulated pharmaceutical industry. The lecture will highlight some of the major questions of this introduction process in our biotech pharma facility:

• How to harmonize the lean phylosophy and the GMP quality approach of the pharma production?
• How to build up a lean introduction program in a biotech facility?
• How to use lean tools (5S, Kanban, visual management, process confirmation) on the shop floor?
• What are the benefits of using systematic problem solving as a quality tool?
• How idea management can influence the lean culture of a pharma plant?
Dr János Dombovári, Project Manager, Biotechnology Division, **Gedeon Richter**

10:10-10:30	Networking Coffee Break and Vendor Viewing
10:30-11:10	**CASE-STUDY PRESENTATION:** **Reserved for Sponsor Presentation**
11:10-11:30	Networking Coffee Break and Vendor Viewing
11:30-12:10	**PANEL DISCUSSION:** **Serialisation – How to Meet the Expectations and Increase Supply Chain & Patient Security?** • Current results of fights against anti-counterfeiting • Where is the risk of fake medicines? • Best practice solutions for smaller companies • Status of wholesaler integration **Geoffroy Bessaud**, Associate VP, Corporate Anti-Counterfeiting Coordination Corporate Security, **SANOFI** **Vasil Pavlov**, Plant Manager, **Tchaikapharma High Quality Medicines INC.** **Tamás Rácz**, Director - Global Serialization Implementation / EU sites, **TEVA** Representative of the Safety Feature Committee, **MAGYOSZ**
12:10-13:10	Lunch and Vendor Viewing
13:10-13:50	**Project Presentations of the Award Winners of the** **5th CEE Pharmaceutical Manufacturing Excellence Award** 13:10 – 13:30 Winner in manufacturer category 13:30 – 13:50 Winner in solution provider category
13:50-14:10	Networking Coffee Break and Vendor Viewing
14:10-14:50	**CASE-STUDY PRESENTATION:** **Formulation Possibilities for Delivery of Biopharmaceuticals** • Introduction of FIP perspective on the formulation and development of biopharmaceuticals • Grouping of Biopharmaceuticals Devices for parenteral and transdermal protein delivery • Possibilities in oral protein delivery • Challenges in protein processing and protein absorption • Possibilities in nasal and pulmonar protein delivery • Challenges and delivery devices **Dr Tamás Sovány**, Assistant Professor at the Institute of Pharmaceutical Technology and Regulatory Affairs, Faculty of Pharmacy, **University of Szeged**
14:50-15:10	Networking Coffee Break and Vendor Viewing
15:10-15:50	**CASE-STUDY PRESENTATION:** **Building a New Pharmaceutical Plant** • Planning and Preparation of the Project • Design Phase • Execution Phase **Tomislav Đuranek**, Director of Maintenance & Energetics, **Belupo Pharmaceuticals**
15:50-16:00	**CHAIRPERSON'S CLOSING REMARKS** TECHNOLOGICAL: **Prof. Dr Stane Srčič**, Head of Pharmaceutical Technology Department, **Faculty of Pharmacy, University of Ljubljana** INDUSTRIAL: **Prof. Dr Romána Zelkó,** Dean Faculty of Pharmacy, **Semmelweis University**

PRE - EVENT PROGRAMME | 11th MARCH 15:00

SITE VISIT TO MEDITOP PHARMACEUTICAL

The Winner of the 3rd CEE Pharmaceutical Manufacturing Excellence Award in 2017

Participants of PHARM Connect 2019 can learn more about the award winning innovation and 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 11th March.

Meditop Pharmaceutical Ltd. as a middle size company develops and manufactures its own products and offers services as a Contract Manufacturing Organisation to produce solid dosage forms in flexible manner and to provide support in development and manufacturing of pharmaceutical and nutraceutical products suffering with special sensitivity.

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 Novotel Budapest City Hotel which is connected to the Budapest Congress Centre on 11th March at 14:00 and will return after the visit at approximately 18:00.

PRE - EVENT PROGRAMME | 11th 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 11th 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 300 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 walkaround 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 Novotel Budapest City Hotel which is connected to the Budapest Congress Centre on 11th March at 12:00 and will return after the visit at approximately 19:30.

POST - EVENT PROGRAMME | 13th MARCH 17:00

SITE VISIT TO SANOFI

Ujpest plant in Budapest

The congress also provides an opportunity to visit the SANOFI plant in Budapest limited for 100 delegates and available on a first come first serve complimentary basis at 17:00 on 13th March and will last for approximately 1-1.5 hours.

Delegates will have the opportunity to select among the following 4 focus groups: **Warehousing** (max. 25 people), **Production** (max. 25 people), **Quality Management** (max. 25 people) and **Chemical Development** (max. 25 people).

The excursion will start with a short company presentation followed by four different guided tours.

TRANSFER: The bus will leave from the front entrance of the Novotel Budapest City Hotel which is connected to the Budapest Congress Centre on 13th March at 16:00 and will return after the visit at approximately 19:30.

Introduction of Sanofi – Ujpest Site (Chinoin)

Welcome at significantly reshaped Ujpest facility. We hope the visitors could realize how we, as API manufacturer, progress on the adaptation of Lean culture, simplification of our processes and using this culture change to involve, empower and motivate of our 700 employees.

| **Development Center Ujpest** |

The Development Center Ujpest, flagship of Sanofi Active Ingredient Solutions business unit is operating on the Ujpest site. DCU gives the main part of the development potential of SAIS, both in terms of number of employees and capacity.

The Development Center Ujpest name was taken up in 2018 by the organization which was founded with the goals to bridges the differences between the research and development and industry, and translates the laboratory recipes to an industrialized technology.

The current tasks of our organization are wide-ranging, so our customers are very diverse. Our partners include Chemistry of Újpest for whom we give process improvement support to develop and optimize the already industrialized technologies and we also have similar tasks for the Vertolaye site in France. For PG business unit we have been manufacturing non-active intermediates in small volume, and validation of the processes.

Our third-party costumers may require laboratory development of a process, sample preparation/production from a few grams to hundreds of kilograms, GMP production or process validation. We are primarily in contact with Japanese, American and French partners for whom we produce ingredients for early clinical phase. We regularly manufacture commercial products in small volume for which the required technical conditions are available in a high quality. Among other things, this fact and our colleagues' outstanding expertise, we are present in the Japanese market, which has very high customer needs.

Our activity could not be complete, without a high level of analytical tasks related to the laboratory and plant activities. This should include the analytical method development, their transfer, the examination of laboratory and plant samples, the qualification and release of raw materials, the intermediates and final products for development productions, as well as the stability studies of the products. For those tasks we can use wide range analytical techniques for testing from XRPD, HS-GC, trough HPLC, and HPLC-MS, up to I-Class UPLC and NMR.

The effectivity of our team is well reflected in the fact that, according to the successful development work we could keep so large development projects such as Volixibat or Olmesartan, which has been manufacture in industrial scale since then.

| **Chemical manufacturing** |

Chemical production in Újpest site is a prominent organization of Sanofi industrial affairs. It plays significant role in producing APIs of the leader products of the Company, for example the anti-hypertensive Aprovel (Irbesartan), the anti-thrombotic Plavix (clopidogrel) and the prostaglandine-products which are applied in wide-spectrum of indications.

PLANT EXCURSIONS

Today about 50% of the site activity belongs to production of APIs for Sanofi, other 50% of our active products are sold across the globe, from US till Japan.

The plants have gone through a spectacular development in the last 15 years. The level of technological equipment, and the process control system, the equipment for environmental protection (e.g. thermal hydrolysis, catalytic oxidation, cryotrapping, evapo condens) and the GMP-compliance fulfills the expectations of 21st century.

Yearly, our more than 300 colleagues provide for everyday quality of 3000 batches of 28 APIs and their intermediates.

| **Quality Management** |

Quality Management is located in one building in the centre of the site. There are the Quality Assurance and Regulatory offices and the main QC activities: chemical and microbiology laboratories, retain and stability sample storage areas and analytical reference standard management. The laboratories are well equipped with modern techniques fulfilling data integrity requirements and providing solution also for the challenging quality requirements such as organic impurities, foreign particle, elemental impurities and physical characters of the APIs.

The design of the laboratories is one of the most attractive within Sanofi and all above compliant with GMP and HSE requirements. All visitors and inspector found it very impressive. We are very proud of the results of our Quality System. We have successfully managed the recent inspections led by US, Japanese, Russian and of course Hungarian Authorities.

| **Warehouse management** |

CHINOIN's warehouse management is responsible for handling of raw materials, intermediates, pharma APIs and by-products, waste materials of manufacturing. Materials could be solid or liquid form. Warehouse handles industrial gases in a significant volume.

CHINOIN specialized for receiving liquid organic solvents, raw materials by rail and handling of these materials in a closed pipeline system. This closed system is also used for transferring liquid raw materials; solvents are received in tank car.

Solid raw materials and barrels are received in our warehouse dedicated for this purposes. The new high level storage warehouse was handed over in 2011 in which the capacity was maximized by rolling racks.

The warehouse management uses Oracle electronic business solution including the usage bar code readers during its processes.

| **Main data of 2018** | 3 344 T products, 13 572 T raw materials, 18 836 T waste materials