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** and
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:**
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**

12:20-13:20 Lunch & Vendor Viewing

13:20-14:00 **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**

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

14:20-15:00 **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 Franciškovič, Head of Processes and Products Quality, **BELUPO**

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

15:20-16:00 **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**

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

16:20-17:00 **CLOSING KEYNOTE PRESENTATION:**
Science Fiction in Healthcare
Science fiction that helps prepare for the future sneaked into our lives except the most important field: healthcare. The cultural transformation we call digital health is making it happen through the use of advanced technologies. Of all the trends and technologies, artificial intelligence is far the most promising and dangerous technology that requires attention today as it, with patient design, transforms how pharmaceutical companies are developing their products, approaching their consumers and planning ahead.
Dr Bertalan Mesko, PhD, The Medical Futurist, Director of **The Medical Futurist Institute**

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

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:
Hot-Melt Extrusion (HME): A Cost Effective Approach Leading to Enhancement of Bioavailability
• Hot melt extrusion (HME): Introduction, A single solution to various problems
• Screening of polymer for HME • Common plasticizers used for HME
• HME process and equipment, Twin-screw extruder - screw elements
• Evaluation of HME formulations • Advantages and disadvantages of HME
Dr Devendra Ridhurkar, Expert Scientist Modified Release Formulations, **Neurax Pharmaceuticals**

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**

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 manufacturing 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**

2019 CHAIRPERSONS

Regulatory

Associate Professor
Dr Ildikó Csóka

Head of the Institute of Pharmaceutical Technology and Regulatory Affairs, Faculty of Pharmacy, University of Szeged

She works at University of Szeged since 1990, after graduating as a pharmacist at University of Szeged.
Between 1990 – 2003 she worked as an assistant lecturer and later as an Assistant Professor at the Department of Pharmaceutical Technology.
Experiences and competencies: dermal and transdermal dosage form design, the teaching of drug manufacturing processes, process development. Based on her research on colloidal drug delivery systems, she got the PhD title in the year 1997. Between 2004 – 2016, she worked at the Institute of Drug Regulatory Affairs; since 2008 as the Head of the Institute. She got the Dr. habil. degree and became Assoc. Professor in the year 2007. Paralelly with these activities she worked as Educational Vice-Dean of the Faculty of Pharmacy between 2009-2012; was the Head of the „Office for Postgraduate Studies" at Faculty of Pharmacy (2010-2012), and also for two years (2010-2011) she was the Head of Department of Clinical Pharmacy.
Prof. Ildikó Csóka has been working for the University Management since 2012; presently as the General-Director for Strategy. Based on the close cooperation between the Department of Pharmaceutical Technology and Institute of Drug Regulatory Affairs, in 2016 she founded a new Institute dealing with a „Quality by Design" based dosage form development and manufacturing process optimisation together with 50 colleagues in teaching and research, and presently she is the Head of this Institute. She has postgraduate specialisations in Pharmaceutical Technology, Health Care and Pharmacy Management and Quality Assurance.

Her research field covers: regulatory pharmacy based dosage form design in the field of nano and biotechnology, developments in alternative drug delivery routes; co-creation and knowledge transfer in healthcare and pharmaceutical R & D; patient expectations, satisfaction and adherence evaluations in connection with the quality of life measurements.

Biotech and R&D

Dr András Ballagi

Chief Technology Officer,
Diagon

Dr. Ballagi moved to Sweden shortly after completing his degree in Bioengineering. There he worked in the field of the diagnosis and molecular evolution of veterinary viruses at the Swedish Veterinary Institute. He received his Ph.D. for his research on the application of PCR for virus detection and analysis of viral outbreaks. Later he moved on to fermentation technology of recombinant microorganisms at the University of Uppsala. After almost 20 years in Sweden, he returned to Hungary in 2006 and joined Gedeon Richter Plc. to lead the technology development for biosimilar medicine production using bacteria (E.coli) as well as mammalian (CHO) cells.
In 2014 he formed the Biotechnology unit in the newly established Pharmatech Model Laboratory (PML) at the Budapest University of Technology and Economics, where he also holds an Honorary Professorship.
Since November 2016 he has been responsible for the recombinant protein development and production of human diagnostic at the Diagon Ltd, Budapest.

Industrial

Professor
Dr Romána Zelkó

Dean Faculty of Pharmacy,
Semmelweis University

Romána Zelkó Ph.D., D.Sc. has her expertise in formulation and stability tracking of polymer-based drug delivery systems including various micro- and nanofibrous systems.

Her research work focuses on different synthetic and natural polymeric delivery systems, physical ageing of polymers, microstructural characterization of dosage forms associated with their functionality-related characteristics.
She is the author of 190 journal full papers and 5 patents and expert works. From 1991 she is employed by the Faculty of Pharmacy of the Semmelweis University.
She advanced her studies in the pharmaceutical technology at the Ghent University, Belgium. She has been successfully passing the achievements of her scientific research work on to her students at various PhD studies. She has held a variety of functions. She has served as a Vice-Dean (2003-2009) and from 2013 as the Dean of the Faculty of Pharmacy of the Semmelweis University.

Technological

Professor Dr Stane Srčič

Head of Pharmaceutical Technology Department, Faculty of Pharmacy, University of Ljubljana

Dr Stane Srčič is a Professor of Pharmaceutical Technology at the Faculty of Pharmacy, University of Ljubljana, Slovenia. His expertise is focused on solid oral dosage forms development and manufacturing and includes pre-formulation and formulation, new manufacturing methods and customised equipment.
After PhD, he spent as post-doc at the University of Regensburg and was/is acting as a visiting Professor at the University of Liverpool, Szeged, and Sarajevo.
He served for more than ten years as an expert from Slovenia on EMA (London) in the Committee for drugs in veterinary medicines and was responsible for quality parts of the dossiers.
He published more than 150 papers and is a holder of numerous patents and patents applications in the EU, US, Russian Federation and India.
He is strongly connected with the domestic and foreign pharmaceutical industry and was leading a lot of different academia-industry projects.
His international collaboration on the education and research areas have been recognised and awarded with the honorary doctorate from the University of Szeged (Hungary).

2019 PRESENTERS

Dr György Németh

Chief Medical Officer, Gedeon Richter Plc.

President of Hungarian Personalized Medicine Society

György Németh has been the Chief Medical Officer for Gedeon Richter Plc. since 2002. He is responsible for leading Gedeon Richter's Medical Division, which includes chairing global clinical research, development and strategy teams; managing medical-regulatory-marketing issues and supervising pharmacovigilance activities.

He began his carrier at the Medical School of Debrecen University, Department of Neurology and Psychiatry. Later on, he worked as a fellow of Alexander von Humboldt Foundation at the Department of Pathochemistry and General Neurochemistry, University of Heidelberg, Germany.

Afterwards, he had different fellowships at the Karolinska Institute in Stockholm, Sweden and New York University Medical Center in New York, USA. He continued his professional career as a clinical researcher at Knoll AG, Department of CNS R&D, where later, he took over the responsibility as Global Strategic Director for worldwide clinical and regulatory activities, launching among others two new chemical entities.

His main activities were the international leader of drug candidates for the treatment of stroke; Parkinson's disease, major depression, schizophrenia, and other non-CNS indications.

One of the success stories under his clinical leadership at Gedeon Richter was that the FDA and EMA approved a pioneering antipsychotic (cariprazine). He succeeded in verifying the efficiency of cariprazine in predominantly negative symptoms of schizophrenia which was previously lacking therapeutic possibilities. Thus, he instituted and led the clinical developments of a first-in-class drug.

Owing to his comprehensive science operation, he is an active member of umpteen societies including Hungarian, European and American societies. He is committed to personalised medicine. He has been the President of Hungarian Personalized Medicine Society since its foundation (2010).

Dr Christian Hetzel

Integrated Solutions Manager,
PALL Biotech

Dr Christian Hetzel has over 14 years of experience in the field of biotechnology and is currently Integrated Solutions Manager at PALL Biotech. He is responsible for managing strategic and high-value end-to-end solution biotech projects in Europe, covering complete manufacturing processes from USP up to Formulation and Filling.

Dr Christian Hetzel has a degree of Biology from the University of Bonn and has spent three years for his PhD in Science at the Fraunhofer IME in Aachen. After PhD Christian moved to the industry becoming an expert for upstream process technologies. He was spending several years in the biotech industry as Product Specialist and European Sales Manager and joined PALL in 2016 as Specialist for Cell Culture Technologies. In 2018 Christian changed his position within PALL to the Biotech Integrated Solutions Teams moving in his current role.

Sándor Polányi

CEO,
RotaChrom

Sándor Polányi is an innovative CEO with decades of management experience, leading variety of companies (smaller and bigger; Hungarian and multinational; private and state-owned) with full P&L responsibilities. He has a strong practice in several sectors: telecommunications, electronics, manufacturing, financial services and public sectors, working for such companies like Vivendi Telecom Hungary (currently Invitel) and Herend Porcelain Manufacture. He is highly skilled in corporate strategy, team building, M&A, restructuring, turnarounds and crisis management. Also, he is well-trained in the building, boosting and coordinating the integration of firms.

Currently, he is operating as the CEO of RotaChrom Technologies which is the first company to manufacture industrial scale Centrifugal Partition Chromatography (iCPC) platforms that have revolutionised the purification industry. Mr Polányi joined the company in 2017 to build it up to a larger international scale based on his business skills and leadership background. His positive attitude and innovative solutions highly contribute to the ground-breaking achievements and worldwide fame of RotaChrom.

Dr Piotr Lipiński

Global Quality Auditor,
Audit & Compliance, Europe II,
Novartis Technical Operations Quality

Piotr has over 12 years of experience in pharmaceutical companies. Currently, he is a Global Quality Auditor in Novartis, before he worked in pharmaceutical manufacturing sites as Quality Assurance Specialist, Qualified Person and Quality Systems Manager.

The experience includes particularly quality systems implementation, self-inspections, training and auditing of materials, products suppliers and service providers.

Piotr has detailed knowledge in the scope of all GxP rules with a special focus on Good Manufacturing Practice and Good Distribution Practice.

Piotr is a PhD Eng. in the scope of Technology of Chemistry. Additionally, he completed post-graduate studies in the scope of Industrial Chemistry at the Medical University of Gdansk. He was participating as well in numerous courses related to GMP aspects in the pharmaceutical industry.

Izabela Majić

Head of Inspectorate,
Agency for Medicinal Products
& Medical Devices of Croatia,
HALMED

Izabela Majić is a pharmaceutical quality and regulatory management professional and leader with years of experience in both industry and regulatory. Currently, she is a head of successful Inspectorate - recognised by the FDA among first 8 EU Inspectorates, a PIC/S member and was rated with highest grade 5 during benchmarking audit (BEMA) of regulatory agencies in December 2018.

She shows high involvement in international cooperation in the area of GMP and GVP, PIC/S, EMA, MRA, EDQM.

Before joining the Agency, she gained strong Quality and Manufacturing background in global companies such as Teva and start-up pharmaceutical facilities with both managerial and operational functions.

The experience includes implementation of QMS and validation of IT systems, manufacturing processes (parenterals, API (synthetic, fermented), biotechnological products, dry oral dosages and topicals) and equipment and analytical methods.

HALMED

Dr Ivan Bašic PhD

GMP Inspector Expert,
Agency for Medicinal Products &
Medical Devices of Croatia,
HALMED

Ivan has more than 27 years of experience (18 in pharmaceutical companies).

Currently, he is a GMP Inspector Expert in the Croatian Agency for Medicinal Products and Medical Devices. Before joining the Agency, he worked at the Rudjer Bošković Institute as a Scientist, in PLIVA and Hospira/ Pfizer as Chem/Bio and Validation Expert and in PharmaS as Global IT and Compliance Director. The experience includes implementation of quality systems, internal audits, implementation of pharma-specific IT systems, validation of instruments and equipment in quality control laboratories as well as in production, implementation of data integrity practices and training within GMP environment. Ivan received his PhD from the University of Zagreb. Additionally, he was a guest Scientist at the Max-Planck Institute in Germany.

BELUPO

Lenka Franciškovic

Head of Processes and
Products Quality,
BELUPO

Lenka is a Pharmaceutical Professional with a unique combination of pharmaceutical management experience and exceptional knowledge in the areas of the New Product Evaluation, Laboratory Operations, Pharmaceutical Analysis and Project Management. She has extensive experience in the pharmaceutical industry in Research and Development, Regulatory Affairs, Quality Assurance and Quality Control Environment as well as profound knowledge of TPB and FDA, EU and Croatian regulatory submission requirements. Strong knowledge of GMP, GLP, ICH guidelines and Pharmacopoeia is an inevitable part of Lenkas'professional skills. Lenka is currently Head of Processes and Products Quality for Belupo Pharmaceuticals Croatia. Prior to this work, she worked in several positions at Apotex Inc. Toronto, Ontario and Genpharm Inc. (now Milan Pharmaceuticals) in Etobicoke, Ontario. Lenka has published several publications, is a member of Pharmaceutical Sciences Group, Toronto and Croatian Association for Quality.

GEDEON RICHTER

Dr János Dombovári

Project Manager,
Biotechnology Division,
Gedeon Richter

Dr János Dombovári is Commissioning and Qualification Manager at Chemical Works of Gedeon Richter Plc., Debrecen, Hungary. In his position, he is responsible for the management of equipment and systems qualification projects, as well as for the introduction of lean philosophy on the site. He previously served as Operational Excellence Manager and Manager of Dry Production at TEVA Pharmaceutical Works Ltd. Among other matters, he was responsible for the reconstruction and capacity extension of production facilities, the installation and integration of new equipment and supporting technologies especially for tabletting and encapsulation equipment. In this role, he was involved in the selection and qualification of the new equipment and the validation of the existing products.

He received his chemistry MSC and analytical chemistry PhD degrees from the University of Debrecen.

SANOFI

Geoffroy Bessaud

Associate Vice President,
Corporate Anti-Counterfeiting
Coordination Corporate Security,
SANOFI

Geoffroy Bessaud is Associate Vice-President, in charge of anti-counterfeiting coordination activities at Sanofi.

He started his career as a sales representative with ICI Pharmaceuticals, then joined Sanofi Pasteur and Sanofi where he became successively International Product Manager, Marketing Director, Business Unit Manager, managing diverse programs in the USA, Europe, Latin America and Asia, with positions successively based in France, Italy, and Asia. He then joined Sanofi Corporate Communications as a spokesperson, also managing key global partnerships with Communications and Media Buying Agencies.

Vasil Pavlov

Plant Manager,
Tchaikapharma
High Quality Medicines INC.

Vasil has over 14 years of experience in the field of pharmaceutical business. Currently, he is the production manager at Tchaikapharma High-Quality Medicines INC.

Vasil also gained experience as a technical supervisor, operator, shift manager, plant manager and regional production manager. As the regional production manager, he is currently administrating the workflows between all local production shops and is responsible for the supply chain management, new projects management and the local business development. His experience includes implementation of innovative technologies, e.g. Vasil implemented a new type of robotised blister feeding system and increased the production speed by 45 %, vastly decreased the startup time and the time for cleaning and also reduced the final products cost.

He also implemented a special design serialisation project, based on specific internal requirements and technological restrictions.

Tamás Rácz

Director - Global Serialization Implementation / EU sites,
TEVA

Tamás Rácz is the Director for EU region Serialization Implementation at TEVA and is working as a member of the Global Engineering Project Management team. He is responsible for supporting 20 sites over the TEVA TGO EU network in Global Serialization program implementation. Tamás is giving guidance in CAPEX and project management processes, is supervising the implementation process, and is keeping contact with sites and vendors. In addition, he is participating in the global team decision-making process.

Tamás is an experienced Regional Project Director with a demonstrated history of working in the pharmaceuticals industry. He is skilled in Pharmaceutical Engineering, Packaging, Change Control, Validation, Lean Management, and GMP. He has been working in the multinational environment for more than 15 years, with excellent English knowledge and a result-oriented mindset.

Dr Tamás Sovány

Assistant Professor, Institute of Pharmaceutical Technology & Regulatory Affairs, Faculty of Pharmacy, University of Szeged

Dr Tamás Sovány studied pharmacy at the University of Szeged, Faculty of Pharmacy. After graduation, he stayed for PhD in the Department of Pharmaceutical Technology, with the topic: modelling of the subdivision of scored tablets with artificial neural networks.

He has received his PhD in 2011 and became a specialist of pharmaceutical technology in 2012. He has started to work at the Department of Pharmaceutical Technology as an assistant lecturer in 2009. In 2016 he got a promotion as an assistant professor and works in this position in the Institute of Pharmaceutical Technology and Regulatory Affairs which was formed in the same year after the merging of the two departments. His current research topics are the use of various modelling tools in pharmaceutical development and formulation of biopharmaceuticals into solid dosage forms.

Tomislav Đuranek

Director of
Maintenance & Energetics,
Belupo Pharmaceuticals

Tomislav has been working in the pharmaceutical industry for 20 years. After completing his degree in electrical engineering, he joined Belupo Pharmaceuticals & Cosmetics Inc. as Maintenance Technologist.

At the moment he is director of Maintenance & Energetics department in Belupo. Through years he gained valuable experience on Maintenance in Pharmaceutical industry, Solid, Semisolid and Liquid Manufacturing, Validation and Qualification, Calibration, Purified Water Production, Central GMP Media systems, Cleanroom, HVAC and many other processes in pharmaceutical industry.

Tomislav participated as a team member or leader in lots of various projects, from purchasing new or upgrading existing equipment, refurbishment of production and laboratory facilities, expanding warehouse capacities or implementing new IT systems. From 2013 to 2017 he has been leading Belupo's new factory construction project.

Dr Bertalan Mesko, PhD

The Medical Futurist
Director of
The Medical Futurist Institute

Dr. Bertalan Mesko, PhD is The Medical Futurist and the Director of The Medical Futurist Institute analyzing how science fiction technologies can become reality in medicine and healthcare.

As a geek physician with a PhD in genomics, he is also an Amazon Top 100 author. He is also a Private Professor at Semmelweis Medical School, Budapest, Hungary.

With 500+ presentations including courses at Harvard, Stanford and Yale Universities, Singularity University's Futuremed course at NASA Ames campus and organizations including the 10 biggest pharmaceutical companies, he is one of the top voices globally on healthcare technology.

Dr. Mesko was featured by dozens of top publications, including CNN, the World Health Organization, National Geographic, Forbes, TIME magazine, BBC, and the New York Times. He publishes his analyses regularly on medicalfuturist.com.

PLANT EXCURSIONS

12 - 13 March 2019 | www.pharmconnect.eu

GEDEON RICHTER

PRE - EVENT PROGRAMME | 11th MARCH 12:00

SITE VISIT TO THE GEDEON RICHTER Biotechnology plant in Debrecen

4031 Debrecen, Richter Gedeon u. 20.

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.

PRE - EVENT PROGRAMME | 11th MARCH 14:00

SITE VISIT TO MEDITOP PHARMACEUTICAL plant in Pilisborosjenő

2097 Pilisborosjenő, Ady Endre u. 1.

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.

POST - EVENT PROGRAMME | 13th MARCH 17:00

SITE VISIT TO SANOFI Ujpest plant in Budapest

1045 Budapest, Tó u. 1-5.

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.

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