DAY 1 | TUESDAY, MARCH 10th

09:00	**DOOR OPENING AND EVENT REGISTRATION**
09:30-09:40	**TEG Welcome Address** - Katy Säurich, Head of Operations & Production, **TEG The Events Group** **CHAIRMAN'S OPENING ADDRESS:** **Prof. Dr Ildikó Csóka,** Director of the Institute of Pharmaceutical Technology & Regulatory Affairs, Faculty of Pharmacy, **University of Szeged** **Prof. Dr Stane Srčič**, Head of Pharmaceutical Technology Department, Faculty of Pharmacy, **University of Ljubljana**
09:40-10:20	**OPENING KEYNOTE PRESENTATION:** **MES with Electronic Batch Records - Manufacturing Digitalization Backbone** • Project scope – manufacturing processes and software, architecture, interfacing with other systems • Key implementation lessons learnt – initial expectations vs. reality check, key troubleshooting areas, go-live experiences • Electronic batch record – perspective of operators, QA, inspectors, third parties • MES as backbone for digitalization within manufacturing area - wider context, how to use the system in building process and product knowledge **Wojciech Kisielnicki**, Finished Dosage Form Manufacturing Director, **Polpharma**
10:20-10:40	Networking Coffee Break and Vendor Viewing
10:40-11:20	**KEYNOTE PRESENTATION:** **Functional HPMC-based Capsules for both Oral Dosage Forms and Dry-powder Inhalation** **Frédérique Bordes-Picard**, Pharmaceutical Business Development Manager, **Capsugel (a Lonza Company)**
11:20-11:40	Networking Coffee Break and Vendor Viewing
11:40-12:20	**CASE-STUDY PRESENTATION:** **Serialisation, the Past, the Present and the Future** • The Origins of Serialisations and the fight against fakes • The current global trend and the need for Harmonisation • Lessons learned and the emergence of UDI and Cosmetics UPI • Future opportunities and how to build on the foundation **Neil Lawrence**, Global Serialisation Champion, Global Manufacturing and Supply, **GSK**
12:20-13:20	Lunch & Vendor Viewing
13:20-14:00	**CASE-STUDY PRESENTATION:** **How to choose the best API & raw material suppliers?** • Lessons learnt from the impurity case of Valsartan • How to avoid similar problems in the future? • How to provide high quality API products and raw materials to pharma companies? • What is the channel for API selection? - Indian vs. Chinese vs. EU APIs • How to avoid impurities, esp. elemental, toxic impurities? **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:** **Is the time over for the at-line/off-line bioprocess monitoring methods?** • Current trends in the field of process analytical technology • What kind of advantages can the in-line sensors provide? • Real-time predicting viable cell density values vs at-line measurements • Benefits of viable cell density predictions **Andrea Weinémer**, Biostatistician, Production Department, **Gedeon Richter**

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

15:20-16:00 CASE-STUDY PRESENTATION:
How to implement Ongoing Process Verification of the Process Validation Life Cycle in the routine Production?
- What are the differences between Continued (CPV) and Ongoing Process Verification (OPV)?
- What are the expectations of inspectors?
- How is OPV linked to Product Quality Review (PQR)/ Annual Product Review (APR)?
- What statistic parameters could help and what tools can be used?
- What situations can happen and examples on what to do in certain situations?
- Is the process capable and compliant for the production?

Izabela Majić, Group Quality Director, **Dechra**

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

16:20-17:00 CASE-STUDY PRESENTATION:
Digitalization, Industry 4.0
- Digitalized shop floor on the example of solid dosage form production
- Mature usage of MES on shop floor (benefits and issues basis on 10 years of experience)
- Production efficiency monitoring systems
- Application of 3D printing
- Work/ reports automation with SAP and MS Excel
- Robotics
- Ongoing projects and future plans (automation master plan, CMMS, MES upgrade, VR/AR)

Tomasz Pałka, Production Head, **Novartis** and **Piotr Wojciechowski**, MES Manager, **Novartis**

17:15 Cocktail Reception & Award Ceremony of the 6th 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 11th

09:00 DOOR OPENING AND EVENT REGISTRATION

09:30-10:10 OPENING KEYNOTE PRESENTATION:
Formulation and Manufacturing of Biosimilar Drug Products
- Formulation challenges of biosimilar drug products – role of excipients, determination of drug product composition
- Selection of primary packaging materials - administration, product stability and other perspectives
- Fill and finish activities from laboratory to production scale
- Stability of biosimilar drug products – applied analytical techniques, types of stability studies
- Biosimilarity / Comparability at DP level

Dr Erik Bogsch, Head of the Biotechnology R&D Division, **Gedeon Richter**

10:10-10:30 Networking Coffee Break and Vendor Viewing

10:30-11:10 CASE-STUDY PRESENTATION:
Quality Assurance for Single Use Systems: Implementation and Validation, Integrity, Transport and Packaging
- Broad usage of single use technologies, SUT, evolves into commercial operations and drug manufacturers look for solutions to industrialize its usage in a safe and reliable way
- With SUT adoption, quality ownership involves shared responsibilities between supplier and end user
- Part of supply and quality chain shifts to supplier
- Join us to discuss existing good practices to ensure critical quality attributes (CQAs) of the SUS throughout their life cycle

Patrick Evrard, Sr. Principal Engineer, Single-use Technologies, **Pall Biotech**

11:10-11:30	Networking Coffee Break and Vendor Viewing
11:30-12:10	**Presentations of the Award Winners of the 6th CEE Pharmaceutical Manufacturing Excellence Award** 11:30 – 11:50 Winner in manufacturing category | 11:50 – 12:10 Winner in solution provider category
12:10-13:10	Lunch and Vendor Viewing
13:10-13:50	**PANEL DISCUSSION:** **Training of personal & finding the best considering the lack of workforce** Intro by: **Olga Nazaruk**, Training and Development Manager, **Arterium Corporation** • What strategies are Pharm companies applying to address the lack of qualified people? • Most efficient training methods due to high fluctuation of staff and migration of young professionals to Western Europe • Impact on R&D, growth and new investments in CEE • Gap between the competences of University graduated specialists and expectances of Pharma Industry • How can outsourcing support the processes, esp. outsourcing of R&D? **Dr Sergii Sur**, Regulatory Affairs Director, **Arterium Corporation** **István Király**, Managing Director of HUMAN BioPlazma, **Kedrion Biopharma** **Rafał Maludziński**, Head People & Organization, **Novartis** **Piotr Lipiński**, Global Quality Auditor, Audit & Compliance, Europe II, **Novartis Technical Operations Quality**
13:50-14:10	Networking Coffee Break and Vendor Viewing
14:10-14:50	**CASE-STUDY PRESENTATION:** **Bioanalytical method validation according to draft ICH M10 Guideline** • Reliability in bioanalysis (focus on small molecules) • ICH M10 – a hybrid EMA and FDA guideline? • What is missing & future perspective **Piotr Rudzki, PhD, D.Sc**., Head of Pharmacokinetics Department, Steering Committee Director of ORBIS project Horizon2020-MSCA-RISE, **Lukasiewicz Research Network - Pharmaceutical Research Institute**
14:50-15:10	Networking Coffee Break and Vendor Viewing
15:10-15:50	**CASE-STUDY PRESENTATION:** **Capacity Planning Model in QC Laboratory** • How to understand capacity in QC Laboratory? • What testing model is good for your laboratory? • Key factors for successful planning • Tactical & operational planning • RCI **Olga Bartocha**, Quality Control Manager, **Novartis**
15:50-16:00	**CHAIRPERSON'S CLOSING REMARKS** **Prof. Dr Ildikó Csóka,** Director of the Institute of Pharmaceutical Tech-nology & Regulatory Affairs, Faculty of Pharmacy, **University of Szeged** **Prof. Dr Stane Srčič**, Head of Pharmaceutical Technology Department, Faculty of Pharmacy, **University of Ljubljana**

CHAIRPERSONS

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.

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).

DAY 1 | PRESENTERS

Wojciech Kisielnicki

Finished Dosage Form Manufacturing Director,

Polpharma

Wojciech Kisielnicki, Pharma Manufacturing Director in Polpharma Starogard Site. He started his career in 90's as a management consultant, undertaking process reengineering and privatization projects. For fifteen years he was developing SCM function of Polpharma, the leading Polish pharmaceutical company, facilitating rapid growth across domestic and international operations.

Wojciech, being responsible for Polpharma Group end-to-end supply chain, was also working on development

of materials management best practices in affiliated pharmaceutical plants and companies. Five years ago he became responsible for finished dosage forms manufacturing in the largest pharmaceutical facility in Poland, consisting of three plants: Solids, Glass Ampoules and Infusions.

Capsugel | Lonza Pharma & Biotech

Frédérique Bordes-Picard

Pharmaceutical Business Development Manager

Capsugel (a Lonza Company)

Biochemist Engineer by training (Bordeaux Polytechnic Institute), Frédérique holds also a Master of Business Administration from KEDGE Business School. Frédérique has been working in the Pharmaceutical Industry for more than 20 years, first at AstraZeneca UK working on analytical development of therapeutic proteins and antibodies then within CDMO Bertin Pharma (now Eurofins) mainly on Generic product development and licensing out. Frederique joined Capsugel® in 2010 as Pharmaceutical Business Development Manager providing technical and regulatory support for new capsule-based product developments.

Frederique has developed specific expertise around capsule-based DPI product development & filing, supporting multiple companies in EMEA and US working on innovative or generic DPI projects.

GlaxoSmithKline

Neil Lawrence

Global Serialisation Champion, Global Manufacturing and Supply

GlaxoSmithKline

Neil Lawrence has been successfully leading the global implementation of serialisation at GlaxoSmithKline for 4 years, having previously lead a globally recognized patient safety programme for the Department of Health in the UK. Working with competent authorities, standards associations, trade groups and many other stakeholders to ensure levels of patient safety are increased and counterfeit medicines are decreased from the supply chain, Neil drives forward GSK's adoption of global standards and pack safety features to ensure the protection of our patients.

NOVARTIS

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.

GEDEON RICHTER

Andrea Weinémer

Biostatistician

Gedeon Richter

Andrea Weinémer has been working as a biostatistician at Gedeon Richter Plc, Debrecen, Hungary. She graduated as an applied mathematician, yet she has become familiar with the biotechnology industry since the establishment of the Debrecen biotechnology production plant.

Andrea and her team have introduced and improved the Process Analytical Technology (PAT) tools at Gedeon Richter Plc. The team won the company's recognition award for this innovation.

During the last 9 years, she applied Multivariate Data Analytics (MVDA) tools to visualize more than 2 million data per fermentation and predict significant parameters real-time during the production of monoclonal antibodies.

Providing data for various departments during process validation also belongs to her tasks.

Dechra

Izabela Majić

Group Quality Director
Dechra

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 Group Quality Director at Dechra Pharmaceuticals. Before she held a position as 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.

NOVARTIS

Tomasz Pałka

Production Head
Novartis

Tomasz Pałka, Production Head in Novartis Warsaw Site. Professional career started in 2008, from the beginning in operation structures. After 8 years, in various positions (e.g. Technology and Laboratory Manager, Production Manager) in Reckitt Benckiser company, for over three years at Novartis Technical Operations. Experienced in the technology of liquids, powders and solid forms. Interested in psychology in the context of people management and process improvement. Tomasz is a mechatronics engineer, graduated at Military University of Technology and the MBA program at the Kozminski University.

NOVARTIS

Piotr Wojciechowski

MES Manager
Novartis

Over 14 years' experience in pharma industry of solid dosage forms production. Currently holds role of Production Support Systems Manager at Novartis Poland acting as bridge between IT and business.

Before, successfully held different roles starting on shop floor (supervisory of dispensing and granulation area) through different positions in supporting production within MES and SAP systems as well as managing projects and teams. Broad knowledge of IT systems implementation, integration, maintenance and validation. The experience include also team management, SAP Super User role, application development (KPI measurement), reports design, and process handling (MBR), work automation, paperless production, architecture and standardization advisory. Currently focused on shop floor digitalization and work automation. Bachelor of engineer in Computer Science and graduate Pharmaceutical College gives unique opportunity for understanding and digitalization of pharmaceutical production processes.

DAY 2 | PRESENTERS

Gedeon Richter

Dr Erik Bogsch

Head of the Biotechnology R&D Division
Gedeon Richter

Dr Erik Bogsch is the Head of the Biotechnology R&D Division at Gedeon Richter Plc. He is responsible for leading the R&D effort in the development of GR's biosimilar pipeline. Gedeon Richter Plc. is engaged in the development and manufacture of both bacterial cell fermentation based and mammalian cell fermentation based biosimilar products. GR has R&D, analytical & manufacturing capabilities in multiple locations in Hungary & Germany.

Dr Bogsch, a Hungarian national, has a Natural Sciences degree from the University of Cambridge and a PhD in cell biology from the University of Warwick. Following a brief postdoctoral academic research career, he worked in the food industry for many years in R&D, Quality & Manufacturing roles in the UK, Hungary & Germany. He joined Gedeon Richter Plc. in 2012, as commissioning lead for GR's biotechnology factory in Debrecen, Hungary, before moving into his current role.

PALL Biotech

Patrick Evrard

Sr. Principal Engineer
Single-use Technologies
Pall Biotech

Patrick Evrard joined Pall Biotech in 2017, and is providing expert technical, validation and regulatory support, as well as being an internal "voice of the end-users" on the single-use technologies. Specific fields of expertise are: redesign processes with single-use technologies to achieve closed systems operation, aseptic processing, particles and integrity control for single-use systems. Before joining Pall, he led for more than 10 years a global technical team in charge of developing and implementing single-use technologies in GSK Vaccines' commercial manufacturing operations. Patrick and his team implemented at global level single-use technologies in critical sterile applications and re-engineered several vaccines processes, switching from classical grade A open processes to closed systems ones. Patrick has written and contributed to several articles and white papers on single-use technologies, was part of the Board of Directors of the Bio-Process Systems Alliance (BPSA). He has been participating since 2012 in several single-use technology industry work groups, from BPSA, BioPhorum Operations Group (BPOG), American Society of Mechanical Engineers (ASME BPE) and ASTM International.

ARTERIUM

Olga Nazaruk

Training and Development Manager
Arterium Corporation

Olga Nazaruk represents company "Triglav International" that is a partner of Ukrainian Pharmaceutical Corporation Arterium, which provides training and development for its staff. Prior to that, Olga worked for 9 years in the Corporation, for the last 5 years holds the position of Training and Development Manager.

Olga conducts different learning activities, manages various projects in T&D, specializes in cooperation with universities and is responsible for the Employer brand of Arterium. The most successful projects in Arterium were implemented in the field of communication, corporate culture and time management for line and middle management.

Olga says she is fan of all kinds of learning, believes that people can change if they are eager to and does a lot so people in her company become more efficient and happy and the company itself more prosperous.

Olga is also a business trainer, coach, and Master of Psychology (Taras Shevchenko National University of Kyiv and Wiesbaden Academy of Positive Psychotherapy).

KEDRION BIOPHARMA

István Király

Managing Director
of HUMAN BioPlazma
Kedrion Biopharma

István Király graduated from the Technical University in Budapest as a mechanical engineer. During his professional career he has filled several technical- and production-related management positions in different industries at large international companies such as General Electric, DANONE, Alcoa and GlaxoSmithKline.

These challenges allowed him to be involved in the implementation and operation of different management and quality systems such as ISO, HACCP, GMP, Toyota Production System, Six Sigma and Lean Sigma. In 2006 he joined GSK Vaccines and started his career in Gödöllő Manufacturing site. He held various senior management positions until he was appointed as Managing director of the site in 2011. In 2015 he was nominated to VP, Head of Operations of the legacy Novartis Vaccines sites, overseeing the industrial operations of those sites and also managing the integration of those newly acquired manufacturing units into GSK Vaccines industrial network.

In 2016 he was promoted to VP, Site Director Siena & Rosia Operations, Italy at GSK Vaccines. In 2018 István returned to Hungary, and joined HUMAN BioPlazma (part of Kedrion Group) as Site Director.

ARTERIUM

Dr Sergii Sur

Regulatory Affairs Director
Arterium Corporation

Dr Sur has over 25 years of work experience in the pharmaceutical market, including 14 years in management positions. He received his PhD degree in Pharmacy and published approximately 100 scientific publications. Between 1993 and 1998 he was the Head of State Laboratory for Quality Control of Medicines at the Institute of Pharmacology and Toxicology at the Ukrainian Academy of Medical Sciences in Kiev.

Between 1998 and 2005 he worked for the Ukraine Ministry of Health, firstly as the Director of Central Laboratory for Quality Control of Medicines and since 2000 as the Deputy Chief Inspector for Quality Control of Medicines. Since 2005, Dr Sur has been in his current position responsible for the development of a functional strategy in R&D; the development and introduction of R&D business processes and structure; and the organisation of research, development and registration of new products.

Additionally, Dr Sur is a member of the International Federation of Pharmacists (FIP) and since 1998 has been an adviser on International Pharmacopoeia and Pharmaceutical Preparations and since 2002 also on Traditional Medicines for the WHO which is headquartered in Geneva.

NOVARTIS

Rafał Maludziński

Head People & Organization
Novartis

HR leader with extensive professional experience in the areas of building the employer's brand image, leading selection and recruitment processes, change management, in particular the creation, implementation and development of competence models. For over 15 years associated with business in sectors such as production, sales and marketing, consulting and SSC. A member of international project groups responsible for the development of processes and tools supporting organizations in building career paths and succession plans. Author and facilitator of trainings and workshops in the field of identification and development of employees' potential. A graduate of the Faculty of Political Science at the College of International Relations and Diplomacy, postgraduate studies in Human Resources Management at the Lodz University of Technology and a number of business coaching and coaching courses. Currently, holds People & Organization Head role at Novartis Technical Operations (NTO) Poland and is a Member of the Management Board of LEK S.A. being the legal entity of the NTO Division in Poland.

NOVARTIS

Olga Bartocha

Quality Control Manager
Novartis

Olga Bartocha has been working in pharmaceutical industry for 16 years. Olga is a Pharmaceutical Professional in the field of quality control, quality auditing, project management and contract services.

She has the knowledge of pharmaceutical technologies: solid dosage forms and sterile manufacturing (glass ampoules, infusions). Olga started her carrier in 2003 in Pharmaceutical Works Polpharma S. A. holding several specialist and manager positions in quality control as well as in contract manufacturing. In 2017, Olga joined Novartis and became Quality Control Manager. In this role, Olga is responsible for Novartis Quality Control in Poland.

ORBIS

Piotr Rudzki PhD, D.Sc.

Head of Pharmacokinetics Department, Steering Committee Director of ORBIS project Horizon 2020-MSCA-RISE, Lukasiewicz Research Network - Pharmaceutical Research Institute

Pharmacist with over 15 years in a GLP-certified laboratory, involved bioequivalence projects (bioanalysis, pharmacokinetics, statistics). Head of Pharmacokinetics Department at Łukasiewicz Research Network – Pharmaceutical Research Institute since 2009, director of ORBIS project Steering Committee (Horizon 2020).

D.Sc. in medicine and health sciences (2019), co-author of over 30 papers and over 50 conference communications, involved in the EMA public consultations, author of expert opinions and pharmacokinetic study designs.