# PHARM connect congress

2017 BUDAPEST 22-23 FEBRUARY

PHARMACEUTICAL AND BIOTECHNOLOGY
MANUFACTURING CONGRESS FOR ENLARGED EUROPE



## **MEMBERS**

of the Programme Advisory Committe

Dr. András Ballagi

Director of Bioprocess Development and Manufacturing, Diagon





CHRISTOPHER
HUNLEY
Site Director, GSK
Biologicals Kft.



PR. ERIK BOGSCH

Head of the

Biotechnology R&D

Division, Gedeon

Richter



GRZEGORZ BRZOSKOWSKI Security Director CEE/Baltic, SANOFI



Head of the Center of Biological Business Development and Technology, EGIS



LENKA FRANCIŠKOVIĆ Head of Processes and Products Quality, Belupo Pharmaceuticals



MCDONNELL Global Innovation Strategy & External Partnerships Manager, SANOFI and Technical

## and services available on the market. All this combined with informal networking opportunities will provide an exclusive interactive platform. 3rd CEE PHARMACEUTICAL MANUFACTURING EXCELLENCE AWARD

**A UNIQE EVENT** | The Events Group is delighted to invite you to the 7<sup>th</sup> PHARM Connect Congress, the annual market leading and only regional pharmaceutical and biotechnology manufacturing business summit for the CEE and CIS region. Your most respected peers and European industry leaders will provide you with the most up to date market insights. Moreover, during the pre-scheduled one-to-one meetings leading solution providers will offer the most innovative products

Supported by the Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ), TEG is proud to announce the 3<sup>rd</sup> CEE Pharmaceutical Manufacturing Excellence Award. The aim of the award is not only to celebrate excellence in manufacturing, but to encourage professionals to constantly raise standards contributing to the development of CEE as a region.

#### Applications from all members of the industry are welcome in two categories:

- Innovative and generic pharmaceutical and biotechnology manufacturers
- Service providers with a customer project

#### CLOSING DATE: 16th OF JANUARY 2017.

All projects will be evaluated based on their cost-effectiveness, quality level, service level and level of innovation by our **independent regional academic jury** in order to guarantee the quality and the regional scope of the award.

The winners will be announced during the cocktail reception and will have the opportunity to present their projects at PHARM Connect to the top pharmaceutical and biotechnology management professionals of the region during the second day of the market leading summit.

**THE DELEGATION** | The quality of the PHARM Connect Congress is a direct result of its exclusivity. Participation at the congress is by invitation only, which enables to maintain the quality and networking value of the congress participants.

**THE CONGRESS WILL BE BRINGING TOGETHER** | Managing directors, Regional and Local Production, R&D and Plant Directors, Regional and Local Purchasing and Sourcing Directors, Key Quality Assurance and Quality Control Managers and Maintenance Managers, Logistics and Supply Chain Directors from Europe's leading pharmaceutical and biotechnology manufacturing companies.

### **JURY MEMBERS**

of the 3rd CEE Pharmaceutical Manufacturing Excellence Award



PROFESSOR
IMRE KLEBOVICH
Department of
Pharmaceutics,

Semmelweis University

Budapest

PROFESSOR

PROFESSOR VLADIMIR KRAL

University of Chemistry and Technology and First Faculty of Medicine, Charles University Prague



Professor Stane Srčič

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



Dr. Lajos Hegedűs

Former General Manager of TEVA, Hungary Chairman of the Production Commission of the Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ)



PROFESSOR CONSTANTIN MIRCIOIU

"Carol Davila"
University of Medicine
and Pharmacy,
Bucharest and Head
of Pharmaceutical
Section, Academy
of Medical Sciences,
Romania



DR. BARTŁOMIEJ MILANOWSKI

Assistant Professor at the Department of Pharmaceutical Technology, Faculty of Pharmacy, Poznan University of Medical Sciences

#### **EXCURSION | FEBRUARY 21<sup>ST</sup>** at 1:00 p.m. for max. 50 delegates

GlaxoSmithKline Biologicals, Gödöllő

At the Gödöllő site GSK is producing, testing and releasing Tetanus and Diphtheria bulk antigens for shipment to other GSK Vaccines sites. The site visit will start with an introduction of the GSK Vaccines business division and the Gödöllő site, including a short movie about the activities which is followed by a site tour including a visit to the production corridor, Biochemistry lab, Microbiology lab and warehouse.

**EXCURSION** | **FEBRUARY 23**<sup>rd</sup> at 5:00 pm for max. 60 delegates Research Centre for Natural Sciences of the Hungarian Academy of Science

The congress provides the opportunity to visit the Research Centre for Natural Sciences of the Hungarian Academy of Science (MTA TTK) in Budapest limited for 60 delegates only and available on a first come first serve complimentary basis. The Research Centre carries out multidisciplinary research in natural sciences, priorities are given to the following disciplines:

ORGANIC CHEMISTRY | MATERIALS- AND ENVIRONMENTAL CHEMISTRY | MOLECULAR AND CELLULAR LIFE SCIENCES | COGNITIVE NEUROSCIENCE AND PSYCHOLOGY

The visit will start with a short introductory presentation, afterwards the delegates will have the opportunity to join a tour and to visit one of the four research institutes.

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#### **CHAIRMAN OF PHARM CONNECT 2017**

DR. ANDRÁS BALLAGI, Director of Bioprocess Development & Manufacturing, Diagon

#### INDUSTRY 4.0 AND SINGLE USE TECHNOLOGY IN BIOPHARMA

- The 4th Industrial Revolution
- Improving Competitiveness
- Impact for BioPharma
- Continuous Manufacturing
- Examples of implemented Smart Factories

DIRK TILLICH, VP Global Sales, Core Business, Finesse Solutions

#### NEW EQUIPMENT AND EQUIPMENT SUBSTITUTES - BEST PRACTICES OF INTEGRATION AND PROCESS VALIDATION

- · Considerations during tablet press substitution: how to integrate the new machine into the existing production system and how to validate operation
- How to handle differences and analogies
- Incorporation of technical improvements into the production process

DR. JÁNOS DOMBOVÁRI, Director Operational Excellence Pharma Division, TEVA

#### CONCEPTS TO IMPROVE THE PRODUCTIVITY OF DRUG INNOVATION

- Trends in performance of drug innovation, an overview
- Limitations of productivity
- Some principles for (more) effective preclinical research
- The possible contributions of University to drug discovery

PROFESSOR PÉTER MÁTYUS, Director of the Drug Discovery and Safety Centre and CEO of the Bionics Innovation Center, Semmelweis University Budapest

#### TERROSA - FIRST BIOSIMILAR APPROVAL FOR GEDEON RICHTER

- Key development steps for biosimilars
- Technology platforms applied
- Medical device aspects
- Clinical development programme challenges of biosimilars
- A complex IP landscape
- Market access challenges

DR. ERIK BOGSCH, Head of Biotechnology R&D, Gedeon Richter ILDIKÓ ARADI, Head of Clinical Development of Biologics, Gedeon Richter KATALIN FOGASSY, TERROSA Project Manager, Gedeon Richter

#### "SPREAD THE WORD"

- How are the fake drugs distributed?
- Who buys on the internet?
- How to inform the customers about the risk?
- Program for generation Z
- What is their reflection?

### DR. LÍVIA ILKU, Director, Hungarian Pharmaceutical Manufacturers Association

ERZSÉBET ÓDOR, Country Security Partner, SANOFI & Head of the Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ) Environment Subcommittee

#### EFFICIENCY INCREASE FOR SINGLE-USE CELL REMOVAL (MIDSTREAM) USING FILTER AID AND CONTINUOUS PROCESS DESIGN

- Increasing cell removal efficiency
- Continuous process
- Cost effective process

RALPH DAUMKE, Market Manager Biologics, FILTROX

#### DISCOVER PALL'S FULL mAb PURIFICATION PLATFORM

The presentation illustrates recent evolutions in Bioprocessing and describes in detail all potential opportunities for a process platform run in continuous mode.

The content rounds up with an overview of selected Pall products and gives useful application details in Downstream Processing.

ADRIANE RANINGER, Bio-Purification Process Specialist CEE, Pall Life Sciences

#### CHALLENGES IN MEETING GOOD PRACTICES FOR DATA MANAGEMENT AND INTEGRITY IN REGULATED GMP ENVIRONMENTS GUIDANCE

- General requirements related to data integrity
- Main FDA and EU inspections observations in scope of data management and integrity
- Data management and Integrity program for pharmaceutical company

DR. PIOTR LIPINSKI, Quality Systems Manager/QP, Novartis Technical Operations -Platform Solids Europe, Lek / Novartis

#### REGULATORY AND QUALITY MANAGEMENT SYSTEM CHANGES IN RUSSIAN PHARMA MARKET: RECENT DEVELOPMENTS AND FUTURE PERSPECTIVE

- The impact of main regulatory requirements on drugs turnover
  - Local clinical trials
  - Russian GMP inspections
  - State quality control system
  - Price regulation
- Eurasian Union pharmaceutical market. What exactly was introduced and what are the expectations?

EKATERINA TVOROGOVA, Regulatory Affairs Manager, Egis Pharmaceuticals, Representation in Russia



#### REGULATORY AND QUALITY MANAGEMENT SYSTEM CHANGES IN RUSSIAN & UKRAINIAN PHARMA MARKET

- Comparison between Russian, Ukrainian and European GMP requirements
- New reimbursement requirements
- What exactly was introduced and what are the expectations?

EKATERINA TVOROGOVA, Regulatory Affairs Manager, Egis Pharmaceuticals, Representation in Russia

DR. SERGII SUR, Regulatory Affairs Director, Arterium corp.

DR. HERTA PÁLFI GOÓTS, Director, Regulatory Affairs, Gedeon Richter & Head of the Regulatory Affairs Committee of the Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ)

#### EU'S FALSIFIED MEDICINES DIRECTIVE (FMD): HOW TO PREPARE NOW FOR THE 2019 **DEADLINE?**

- Preparing for compliance: How to protect the market?
- Global look at Big Pharma business-critical practicalities of serialisation
- GSK best practice case study and lessons learnt

NEIL LAWRENCE, Global Serialisation Champion, Global Manufacturing and Supply, GlaxoSmithKline



#### PANEL DISCUSSION:

EU'S FALSIFIED MEDICINES DIRECTIVE (FMD): HOW TO PROTECT THE MARKET? NEIL LAWRENCE, Global Serialization Champion, Global Manufacturing and Supply, GlaxoSmithKline

GRZEGORZ BRZOSKOWSKI, Security Director CEE /Baltic, SANOFI **RÉKA BALOGH**, Leader of the Safety Feature Committee of the **Hungarian** 

Pharmaceutical Manufacturers Association (MAGYOSZ) & Serialization Project Coordinator, Quality Assurance Expert, TQM, Gedeon Richter

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To ensure the success of the PHARM Connect Congress, TEG is pleased to partner with a limited number of companies in each sponsor category offering valuable solutions and expertise in these kev areas:

#### PHARMACEUTICAL INGREDIENTS

- Raw materials, API's
- Excipients and Fine chemicals

CUSTOM/CONTRACT MANUFACTURING

DRUG DELIVERY SYSTEMS

PROCESS AUTOMATION

PROCESSING MACHINERY & COMPONENTS

- Pumps, compressors and blowers
- Valves and fittings, Blending
- Coating, Drying, Encapsulation



- Centrifuges, Filtration, Milling
- Mixing, Tableting

STERILE SUPPLIES

**SOLUTIONS FOR BIOPHARMACEUTICALS &** BIOLOGICALS

#### QUALITY CONTROL & MONITORING SYSTEMS

- Inspection systems, Automated inspection systems
- Data loggers, Measurement control

LABORATORY EQUIPMENT

#### **LABORATORY & ANALYTICAL TECHNOLOGY**

#### PHARMACEUTICAL PACKAGING

- Machinery & Components, Packaging materials
- Labelling & RFID, Auto ID equipment
- Security Solutions, Anti Counterfeiting

#### IT FOR THE PHARMACEUTICAL INDUSTRY **COLD CHAIN STORAGE & DISTRIBUTION**

BENEFITS

OF ATTENDING

#### CLEANROOMS & ACCESSORIES

- Measuring devices for cleanrooms
- Cleanroom monitoring systems
- Cleanroom construction
- Cleanroom flooring
- Ventilation, Cleanroom garments
- Validation

#### PLANT ENGINEERING & MAINTENANCE

Modular production facilities

PHARMACEUTICAL STORAGE, WAREHOUSING

PHARMACEUTICAL LOGISTICS & DISTRIBUTION

PHARMACEUTICAL CONSULTANCY

OUTSOURCING

#### **TESTIMONIALS**

"I was very impressed with the programme. I think the two days really covered some of the most exciting and important areas. There was a very good set of service providers present. As always I left with important business cards."

Dr. Erik Bogsch, HEAD OF BIOTECHNOLOGY R&D DIVISION, Gedeon Richter

"Good location, well organised event; the fact that I can meet my peers from this region at that time makes sense."

Geoffroy Bessaud, AVP, CORPORATE ANTI-COUNTERFEITING COORDINATION CORPORATE SECURITY, SANOFI

"We have met a lot of solution providers from the region, a very important aspect when it comes to launching new projects. And it is a very active, interactive conference, very fruitful I would say this is something that I really like and what makes it unique and different from the others."

Lenka Franciskovic, HEAD OF PROCESSES & PRODUCTS QUALITY, Belupo

"It was very good and productive. Congratulations to the team who organized the event."

Cristina Vlase, RESEARCH & BUSINESS DEVELOPMENT MANAGER, Antibiotice

"I am extremely impressed by the quality of attendees from many different countries and their level of interest in our technology. We felt like more than 50% of the customers that visited us, they are going to eventually buy something."

Bill Frohlich, HEAD OF GLOBAL BUSINESS DEVELOPMENT, Exergy

#### **SPONSORS**









#### VENUE AND LOCATION

Hungary is one of the largest and most developed drug markets in CEE. Large international pharmaceutical companies are among those that have invested in local manufacturing, as well as early and late stage R&D. Additionally Hungary boasts the strongest biotech sector of the 14 new EU member states.

On top you will meet your peers, clients and business associates at the luxury five stars CORINTHIA Grand Hotel Royal in the heart of Budapest, which truly is a one of a kind luxurious venue. The hotel is located in central Budapest and is easily accessible from throughout the city. Underground parking is available.

#### \*\*\*\*\*CORINTHIA GRAND HOTEL ROYAL BUDAPEST

Erzsébet körút 43-49, H-1073 Budapest, HUNGARY T: +36 1 479 4000, F: +36 1 479 4333 www.corinthia.com

ARRIVING BY PLANE: The CORINTHIA Grand Hotel Royal Budapest is located 25 minutes from the airport on the Pest side of the city. ARRIVING BY CAR: Parking is possible in the hotel's park house next to the hotel.

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- An invitation only event giving access to the congress floor
- PERSONALISED CONFERENCE and pre-scheduled meetings through the secured Meeting Scheduler website to suit individual requirements and provide efficient use of time
- KEYNOTE PRESENTATIONS, case studies and interactive sessions by world-class industry experts and pioneers
- PROFESSIONAL BUSINESS ENVIRONMENT in which to explore new ideas, strategies and technical developments with industry colleagues, experts, and peers
- BENEFITS OF ATTENDING PARTIES OF ATTENDING PARTIES
  - An opportunity to relax and enjoy the superb informal NETWORKING opportunity at the cocktail reception and a luxury seated buffet lunch
  - PLANT EXCURSION to leading manufactures & research centers
  - Complimentary congress INFORMATION PACK on arrival
  - DOWNLOADING the conference presentations through our password protected website
  - DISCOUNTED ROOM RATES at the Corinthia Grand Hotel Royal if booked via TEG
  - Privileged status TRAVEL offers

### THE EVENTS GROUP PRIDES ITSELF ON BRINGING THE REGIONS EXPERTS TOGETHER TO DELIVER STRATEGIC CASE STUDIES TO A PAN EUROPEAN DELEGATION

Production Director, Abela Pharm Serbia Country Manager, Actavis Slovakia R&D Director, Alpha-Vet Hungary CRO Manager, Antibiotice Romania Vice President, Apipharma Croatia Regulatory Affairs Director, Arterium Corporation Ukraine Business Development Manager CEE, Avantor Performance Materials Poland Board Member, Avita International Slovakia CEO, Bax Pharma Slovakia Poland & Eastern Europe Business Head, Baxter Poland Sourcing Manager, Bayer Healthcare Germany Head of Process & Products Quality, Belupo Croatia Production Director, Béres Pharmaceuticals Hungary CRM, Berlin-Chemie Menarini Baltic Lithuania President, Biomed WSIS Poland Head of Quality Assurance, Biovet Bulgaria Global Head of Biology Purchasing, Ceva-Phylaxia

Deputy Director of Global Industrialisation & Process Improvement, Ceva-Phylaxia Hungary CEO, Crystal Derma, Serbia

Hungary

Managing Director, Dyntec Czech Republic Plant Manager, Egis Pharmaceuticals Hungary Head of Procurement, Egis Pharmaceuticals Hungary Head of Group Operations, Egis Pharmaceuticals Hungary

Business Development Director, Farmak, Czech Republic

Head of Production, Farmavita Bosnia & Herzegovina Production Manager, Ferring Leciva Czech Republic President, Finepharm Poland Production Director, GalenBio Hungary

Head of Biotechnology Production Plant, Gedeon Richter Hungary

Head of Purchasing, Gedeon Richter Hungary

Head of Biotechnology R&D Division, Gedeon Richter Hungary

Head of Quality, Glenmark Pharmaceuticals Czech Republic

CEO, Globopharm Austria

Business Development Director, Goodwill Pharma Hungary

General Manager, Gopharm Slovenia Managing Director, GSK Biologicals Hungary VP Technical Operations, Hameln Slovakia General Manager, HBM Pharma Slovakia Head of Solid Dosage Forms Plant, Hemofarm Serbia

General Manager, Hofigal Export Import Romania
Global Industrial Operations Director, Human
Bioplazma Hungary

Biopiazina Hungary

Head of Purchasing, Hungaropharma Hungary Production Director, IBSS Biomed-Lublin Poland Plant Director, Infomed Fluids Romania Quality Control Manager, Institute of Immunology

Croatia

Director of Corporate Strategy Interpharma Praha

Director of Corporate Strategy, Interpharma Praha Czech Republic

Executive Director of Pharmaceutical & Technical Operations, Jadran Galenskij Laboratorij Croatia President, Jelfa Poland

Plant Manager, Maco Productions Poland

CEO, Marifarm Slovenia

Technical & Production Director, Mebra Romania Production Manager, Medicproduct Slovakia

General Manager, Meditop Hungary Managing Director, Merck Serbia

EMEA Commodity Manager, Mylan Pharmaceuticals Hungary

Plant Manager, Naturland Hungary Executive Director, Oncomed Manufacturing Czech Republic

Managing Director, Pharmanova Serbia

Head of Quality Assurance EU Logistics, Pliva/TEVA Europe Croatia

Business Development Manager, Polfa Lublin Poland Finished Dosage Form Manufacturing Director,

Polpharma Group Poland

Head of Biotechnology Science, Poznan Science & Technology Park Poland

Quality Assurance Manager, Roche Czech Republic API & Excipients Purchasing Manager Sandoz Romania Associate Vice President, Director of Germany-Hungary-India-Italy Production Group, Sanofi France Associate Vice President, Corporate Anti-Counterfeit,

Sanofi France
Head of Packaging Plant , Sanofi Hungary
Quality Assurance Director, Sanofi Hungary

Site Director, Sanofi Hungary

Country Procurement Head, Sanofi Hungary General Manager, Synthon Czech Republic Head of Purchasing, Terapia Sunpharma Romania Global Advanced Sterile Technologies & OPEX Director,

TEVA Hungary

President & CEO, Unia Poland

Quality Assurance Manager, Unipharm Bulgaria

General Manager, Valeant Hungary

Senior Manager Strategic Business Development,

Woerwag Pharma Germany

Director of Generics Production Europe, Zentiva Czech Republic

Innovation Director, Zentiva Czech Republic Production Director, Zentiva Romania Equipement Qualification Manager, Pliva / Teva, Croatia AVP Corporate Anti-counterfeiting, Sanofi Group,

France

Global Innovation Strategy & External Partnership Manager, Sanofi, United Kingdom