

PHARM connect congress

2018 BUDAPEST
13-14 MARCH

PHARMACEUTICAL AND BIOTECHNOLOGY
MANUFACTURING CONGRESS FOR ENLARGED EUROPE



*"The secret of success
in life is for a man to be ready
for his opportunity when it comes."*

Benjamin Disraeli (1804-1881), British politician

MEMBERS

of the Programme Advisory Committee

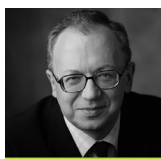
DR. ANDRÁS BALLAGI
CTO, Diagon



**CHRISTOPHER
HUNLEY**
Site Director, GSK
Biologicals Kft.



DR. ERIK BOGUSCH
Head of the Biotechnology
R&D Division
Gedeon Richter



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Regulatory Affairs
Director, Arterium
Corporation



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



**LENKA
FRANCIŠKOVIČ**
Head of Processes
and Products Quality,
Belupo Pharmaceuticals



DR. TOMAS GROH
Part of the
Biotechnology R&D
Division, Bioinova, Ltd.



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



MAREK CICHOCKI
Head of Operational
R&D, Polpharma



ISTVÁN KIRÁLY
Site Director Siena &
Rosia Operations, Italy,
GSK Vaccines S.r.l.

JURY MEMBERS

of the 4th Pharmaceutical Manufacturing Excellence Award



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Semmelweis University
Budapest



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Charles University
Prague



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University of Ljubljana



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HEGEDŰS**
Hungarian
Pharmaceutical
Manufacturers
Association



**PROFESSOR
CONSTANTIN
MIRCIOIU**
"Carol Davila"
University Bucharest



**DR. BARTŁOMIEJ
MILANOWSKI**
Poznan University of
Medical Sciences

A UNIQUE EVENT | The Events Group is delighted to invite you to the 8th 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 and services available on the market. All this combined with informal networking opportunities will provide an exclusive interactive platform.

4th CEE PHARMACEUTICAL MANUFACTURING EXCELLENCE AWARD

Supported by the Hungarian Pharmaceutical Manufacturers Association (MAGYOSZ), TEG is proud to announce the 4th 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: 31st OF JANUARY 2018.

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.

EXCURSION | MARCH 12th at 15:00 for max. 30 delegates

Meditop Pharmaceutical near Budapest

Meditop develops and manufactures its own products and offers services as a CMO to produce solid dosage forms in flexible manner. It 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. Participants can learn more about it and visit the plant near Budapest.

EXCURSION | MARCH 14th at 17:00 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:

MATERIALS & ENVIRONMENTAL CHEMISTRY | COGNITIVE NEUROSCIENCE & 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 two research institutes.



DAY 1 | TUESDAY March 13th

CHAIRPERSONS OF PHARM CONNECT

BIOTECH AND R&D: DR. ANDRÁS BALLAGI, Chief Technology Officer, **Diagon**

INDUSTRIAL: PROF. DR. ROMÁNA ZELKÓ
Dean Faculty of Pharmacy, **Semmelweis University**

TECHNOLOGICAL: PROF. DR. STANE SRČIČ, Head of Pharmaceutical Technology
Department, Faculty of Pharmacy, **University of Ljubljana**

REGULATORY: ASSOC. PROF. DR. ILDIKÓ CSÓKA
Director of the Institute of Pharmaceutical Technology and Regulatory Affairs Faculty of
Pharmacy, **University of Szeged**

OPENING KEYNOTE PRESENTATION:

BIOSIMILARS: OPPORTUNITIES AND CHALLENGES FOR PHARMACEUTICAL INDUSTRY. PEGFILGRASTIM CASE STUDY

- Biologics, biosimilars, generics – facts and definitions
- Biosimilar market trends
- Pegfilgrastim case study: focus on clinical development and Phase III study considerations

ANNA AILLERIE, Head of Commercial Operations, Biotechnology Business Unit, **Gedeon Richter**

DR. ANDRÁS ILLÉS, Deputy Head of Clinical Development of Biologics, **Gedeon Richter**

CASE STUDY PRESENTATION:

IMPLEMENTING SINGLE-USE CONTINUOUS BIOPROCESSING: A CASE STUDY ON LARGE-SCALE CONTINUOUS mAb PURIFICATION

- Process intensification through continuous bioprocessing
- Case study on large-scale continuous mAb purification
- Regulatory aspects of continuous bioprocessing

BRITTA BADERTSCHER, MSc, Technical Specialist SLS, **Pall International SARL**

CASE STUDY PRESENTATION:

ENABLING SMOOTH PRODUCT LIFE CYCLING – PROCESS CHARACTERIZATION ON SOUND DATA SCIENCE AND QBD TOOLS

Process characterization is a central tool in process validation from step 1 to 3 in the product life cycle. We need:

- Advanced statistics to be deployed to define NORS and PARS
- Models for experimental design, scale down models qualification and real-time predictive control

UNIV. PROF. DR. CHRISTOPH HERWIG, Head of Research Division Biochemical Engineering, Institute of Chemical Environmental and Biological Engineering
Vienna University of Technology

CASE STUDY PRESENTATION:

OPTIMIZATION OF LYOPHILIZATION PROCESS FOR THE PARENTERAL PRODUCT

- Using PAT tools at the production scale
- Production scale up of the parenteral product
- Development of new lyo cycle in order to reduce total production cost (TPC) and increase production capacity

DR. ALJOŠA MAGLICA, Product Steward Senior, **Lek Pharmaceuticals d.d. / Novartis**

CLOSING KEYNOTE PRESENTATION:

MAKING IT FIT: THE CHALLENGES OF TRANSFERRING NEW PRODUCTS INTO A RUNNING FACILITY

- Key considerations of balancing project speed with manufacturing continuity
- An overview of the main risks of infrastructure modifications around (and inside) a running GMP unit
- Our key lessons learned and how we are executing further transfers effectively
- Interesting challenge - Transferring similar technologies

JUDIT SALLAI, Technology Transfer Project Leader, **GSK Biologicals Kft.**

CHRISTOPHER HUNLEY, Site Head and Managing Director, **GSK Biologicals Kft.**

DAY 2 | WEDNESDAY March 14th

OPENING KEYNOTE PRESENTATION:

CONTINUOUS MANUFACTURING INTO THE CONTEXT OF PRODUCT DEVELOPMENT

- Critical factors to be considered and assessed upfront
- Early vs. late phase, in continuous product development
- Building the team and the technical confidence

MASSIMO BRESCIANI, Executive Director Scientific Operations & Board Member
Research Centre for Pharmaceutical Engineering (RCPE)

CASE STUDY PRESENTATION:

XELLIA CENTRAL LABORATORY SERVICES CASE STUDY

- Xellia history, present and future in a nutshell
- Central Laboratory Services concept and what is behind
- How to select, attract and integrate new colleagues considering the current challenging labor market

ÉVA FARKAS, Quality Director, Head of Centralized Laboratory Services, **Xellia**

CASE STUDY PRESENTATION:

HOW TO MANAGE PROCESS DEVIATIONS AND SHOWCASE YOUR DATA A LABORATORY CASE STUDY

- Increase employees awareness around the concept „total cost of deviations“, as human errors are very often the main culprit
- Reduce process deviations from a daily to a monthly event, so that you can invest your time working on effective preventive actions rather than fire-fighting
- Present your data in the right way after all the hard work done: how to use the concepts of "Defect-free" & 6-Sigma analysis

EUGENIO FILIPPI, Associate Director Plasma Logistics & Analytics Europe, **Shire**

PANEL DISCUSSION:

HOW TO HANDLE IMPURITIES IN GENERAL?

- The improving analytical methods are able to show even the trace of impurities
- Where is the limit of the increasing purity requirements?
- How to satisfy regulatory requirements?
- New guidelines for Elemental Impurities - Implementation best practice examples

DR. DEVENDRA RIDHURKAR, Senior Scientist (special formulations), **Egis Pharmaceuticals**

DR. KATALIN GANZLER, Head of the Analytical Division, Formulation R&D delivery, **Gedeon Richter**

LENKA FRANCIŠKOVIĆ, Head of Processes and Products Quality, **Belupo Pharmaceuticals**



PROJECT PRESENTATIONS OF THE WINNERS OF 4TH CEE PHARMACEUTICAL MANUFACTURING EXCELLENCE AWARD

The awarded projects will be announced and crowned with an international recognition during the first day of the event and the winners will have the unique chance to put their most outstanding products, services or best practices in the spotlight, by presenting their projects to the audience of PHARM Connect.

CLOSING KEYNOTE PRESENTATION:

THREE DIMENSIONAL PRINTING (3DP) TECHNOLOGY IN PHARMACEUTICAL MANUFACTURING

- Technology description
- 3DP techniques & examples
- Spritam – first 3D printed drug product
- Advantages and challenges

MAREK CICHOCKI, Head of Operational R&D, **Polpharma**

CHAIRPERSON'S CLOSING REMARKS:

ASSOC. PROF. DR. ILDIKÓ CSÓKA, Director of the Institute of Pharmaceutical Technology and Regulatory Affairs, Faculty of Pharmacy, **University of Szeged**

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BENEFITS OF ATTENDING



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 key 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

- Separation technology
- 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

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

PARTNERS



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 CORINTHIA 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 HOTEL 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 Hotel 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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BENEFITS OF ATTENDING



- 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
- An opportunity to relax and enjoy the superb informal NETWORKING opportunity at the cocktail reception and a luxury seated buffet lunch
- PLANT EXCURSIONS 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
CEO, Bioinova, Czech Republic
R&D Leader, Alkaloid, Macedonia
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
Vice President, Polfa Lublin, 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 Hungary
Deputy Director of Global Industrialisation & Process Improvement, Ceva-Phylaxia Hungary
CEO, Crystal Derma, Serbia
Medical Director, Biomin, Slovakia
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
Head of Production, Purolite, Romania
CEO, Trepfarm, Kosovo
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
Executive Director of R&D & Production, ZADA Pharmaceuticals, Bosnia and Herzegovina
Business Development Director, Goodwill Pharma Hungary
Corporate Affairs Director, Farmak, Ukraine
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
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 Czech Republic
Executive Director of Pharmaceutical & Technical Operations, Jadran Galenskij Laboratorij Croatia
MMW Area Director Poznan, Glaxosmithkline, 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
Regional Director EU, Woerwag Pharma, Germany
Head of Quality Assurance EU Logistics, Pliva/ TEVA Europe Croatia
Quality Systems Manager, Lek / Novartis, Poland
Head of Operational R&D, Polpharma Group, Poland
Vice President, Polpharma Group, Poland
Head of Biotechnology Science, Poznan Science & Technology Park Poland
Quality Assurance Manager, Roche Czech Republic
CEO, Laropharm, 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
Technical Director, Cantacuzino Institute, Romania
Director of Generics Production Europe, Zentiva Czech Republic
Innovation Director, Zentiva Czech Republic
Production Director, Zentiva Romania
Equipment Qualification Manager, Pliva / Teva, Croatia
AVP Corporate Anti-counterfeiting, Sanofi Group, France
Global Innovation Strategy & External Partnership Manager, Sanofi, United Kingdom