

International Symposium on Pharma Industry: Changing Scenarios

Final Programme



Semmelweis Salon, Semmelweis University Budapest, Hungary September 4, 2023





International Symposium on Pharma Industry: Changing Scenarios

Final Programme



Semmelweis Salon, Semmelweis University Budapest, Hungary September 4, 2023



Final Programme 4 September 2023, Budapest, Hungary

Editors-in-chief: Imre Klebovich, Vinod P. Shah

Technical editors: Balázs Baksa, Róbert Hohol

All rights are reserved for the Symposium Organisers, except the right of the authors to (re)publish their materials wherever they decide.

This book is a working material for the

International Symposium on

Pharma Industry: Changing Scenarios

The professional and grammatical level of the materials is the authors' responsibility.

ISBN 978-615-01-8650-4

Printed in Hungary – 2023 Dorpress Ltd., Budapest, Hungary

Content

Preface	7
Organisers of the PICS 2023 Symposium	8
Co-Chairs	8
International Scientific Advisory Board, Local Organising Committee, Conference Secretariat	9
Participants from All over the World (country flags, map)	12
Scientific Programme	13
Opening - Welcome Ceremony	14
Session I	15
Session II	16
Panel Discussion	17
Closing Ceremony	17
General Information	19
Date and Venue	19
Sponsors	25
Acknowledgement	27
Biographies of Invited Speakers, Members of International Scientific Advisory Board and Organising Committee,	
Moderators, Chairs and Panelists	29
List of Participants	49
Advertisements	59

Semmelweis University

1769-2023



Ignác Semmelweis, the "Saviour of Mothers" (1818-1865)

The old building of the Medical University in Budapest in the 19th century



Distinguished Participants, Ladies and Gentlemen,

The International Symposium on Pharma Industry: Changing Scenarios (PICS 2023 Symposium) will be held at Semmelweis University on September 4, 2023. The symposium will focus on the changing scenarios in Pharma Industry: increase in science-based regulations helping in lowering the regulatory burden; growth of the Brand and Generic Industry and its impact on pharma world globally; and current trends in the pharma industry.

With advancing science, the newer formulations are more complex, making it difficult for generic development. A significant amount of research is being conducted to aid in developing methodologies and *in vitro* bioequivalence development for the generic industry.

The establishment of a unique organisation dealing with dissolution science and educational activities will be presented. Current trends in pharma industry research including newer drug delivery systems to increase patient awareness, compliance, and adherence will be presented along with the new drug approval process.

This is a unique type of symposium dealing with changes taking place in the big and small pharma industry. Panel Discussion will provide plenty of opportunities for participants to interact with the experts in the area.

This International Symposium is organised by the Semmelweis University, Department of Pharmaceutics in the famous Semmelweis Salon of Semmelweis University.

Semmelweis University is a leading institution of higher education in Hungary and the Central European region within the area of medicine and health sciences. Its main commitment is based on the integrity of education, research, and healing, which make Semmelweis University an internationally renowned center of knowledge.

The Co-Chairs and the Organising Committee cordially welcome you to PICS 2023 Symposium in Budapest at Semmelweis University. We are pleased to see that the event is full of registered participants, which show a keen interest in the topic.

We would like to express our sincere gratitude to all the lecturers who have accepted our invitation to debate the newest results of this important discipline. Finally, our thanks go to all the sponsors and Diamond Congress who have contributed in many ways to the success of the Symposium. We wish all participants an enriching stay in our beautiful milieu and the exciting science that will be presented.

Yours sincerely,

Co-Chairs of the Symposium



Prof. Imre Klebovich

) une Chulus

Prof. Vinod P. Shah



V. P. Shar

Organised by the





Semmelweis University,
Department of Pharmaceutics,
Budapest, Hungary

Co-Chairs

Prof. Imre Klebovich, Budapest, Hungary klebovich.imre@semmelweis.hu

Prof. Vinod. P. Shah, North Potomac, MD, USA dr.vpshah@comcast.net

International Scientific Advisory Board

István Antal, Budapest, Hungary
Péter Ferdinandy, Budapest, Hungary
Balázs Hankó, Budapest, Hungary
Imre Klebovich, Budapest, Hungary
Balázs Lendvai, Budapest, Hungary
Gábor Orbán, Budapest, Hungary
Lakshmanan Ramaswamy, Mumbai, India
Vinod P. Shah, North Potomac, MD, USA
Ajit Singh, Mumbai, India
Tamás Szolyák, Budapest, Hungary
Romána Zelkó, Budapest, Hungary

Organising Committee

Imre Klebovich (Chair), Budapest István Antal, Budapest Krisztina Ludányi, Budapest Tamás Tábi, Budapest Romána Zelkó, Budapest

Symposium Secretariat

Diamond Congress Ltd. Mr. Attila Varga H-1255 Budapest, P.O. Box 48, Hungary



E-mail: diamond@diamond-congress.hu Phone: +36 1 225 0210

www.pics2023.hu

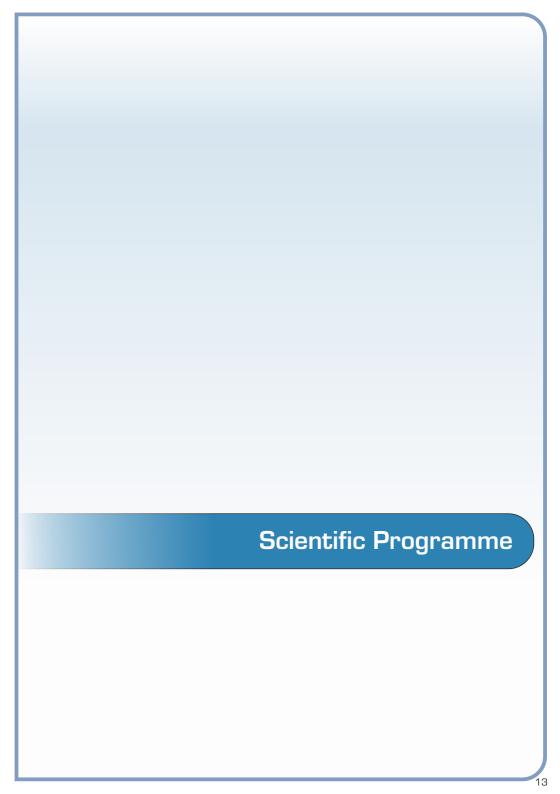
Budapest, Semmelweis University, September 4, 2023, Hungary





Semmelweis University from a bird's eye view





10:00 Opening - Welcome Ceremony

Welcome addresses by:

Prof. Dr. Béla Merkely

Rector of Semmelweis University, Budapest, Hungary The Main Patron of the PICS 2023 Symposium Video Message

Prof. Dr. Balázs Hankó

State Secretary for Innovation and Higher Education Ministry of Culture and Innovation, Budapest, Hungary Former Vice-Rector for Strategy and Development of Semmelweis University, Budapest, Hungary

Prof. Dr. Péter Ferdinandy

Vice-Rector of Science and Innovations, Semmelweis University, Budapest, Hungary

Director of Department of Pharmacology and Pharmacotherapy, Semmelweis University, Budapest, Hungary

President of the Hungarian Society for Experimental and Clinical Pharmacology (HUPHAR), Budapest, Hungary

Prof. Dr. Imre Klebovich

Co-Chair of the PICS 2023 Symposium Chair of the Organising Committee Department of Pharmaceutics, Semmelweis University, Budapest, Hungary

Prof. Dr. Vinod P. Shah

Co-Chair of the PICS 2023 Symposium Formerly with US FDA, Pharmaceutical Consultant, North Potomac, MD, USA

Session I

Regulatory Science and Drug Development

Chairs:

Imre Klebovich, Budapest, Hungary Lakshmanan Ramaswamy, Mumbai, India

10:30 PL-1

Regulatory Science – Science-Based Regulations Helping Pharma Industry

Vinod P. Shah

Formerly with US FDA,

Pharmaceutical Consultant, North Potomac, MD, USA

10:55 PL-2

The Huge Growth of the Generic Pharma Industry in India and

how it Impacts the World

Ajit Singh

Chairman of ACG Worldwide,

Formerly Associated Capsules Group, Mumbai, India

11:20 PL-3

Drug Delivery Systems for the Improvement of

Patient-Centricity, Compliance, and Adherence

István Antal

Dean of Faculty of Pharmaceutical Sciences, Semmelweis University,

Director of Department of Pharmaceutics, Semmelweis University,

Budapest, Hungary

11:45 Coffee Break

Session II

Pharma Industry: Moving Forward

Chairs:

Vinod P. Shah, North Potomac, MD, USA Ajit Singh, Mumbai, India

12:15

PL-4

Dissolution – an Important Scientific Discipline and Establishment of Society for Pharmaceutical Dissolution Science (SPDS) and Dissolution Research Presentations International (DRPI)

Lakshmanan Ramaswamy

General Secretary, Society of Pharmaceutical Dissolution Science (SPDS), Mumbai, India

Managing Director, SOTAX India Pvt. Ltd., Mumbai, India

12.40

PL-5

Current Trends in Original Drug Research

Balázs Lendvai

Head of Division, Pharmacological and Drug Safety Research,

Gedeon Richter Plc., Budapest, Hungary

Director of Department of Richter, Semmelweis University, Budapest, Hungary

13:05

PI -6

Challenges and Opportunities of Regulatory Science

Tamás Szolyák

Director Global Regulatory Science, Gedeon Richter Plc., Budapest, Hungary

Formerly Deputy Director General, National Institute of Pharmacy and Nutrition, Budapest, Hungary

Panel Discussion

13:30

A Forward-Looking Practical Value of Regulatory Science: Brand and Generic Industry

Moderators:

Prof. Romána Zelkó

Director of University Pharmacy Department of Pharmacy Administration, Semmelweis University, Budapest, Hungary

Prof. István Antal

Director of Department of Pharmaceutics, Semmelweis University, Budapest, Hungary

Panelists:

Balázs Lendvai, Budapest, Hungary Lakshmanan Ramaswamy, Mumbai, India Vinod P. Shah, North Potomac, MD, USA Ajit Singh, Mumbai, India Tamás Szolyák, Budapest, Hungary

13:55

Closing Ceremony

Gábor Orbán

CEO, Gedeon Richter Plc., Budapest, Hungary

Chairman of the Board of Trustees of the Foundation for National Health Care and Medical Education, Semmelweis University, Budapest, Hungary Video Message

Vinod P. Shah

Co-Chair of the PICS 2023 Symposium

North Potomac, MD, USA

Imre Klebovich

Co-Chair of the PICS 2023 Symposium

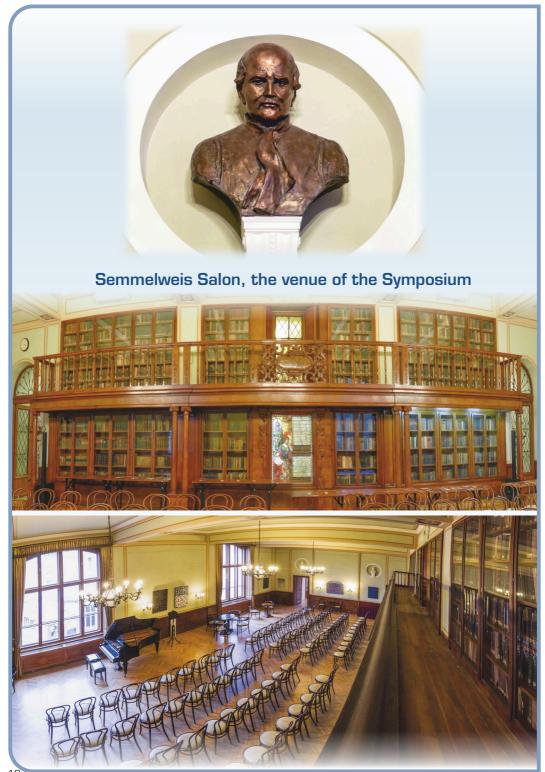
Chair of the Organising Committee

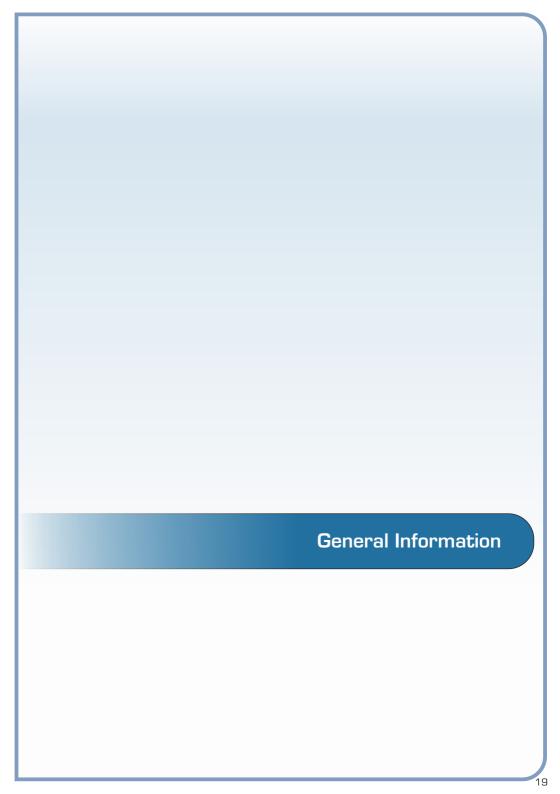
Semmelweis University, Budapest, Hungary

14:15

End of Symposium

Lunch in the Central Building Aula of the Semmelweis University





Date and Venue

The Symposium is held at the Semmelweis University, Semmelweis Salon.

Address: Üllői Str. 26., 1st Floor, H-1085 Budapest, Hungary

The Conference venue can be accessed by metro line M3. or M4. and tram number 4. 6.

Website of the Symposium

www.pics2023.hu

Language of the Symposium

The official language of the Symposium is English.

No simultaneous translation will be provided.

Symposium Assistance

Symposium assistants will be recognisable by their badge.

They will help you in all practical aspects of symposium participation at the registration desk.

Registration and Information Desk

The registration desk is located near the Semmelweis Salon on the 1st floor.

Opening hours:

8:00 - 14:00 Monday, 4 September 2023

Badges

All participants and accompanying persons will receive a personal badge upon registration.

You are kindly requested to wear your name badge when attending the meeting. Only participants who are wearing their name badge will be admitted to the lecture hall and the lunch.

Internet Access

As a courtesy to all delegates, free WiFi is available within the building for your own devices. The name of the network is **KONFERENCIA** Password: **Semmelweis**.

Car Parking

Parking places are available in the parking lot, located in front of the Central Building of the Semmelweis University.

Mobile Phones

Delegates are cordially requested to keep their mobile phones switched off in the meeting room during all sessions.

Smoking

Smoking is strictly prohibited within the building. It is only possible at more than 5-meters from the main entrance of the Central Building.

Liability and Insurance

The organisers cannot accept liability for personal accidents, loss of belongings or damage to private property of participants and accompanying persons that may occur during the Symposium. Participants are advised to make their own arrangements to obtain health, travel and property insurance.

Public Transport in Budapest

Public transport in Budapest is provided by Budapest Transport Ltd. (known to all Hungarians simply as BKV). Budapest has an efficient public transport network. In general, the buses, trams and trolleybuses operate between 4:30 and 23:00. All night bus service operates on the major thoroughfares in the city (night bus timetables are posted at stops and in most metro stations). The three metro lines intersect at Deák Square in the centre of the town, close to the venue. Metros run at 2-to 15-minute intervals from about 4:30 to 23:15.

Telephone

The international code for Hungary is 36, the area code for Budapest is 1. To call a number within Hungary, first dial 06. Budapest telephone numbers have seven digits, all other areas have six digits (in addition to the area codes). To make an international call from Hungary, first dial 00, then the country code followed by the area code and the subscriber's telephone number.

Important Phone Numbers

(English is usually spoken at the emergency numbers listed below.)

Central help number: 112

24/7 medical assistance in English: +36 1 200 0100

Hungarian Automobile Club help number: 188 Budapest Airport Call Center: +36 1 296-7000

Time

Hungary is in the Central European Time Zone. In the summer months clocks are set at GMT + 1 hours.

Weather

The weather in Hungary in September is warm. Temperatures are ranging between around 20-25°C during the day.

Advice for your Departure

Airport Shuttle Service

The company miniBUD is the official airport shuttle service provider for Budapest Airport. They provide comfortable, fast and favorable transfer solutions for passengers wishing to travel from the airport to the districts of Budapest, and from the city to the airport.

You can buy the ticket at the arrival hall immediately or order it online.

miniBUD CONTACT INFORMATION

E-mail: info@minibud.hu, Web: www.minibud.hu miniBUD call center: +36 1 550 0000

Public transport

Bus number 200E connects Terminal 2 and "Kőbánya-Kispest" metro station (metro line M3). From the "Kőbánya-Kispest" metro terminal, you can get to the city center by the M3 metro, boarding in the direction to "Újpest központ".

Phone numbers of some taxi companies:

Főtaxi: +36 1 222-2222 (main airport taxi),

City Taxi: +361211-1111, Tele5 Taxi: +36 1 555-5555, Budapest Taxi: +36 1 777-7777, Taxi 2000: +36 1 200-0000. 6x6 Taxi: +36 1 666-6666

Catering Services in the Venue

Coffee break will be located near the Semmelweis Salon (1st Floor) and at the registration.

Lunch will be located at the Central Building Aula of the Semmelweis University (Ground Floor).

Dedicated time for the catering:

Monday, 4 September 2023

11:45 – 12:15 Coffee break

14:15 - 15:30 Lunch

Presenters' Guidelines

Presentation preparation

Official language: English

Recommended format: Microsoft Office PowerPoint (.ppt, .pptx) and Adobe Acrobat (.pdf)

Use standard fonts such as Times New Roman, Arial, Calibri, Montserrat or Verdana which will be installed on the session room computers. If you use any unique fonts, your presentation may not operate correctly on the session room computer.

Even if you are giving a presentation by means of PowerPoint, please make Adobe Acrobat file (.pdf) of the same contents and bring it for backing up defects of the display.

Please optimize your ppt slide to conform the 16:9 aspect ratio.

Presentation material submission

Please bring your presentation files on a USB drive to the file upload room at least 20 minutes before your session to avoid congestion.

Allocated presentation time

Please check your presentation schedule on the website.

It is important that you arrive at your session room at least 10 minutes before the start of session to make sure that everything is prepared for your presentation.

Please refer to the time standard below.

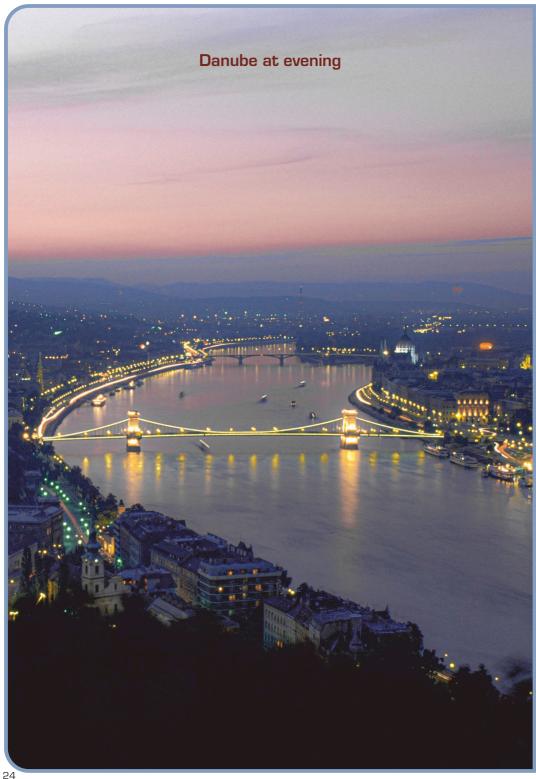
Plenary presentation: 25 minutes per each

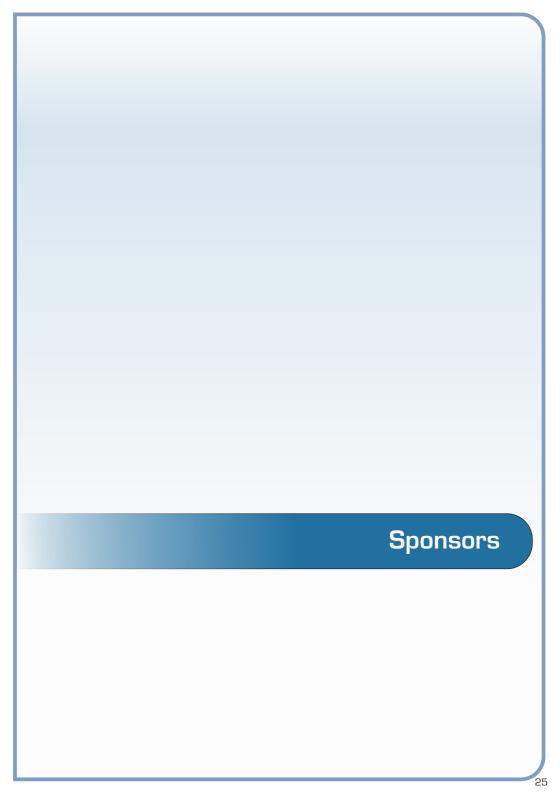
Panel discussion: 25 minutes in total

Presentation equipment

Presenters will be able to control their presentation slides by using wireless remote pointer at the podium.

There will be our staff stationed in each session room to assist with any technical issues.





Diamond Sponsor



Platinum Sponsors





Gold Sponsors







Supporters







membech

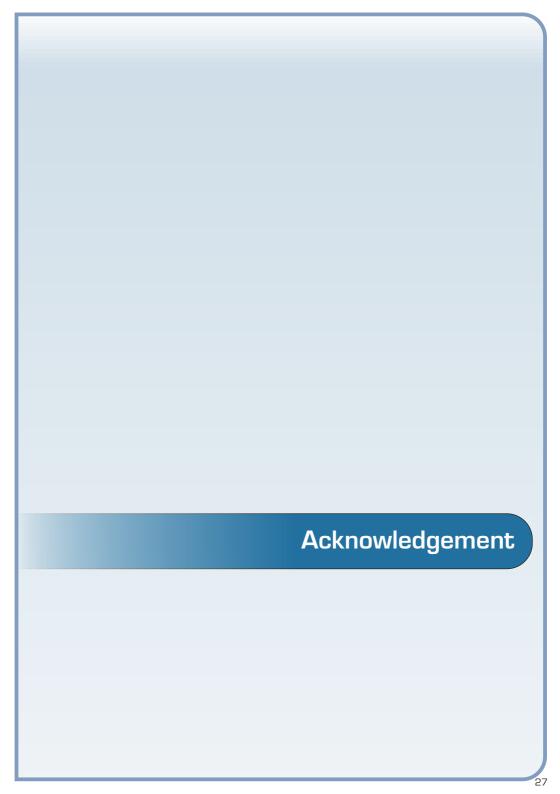












Acknowledgement

Prof. Imre Klebovich, the Chair of the Local Organising Committee of the International Symposium on Pharma Industry: Changing Scenarios (PICS 2023) and its Members wish to express their special thanks to the Co-Chair Prof. Vinod P. Shah and the Members of the International Advisory Board, to our Session Chairs, Moderators, Speakers, Panelists and to the following individuals for their generous and professional assistance with organising this special Symposium.

The Co-Chairs and the Organising Committee would like to express their special thanks to Prof. Béla Merkely, Rector of Semmelweis University and Main Patron of the PICS 2023 Symposium, for organising this special and highly interested Symposium on Pharmaceutical Research at the Semmelweis Salon.

Special thanks go to **Prof. Romána Zelkó** for her outstanding scientific and technical personal assistance.

Without the self-sacrificing work of the distinguished colleagues and friends listed below, **PICS 2023** would not have been made possible at such a high level.

Our gratitude goes to

Mr. Balázs Baksa, graphic artist, designer

Mr. Róbert Hohol, website editor, copy editor

Ms. Dóra Szepesi, directorate general of marketing and communication of Semmelweis University

Ms. Anna N. Nádai, event organiser at Semmelweis University

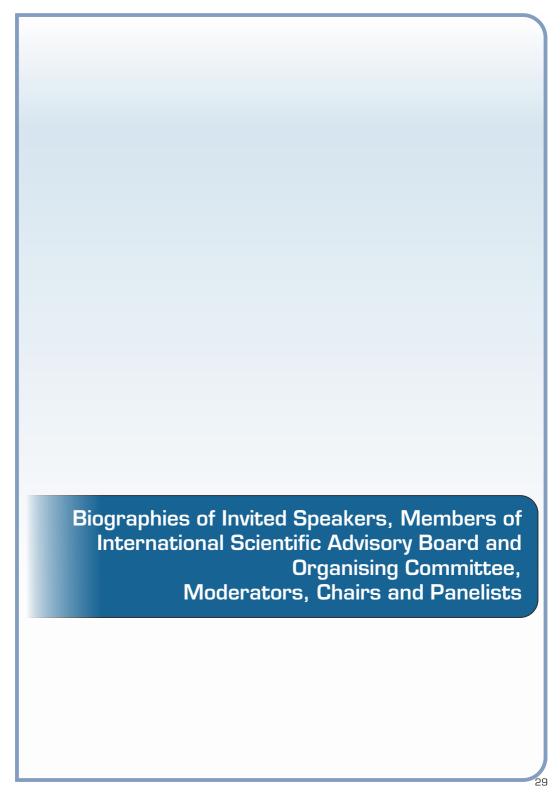
Mr. Attila Kovács, photographer of Semmelweis University

Mr. Attila Varga, CEO, Ms. Gabriella Bánfalvi, Mrs. Ildikó Gémes-Kruppa, Mrs. Nóra Éles-Etele and Mr. Gergely Szakáts, of Diamond Congress Ltd. who contributed with their unparalleled professional work to the success of this human-centered conference...

...and all those who helped in any other way in organising the Symposium.

In addition to the above, we would like to express our sincere gratitude to our **Sponsors** listed in this Programme Book for their continuous valuable support which secured the financial background of this prestigious Symposium.





Professor István Antal

Department of Pharmaceutics, Semmelweis University, Budapest, Hungary Dean of the Faculty of Pharmaceutical Sciences, Semmelweis University, Budapest, Hungary

Professor István Antal studied pharmaceutics at the Semmelweis University, where he obtained Ph.D. in 1995, Dr. Habil. degree in 2003. He is working as professor and director at the Department of Pharmaceutics of the Semmelweis University. In addition, he is the Dean of the Faculty since 2020.



His teaching experiences in Hungarian, in English and in German cover courses in a broad spectrum of Pharmaceutical Technology, including Industrial Pharmaceutical Technology, Biopharmacy-pharmacokinetics, Drug Innovation and Approval, and NIR spectroscopy. In addition, István Antal is the program leader of the "Modern trends in pharmaceutical sciences" Ph.D. program of the Semmelweis University, 12 Ph.D. theses, were written under his supervision. Besides, he has been responsible for several postgraduate residential training programs and scientific workshops for years.

István Antal's main research interest is related to pharmaceutical formulation technology related to biopharmacy, such as development drug delivery systems, characterization of pharmaceutical excipients, multiparticulate systems, *in vitro-in vivo* relationships of drug release, pharmacokinetics, drug formulation, physical pharmacy, drug stability, experimental design, mathematical-statistical modelling, scale-up and near-infrared reflectance spectroscopy.

During his research work he has built close cooperation with the pharmaceutical industry. He is coinventor in 6 patents, one developed extended-release preparation has got approval by the FDA, too. Two developed veterinary medicinal products are marketed in 17 EU countries. His study trip locations include the R&D Center of Sterling Health (Princeton, NJ, USA, 1992), and he was also invited several times as a guest lecturer (e.g., by Glatt Technology Training Center, Germany and BeneoPalatinit GmbH, Germany).

As president of the Pharmaceutical Technological Section, he focused on strengthening the collaborations and scientific network, as well as supporting young colleagues.

István Antal has published more than 150 written papers, more than 300 conference lectures, and posters. The number of his independently cited scientific references is more than 2000.

He is awarded with the 1st Prize of Sándor Mozsonyi Foundation for Education (1993), the Merit of Rector praise (Semmelweis University, 1994), as well as with the Bolyai Research Scholarship of Hungarian Academy of Sciences (1998-2001). He is the Excellent Worker of the Semmelweis University (2003), the Excellent tutor of Student Research (2005) and the Excellent Lecturer of the Semmelweis University (2010). He is the owner of the Hintz György Award (2017, Pharm. Tech. Section of the Hung. Soc. Pharm. Sciences), being as well an Excellent Ph.D. teacher (Semmelweis University, 2018).

István Antal participated in the organization of several meetings (e.g., Conference on Pharmaceutical Technology branded as "Siófok", CPH, BBBB), and the 6th Central European Symposium on Pharmaceutical Technology and Biotechnology in Siófok, Hungary, 2005, when he was also a guest editor for the European Journal of Pharmaceutical Sciences Supplement.

antal.istvan@semmelweis.hu

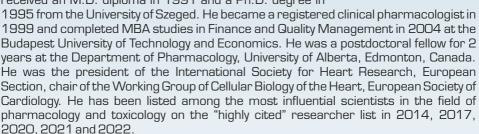
Professor Péter Ferdinandy

Vice-Rector of Science and Innovations, Semmelweis University, Budapest, Hungary

Director of Department of Pharmacology and Pharmacotherapy, Semmelweis University, Budapest, Hungary

President of the Hungarian Society for Experimental and Clinical Pharmacology (HUPHAR), Budapest, Hungary





ferdinandy.peter@semmelweis.hu



Professor Balázs Hankó

State Secretary for Innovation and Higher Education, Ministry of Culture and Innovation, Budapest, Hungary

Former Vice-Rector for Strategy and Development of Semmelweis University, Budapest, Hungary

Professor Balázs Hankó graduated at the Faculty of Pharmacy of Semmelweis University (Pharm.D.), where he obtained his Ph.D. degree summa cum laude in 2005. Over the years, he has obtained specialist qualifications in pharmaceutical organization, administration, pharmaceutical supply, hospital-clinical pharmacy and pharmaceutical care.

He started as a pharmacist in residence at the University Pharmacy Department of Pharmacy Administration at Semmelweis University, later becoming Chief Pharmacist, and then Deputy Rector for Strategy and Development. In addition to management and organisational development, he has two decades of teaching experience and is currently a habilitated (Pharm. Habil.) professor.

From 2010 to 2014, he was a pharmaceutical advisor to the Ministry of National Resources, then to the State Secretariat for Health of the Ministry of Human Resources. From 2011 to 2016, he was the advisor to the Director General of Pharmacy at the Institute for Pharmacy, Health Quality and Organisational Development, later the State Health Care Centre. Between 2017 and 2020, Ministerial Commissioner for the Development of Higher Education Institutions for Medical and Health Sciences at the Ministry of Human Resources, then at the State Secretariat for Higher Education of the Ministry for Innovation and Technology.

From 2020 to 2022, he was Deputy State Secretary for Higher Education at the Ministry for Innovation and Technology, then at the Ministry for Culture and Innovation. From December 2022, he is the State Secretary for Higher Education, Innovation, Vocational and Adult Education.

Married, father of four children.

balazs.hanko@kim.gov.hu

Professor Imre Klebovich

Department of Pharmaceutics, Semmelweis University, Budapest, Hungary

Former Dean of the Faculty of Pharmaceutical Sciences, Semmelweis University, Budapest, Hungary

Professor Imre Klebovich (Pharm.D., Ph.D., D.Sc.) is an emeritus professor of the Department of Pharmaceutics of the Faculty of Pharmaceutical Sciences at Semmelweis University Budapest, Hungary and, further on, Private Professor of the Budapest University of Technology and



Economics, Faculty of Chemical Engineering since 1990. He was a professor of the Pázmány Péter Catholic University, Faculty of Information Technology and Bionic in 2013-2019.

He was a visiting professor at the University of Katowice, Faculty of Chemistry (Poland) in 2016.

He graduated as a pharmacist in 1975 at the Semmelweis University of Medicine and obtained his Pharm.D. in 1977. He postgraduated as a pharmacologist in 1983 at Haynal Imre University of Health Sciences, and he received isotope diploma in 1978 at Budapest University of Technology and Economics. He received the degree of Biomedical Research Management of Harvard University and Copenhagen University in 1990. He obtained his Candidate of Science (C.Sc.-Ph.D.) and Doctor of Science (D.Sc.) degrees at the Hungarian Academy of Sciences in 1989 and 1999, respectively.

He became a research scientist at the Biochemical Institute of the Hungarian Academy of Sciences in 1975, and he continued his research activity in the field of pharmacokinetics and drug metabolism at Gedeon Richter Ltd. in 1977 (senior scientist). In 1989 he founded the Department of Pharmacokinetics and Drug Metabolism of EGIS Pharmaceuticals Ltd., and he was the Head of this Department for 15 years. In 2004 he was applied and accepted the position of being Head of Department of Pharmaceutics (2004 - 2014) of the Faculty of Pharmaceutical Sciences at Semmelweis University. In 2008 he was applied and accepted the position of being Dean of the Faculty of Pharmaceutical Sciences (2008-2009). He is a member of the Board of Drug Discovery and Safety Centre in Semmelweis University (2008-2017). He is a member of the Rectors' Advisory Board of the Semmelweis University (PSK) (2018-), Member of the Public Benefit Supervisory Board of the Semmelweis University (2021-).

His main research interests are bioanalytics-radioanalytics, pharmacokinetics, metabolism, biopharmaceutics, bioequivalence, food-drug interaction, *in-vitro* dissolution studies for the prediction of different types of interactions (IVIVC) and retard drug delivery. He has 26 patents, published more than 270 journal papers, 18 books, 25 book chapters as well as co-editorial works in books, and more than 530 lectures on

Hungarian and International Conferences. He was the chairman and member of the International Advisory Boards of more than 50 national and international conferences.

He has contributed to the research/development and registration of 3 original drugs and 39 generic drugs in Hungary and abroad.

His awards and honours are: Award of Innovative Engineering (1998, 1992, 1994), Honorary Lecturer of the Budapest University of Technology and Economics (2001), Honorary Member of the Slovak Society for Pharmaceutical Sciences (2009), the Schulek Elemér Award (2009), the Bruckner Győző Award (2011), the Issekutz Béla Award (2011), the CEGSS Central European Group for Separation Sciences Medal & Award (2013), Géza Zemplén Medal (2013), Jedlik Ányos Award (2015), SPDS Mumbai-India "Lifetime Achievement Award" in the area of Pharmaceutical Dissolution Science, Biopharmaceutics, Pharmacokinetics, Metabolism, Bioanalytics and IVIVC Research (2019), Officer's Cross – Hungarian Order of Merit (2020), Dr. Orbán István Commemorative Medal (Hungarian Pharmaceutical Manufacturers Association, 2020).

He is the elected representative of doctors (D.Sc.) (2007-2013), furthermore elected secretary (2003-2008), co-chair (2011-2014) and elected chair (2015-2018) of the Committee on Pharmaceutical Sciences and elected president of the Working Committee on Separation Sciences (2012-2018) of the Hungarian Academy of Sciences. He was a member of the Section of Chemical Sciences (2007-2018) and the Section of Medical Sciences (2009-2018) of the Hungarian Academy of Sciences.

He is the editor of Journal of Planar Chromatography (JPC) (2006-2017), Acta Chromatographica (AC) (2008-2018), and the Acta Pharmaceutica Hungarica (APhH) (1994-2005; 2018-), member of the Editorial Board of the Journal of Chromatographic Sciences (JCS) (1998-2017), and reviewer of the Journal of Pharmaceutical and Biomedical Analysis (JPBA), Journal of Controlled Release (JCR), British Journal of Clinical Pharmacology (BJCP) and Biomedical Chromatography.

He is a member of the International Society for the Study of Xenobiotics (ISSX) (1985-2016), European Society for Clinical Pharmacy (ESCP) (1992-2004), International Society for Planar Separations (ISCS) (1998-2017), International Pharmaceutical Federation (FIP) (2007-2017), and a former member of the American Association of Pharmaceutical Scientists (AAPS), European Federation for Pharmaceutical Sciences (EUFEPS), and the Hungarian Chemical Society.

He was the founder (1996) and the member of the board (1996-2022), and the elected president of the Hungarian Society for Separation Sciences (2006-2009), and currently he is a honorary board member. Furthermore, he was the president (2008-2009) of the Central European Group for Separation Sciences (CEGSS), and the Hungarian Society for Experimental and Clinical Pharmacology: president of the Section of Pharmacokinetics and Drug Metabolism (1999-2009), and member of the board of the Society, at present he is an honorary board member, and he was the elected president of the Hungarian Society for Pharmaceutical Sciences (2008-2010).

klebovich.imre@semmelweis.hu

Professor Balázs Lendvai

Head of Division, Pharmacological and Drug Safety Research, Gedeon Richter Plc., Budapest, Hungary

Director of Department of Richter, Semmelweis University, Budapest, Hungary

Professor Balázs Lendvai (M.D., Ph.D., D.Sc.) graduated from general medicine in Semmelweis University Medical School with summa cum laude in 1993. Then, he accomplished the doctoral programme of



Semmelweis University in the area of neurosciences/neuro-pharmacology and received Ph.D. degree in 1998. In 2000 he made a medical board exam for Clinical Pharmacology Specialist in Semmelweis University. He received the Doctor of Science (D.Sc.) degree in neuropharmacology by the Hungarian Academy of Sciences in 2011. In 2023 he was appointed as a head of the Richter Department, a newly organized unit at Semmelweis University.

Currently he has been the Head of Pharmacological and Drug Safety Research at Gedeon Richter Plc. since 2010. As the head of Pharmacological and Drug Safety Research department of Gedeon Richter Plc. he is responsible for preclinical biology studies in original research. The department covers research activites from *in vitro* studies, through in vivo and ADME work, up to safety prediction including toxicology and safety pharamacology. Besides maintaing regular screening of novel molecular structures over several years the Pharmacology department contributed to the identification of several clinical candicate molecules with mode of action in the central nervous system under his supervision. In addition, he established significant translational research at the Pharmacology department to increase the predictive power of preclinical research.

Formerly, between 2004 and 2009 he was the the Executive Head of Department of Pharmacology in the Institute of Experimental Medicine, Hungarian Academy of Sciences (IEM HAS), in Budapest. Between 2002 and 2009 he also led a laboratory (Laboratory of Cellular Pharmacology) at the Department of Pharmacology, IEM HAS. From 1998 he was a postdoctoral fellow in the Svoboda Lab at Cold Spring Harbor Laboratory (Cold Spring Harbor, NY, USA) for 2 years. In 1994 and 1997 he spent 3-3 months as a visiting scientist at Center for Neurochemistry, The Nathan S. Kline Institute for Psychiatric Research (Rockland Psychiatric Center, NY, USA). Between 1993-98 he was a research fellow in the Department of Pharmacology IEM HAS.

He was awarded with Issekutz Béla medal by the Hungarian Society for Experimental and Clinical Pharmacology in 2023. So far he published 73 peer-reviewed papers in international journals and gained 281 cumulative impact factor and more than 3100 citations. His most cited paper was published in Nature (Lendvai et al., Nature, 2000-963 citations).

B.Lendvai@richter.hu

Associate Professor Krisztina Ludányi

Deputy Director of Department of Pharmaceutics, Semmelweis University, Budapest, Hungary

Vice Dean of the Faculty of Pharmaceutical Sciences, Semmelweis University, Budapest, Hungary

Dr. Krisztina Ludányi (Ph.D.) is an associate professor, in the Department of Pharmaceutics at the Faculty of Pharmaceutical Sciences at Semmelweis University, Budapest, Hungary. She also serves as the Vice Dean of the Faculty of Pharmaceutical Sciences.



She graduated as a chemical engineer (M.Sc.) at Veszprém University, Veszprém, in 1993. She obtained her Ph.D. at Eötvös Loránd University, Budapest, in 2000.

She started her career in 1993 at the Chemical Research Center of the Hungarian Academy of Sciences, in the Mass Spectrometry Research Unit. Here, she developed and applied novel mass spectrometry techniques in various biopharmaceutical projects. She was awarded a scholarship at University of Warwick (UK, 1995), a post-doc position at FOM-AMOLF (Amsterdam, Netherlands, 1999), and a Bolyai scholarship (2006). In 2005, she joined the Department of Pharmaceutics at Semmelweis University, where she became the Head of the Bioanalytical Laboratory. Later, she was nominated as an associate professor (2009) and became the Deputy Head of the Department of Pharmaceutics (2018) and Vice Dean of the Faculty (2023).

Dr. Ludányi teaches a variety of subjects at Semmelweis University, including Biotechnology, Biological drugs, Colloids, Physical Chemistry, Drug Technology, Pharmacokinetics and Biopharmacy, and the Use of Bioanalytical Methods in Pharmacokinetics. She is also responsible for various laboratory practices. In post-graduate teaching, she gives lectures on Methods for protein analysis. Additionally, she delivers lectures at Budapest University of Technology. Throughout her career, she has supervised over 20 M.Sc. and 3 Ph.D. students.

Krisztina Ludányi's main research interest lies in the application of various analytical methods in biopharmaceutical and biomedical projects. She is a leading expert in analyzing protein glycosylation – one of the most common and elusive post-translational modifications, which also has potential as an early disease biomarker. Currently, she investigates the degradation of enzyme-containing drugs during formulation or due to environmental effects, which has become of major importance recently. Furthermore, she is also involved in several traditional pharmaceutical analyses, including metabolite research, pharmacokinetics (mainly using HPLC-MS), and the identification of trace levels of impurities. She has over 140 publications with more than 1500 citations.

She is a member of various professional organizations, including the Hungarian Chemical Society and the Mass Spectrometry Society (1994-), a member of the executive board (2007-) and president (2022-) of the Mass Spectrometry Society; Hungarian Society of Separation Sciences (1998-); Hungarian Pharmaceutical Society (2005-); and a member of the Committee of Analytical and Environmental Chemistry of the Hungarian Academy of Sciences (2014-).

She has been granted various prizes and awards; the most prestigious ones are the Rector's Praise (2019), the Hugonnai Vilma Prize of Semmelweis University (2013), and the Bruckner Prize of the Hungarian Academy of Sciences (under the 40 category, 2009).

ludanyi.krisztina@semmelweis.hu

Gábor Orbán

CEO, Gedeon Richter Plc., Budapest, Hungary

Chairman of the Board of Trustees of the Foundation for National Health Care and Medical Education, Semmelweis University, Budapest, Hungary

Gábor Orbán was appointed Chief Executive Officer of Gedeon Richter Plc. as of November 1, 2017. Began his professional career as an economist for the National Bank of Hungary and the European Central Bank.



He later joined Aegon Asset Management where he worked as a fund manager and the head of the fixed income desk. He served as the state secretary in charge of taxation and the financial sector at the Ministry for National Economy for two and a half years, followed by a year spent at Banque Rothschild where he worked as a consultant. He earned his MA degree at the Budapest University of Economics and studied also in the United States. Richter's Director of Corporate Strategy since September 2016, Chief Operating Officer since 2017. Member of the Company's Board of Directors from April 2017.

He is the chairman of the Foundation for National Health Care and Medical Education, maintainer of Semmelweis University from August 2021. Member of the National Science Policy Council and board member of the Stock Exchange Advisory Body. Member of the board of trustees at UNICEF Hungary.

gabor.orban@richter.hu

Doctor Lakshmanan Ramaswamy

General Secretary, Society of Pharmaceutical Dissolution Science (SPDS), Mumbai, India Managing Director, SOTAX India Pvt. Ltd., Mumbai, India

Dr. Lakshmanan Ramaswamy (MMM, MHRDM, Ph.D.), a graduate in chemistry (1973-78) from University of Calicut, (Govt Victoria College, Palakkad), Double post graduated in management Marketing & HR from NMIMS, Mumbai) and a doctorate in pharmaceutical Business Administration. A Professional having nearly 45 years of successful and experience in



various capacities in Indian Pharmaceutical Industry. He is currently the Managing Director of SOTAX India Pvt. Ltd., a company head quartered at Switzerland, pioneer pharmaceutical & Dissolution Testing.

Currently working as the Managing Director of Sotax India Pvt. Ltd., a fully owned subsidiary of SOTAX AG, Switzerland since October 2010. Global leader in pharmaceutical testing services and high-end lab instruments Dr Ramaswamy has also conceived the idea and need to found a Society for Pharmaceutical Dissolution Science and initiated the movement by bringing the Pharma Industry Scientists, Pharmaceutics Faculties from various pharmacy colleges, & Regulators under one roof and registered this Society as Society for Pharmaceutical Dissolution Science (SPDS) under the Board of Charitable Trust at Mumbai which is now emerged as a Global organisation in promoting Pharmaceutical Dissolution Research among Masters and Ph.D. students, Industry professionals & Pharm.D. and thereby enhancing the quality of the drug produced world over since 2012.

Due to the immense & creative honorary work done by Dr Ramaswamy to the Pharma world, The SPDS recognised and honoured him with a special award titled as Creative Legend Award by the hands of none other than the Drugs Controller General of India, Dr Rajeev Raghuvanshi, & AAPS president Dr Patrick Sinko, Former AAPS and FIP Scientific Secretary, Dr Vinod P. Shah, Mr Ajit Singh, Chairman ACG, Current President SPDS-Dr Padma Devarajan, and many other dignitaries on the Diaz, on 25th July 2023.

Prior to SOTAX India, worked with Ambalal Sarabhai Enterprises Ltd., a public limited company listed at NSE and BSE (generally known as Sarabhai Chemicals) as a full time Board of Director and CEO, for 4 years. (2006 to 2010). In 2007 Dr Ramaswamy Represented the BioTechnology Delegation organized by Govt of India to Canada.

In the year 2000, appointed as the country head of Stiefel India Pvt. Ltd. (Which is merged with GSK later).

From 1985 to 2000 worked with Unichem Laboratories in various positions till the General Manager – Marketing & Sales.

Dr. Ramaswamy has been a visiting faculty in reputed management Institutes in Mumbai and given many guest lectures including at IIM (Bang), Madurai Kamaraj University, NMIMS, etc. He has published many articles on Management and Human Resources Development and Brand Building.

Nominated as a member in the International Scientific Advisory Board and session chair of 3rd International Symposium on Scientific and Regulatory Advances in Biological and Non-Biological Complex Drugs (SRACD 2018) at Budapest, Hungary.

Undertaken multiple international travel to many Asian countries, US, UK, Europe including Swiss and USA to spread SPDS and actively participated international Dissolution science conferences like Disso America, Disso Europe.

Lakshmanan.Ramaswamy@sotax.com

Professor Vinod P. Shah

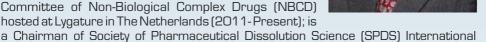
Formerly with US FDA,

Pharmaceutical Consultant.

Member of NBCD Working Group,

Chairman of Society of Pharmaceutical Dissolution Science (SPDS) International, North Potomac, MD, USA

Professor Shah (Ph.D., FAAPS, FFIP) is a Pharmaceutical Consultant. He is a member of Steering Committee of Non-Biological Complex Drugs (NBCD) hosted at Lygature in The Netherlands (2011-Present); is



Dr. Shah retired from US FDA (Food and Drug Administration) as a Senior Research Scientist after 30 years of service in July 2005. At FDA, he has developed several Regulatory Guidances for Pharmaceutical Industry in the area of dissolution, SUPAC, bioanalytical, bioequivalence and biopharmaceutics. He has received several FDA Awards including Award of Merit, Scientific Achievement Award and Distinguished Career Service Award.

(2012 - Present); and expert consultant with NDA Partners (2016 - Present).

Dr. Shah was Scientific Secretary (2003 – 2011) of International Pharmaceutical Federation (FIP), and Chair of Regulatory Sciences Special Interest Group of FIP (2011-2016). He was Biopharmaceutics Consultant at USP (2005-2014). Dr. Shah is author/co-author of over 300 scientific papers and is a co-editor of four books.

Dr. Shah was the President of American Association of Pharmaceutical Scientists (AAPS) in 2003. He is a Fellow of AAPS and FIP. Dr. Shah is a recipient of AAPS Distinguished Service Award; IDMA Eminent Pharmaceutical Analyst Award; FIP Lifetime Achievement Award in Pharmaceutical Sciences; Honorary Doctorate from Semmelweis University, Budapest, Hungary; SPDS Award of Excellence; Honorary Doctorate from University of Medicine and Pharmacy Carol Davila Bucharest, Romania; American Association of Indian Pharmaceutical Scientists (AAIPS) Lifetime achievement award; AAPS Distinguished Pharmaceutical Scientist Award; AAPS Global Leader Award; Marquis Who's Who Albert Nelson Marquis Lifetime Achievement Award; and Pro Universitate Order of Merit Award from Semmelweis University, Budapest, Hungary.

dr.vpshah@comcast.net

Founder & Chairman of ACG Worldwide, Mumbai, India

Former Chairman, Board of Trustees of the Bombay College of Pharmacy, Mumbai, India

Ajit Singh was educated at Millfield School, U.K. and Cambridge University, U.K. and Harvard Business School, USA.

He is the Chairman of ACG Worldwide (formerly the Associated Capsules Group). The Company is one of the

world's leading suppliers of pharma machinery, empty capsules, blister films and other products. His group is headquartered in India with manufacturing facilities on three continents and offices worldwide presently serving 128 countries.

Ajit Singh has received five lifetime achievement awards for service to the pharma industry and also designated as a "Doyen of the Pharmacy Profession" by the Drugs Inspectors Association of India.

He has been an active member of the boards or managing committees of most of the pharmaceutical associations in India, as also Chairman, Board of Trustees of the Bombay College of Pharmacy.

Ajit Singh is a former President of the Indian Pharmaceutical Congress Association (IPCA), the Apex Pharma body. He was also an Advisor to the U.S. Pharmacopoeia (India) when it first set up in India.

He has brought several Global Pharma Scientific Associations to India for the benefit of pharma technologists and academia. His group received an Award from UNIDO for Pharma Research and Training.

Ajit Singh has visited and assisted over 500 pharma factories in over 50 countries. His organization trains over 2000 pharma professionals annually in India and overseas.

ajit.singh@acg-world.com



Doctor Tamás Szolyák

Director Global Regulatory Science, Gedeon Richter Plc., Budapest, Hungary

Formerly Deputy Director General, National Institute of Pharmacy and Nutrition, Budapest, Hungary

"I graduated as pharmacist. As I was interested in economy and was curious how the pharma business works so I joined to Ciba Geigy after my graduation. I spent 21 years with the company, participated in the merger



with Sandoz, and experienced the creation of Novartis and the expansion of our business in pharmaceuticals. I worked mainly in Sales & Marketing, various positions. I was the GM of our local, Hungarian affiliate for 6 years. I have a broad understanding of our industry, was able to follow our development trends. This drive my attention to health care development opportunities, and I left Novartis to work on mainly big, HC development projects. My performance in this public field had been recognized, and our National Competent Authority - National Institute of Pharmacy and Nutrition - offered me an opportunity to work in the regulatory arena. I accepted the challenge and led the fields of regulatory, clinical trials, pharmacovigilance and HTA. It was a great experience with continuous learnings and development. I could understand the way EMA works, drives its decision, the very professional approach they have, their think tanks which deliver strategic directions. Due to some changes towards the Institute's role and strategy I have decided to change direction. I turned back to the industry and joined to Richter Gedeon. I am leading the Global Regulatory Science activities. I am very happy to serve our company with my professional leadership background and regulatory knowledge to achieve the aspirations and expectations had been formulated by our leadership."

szolyakt@richter.hu

Associate Professor Tamás Tábi

Director of Department of Pharmacodynamics, Semmelweis University, Budapest, Hungary

Vice Dean of the Faculty of Pharmaceutical Sciences, Semmelweis University, Budapest, Hungary

Dr. Tamás Tábi (Pharm.D., Ph.D.) has graduated as a pharmacist at the Faculty of Pharmacy, Semmelweis University, Budapest, Hungary. He gained his Ph.D. degree in 2006 and his habilitation degree in 2021 at the Semmelweis University. He has specialized for Pharmacology in 2015.



He works as Associate Professor at the Department of Pharmacodynamics, Semmelweis University and is the Head of the Department since 2020. He is the head-teacher of Pharmacology and Toxicology and also takes part in teaching of other compulsory and elective courses.

His research interest covers the interdisciplinary fields of bioanalytics and pharmacology. He is an expert of capillary electrophoresis technique that is used primarily for analysis of biological samples and pharmacological approaches ranging from metabolism studies to neurochemical analysis of amino acid neurotransmitters or glycolipids of neuronal membranes. He is also interested in the research of neuro- and cytoprotective mechanisms and compounds and pain pharmacology. He actively takes part in the doctoral program as supervisor of Ph.D. and M.D.-Ph.D. students.

He is the Vice Dean of Faculty of Pharmaceutical Sciences responsible for Educational Affaires since 2020 and represents the Faculty in the Council of Students' Scientific Association since 2010.

He is the member of Executive Committee of Hungarian Society for Pharmaceutical Sciences since 2016. Currently he works as Secretary General of the Society. He is also a board member of Hungarian Society of Experimental and Clinical Pharmacology and member of supervisory board of RECOOP HST Association. He works as deputy editor of the scientific journal of Acta Pharmaceutica Hungarica.

He was awarded by several honors including the Excellence in Education, Merit Award and Excellent Scientific Student Tutor of Semmelweis University among others. He is the author of more than 50 scientific papers with more than 1,000 citations.

tahi.tamas@semmelweis.hu

Professor Romána Zelkó

University Pharmacy Department of Pharmacy Administration, Semmelweis University, Budapest, Hungary

Former Dean of the Faculty of Pharmaceutical Sciences, Semmelweis University, Budapest, Hungary

Professor Romána Zelkó (Pharm.D., Ph.D., D.Sc.) is a full professor and the former dean of the Faculty of Pharmaceutical Sciences of Semmelweis University, Budapest. She graduated as a pharmacist from



Semmelweis University of Medicine in 1991. In 1993 she received a doctorate (dr. univ.), and a Ph.D. in 1996. She gained her habilitation degree in 2003 at the Semmelweis University, and in 2008 she received the Doctor of Science (D.Sc.) title from the Hungarian Academy of Sciences. Since graduating, she has been employed at Semmelweis University in various positions. In 2005 she was appointed director of the University Pharmacy Department of Pharmacy Administration. She was appointed full professor in 2009. She was the Dean of the Faculty of Pharmaceutical Sciences at Semmelweis University for two terms (2013-2020), before which she was Deputy Dean for 6 years.

Her research work focuses on polymeric drug delivery systems, the physical aging of polymers, microstructural characterization of dosage forms associated with their functionality-related characteristics, and the quality aspects of pharmacy. She is the author of several scientific (more than 230 journal papers with more than 3000 citations, 6 patents) and expert works. Her expertise covers the planning, development, solid-state characterization, and quality assurance of different dosage forms, including novel nanofiber-based scaffolds for various pharmaceutical and biomedical purposes. Her research interests include the aging of excipients used in the manufacture of pharmaceuticals, and the stability of the pharmaceutical dosage form by monitoring the changes in the secondary chemical structure.

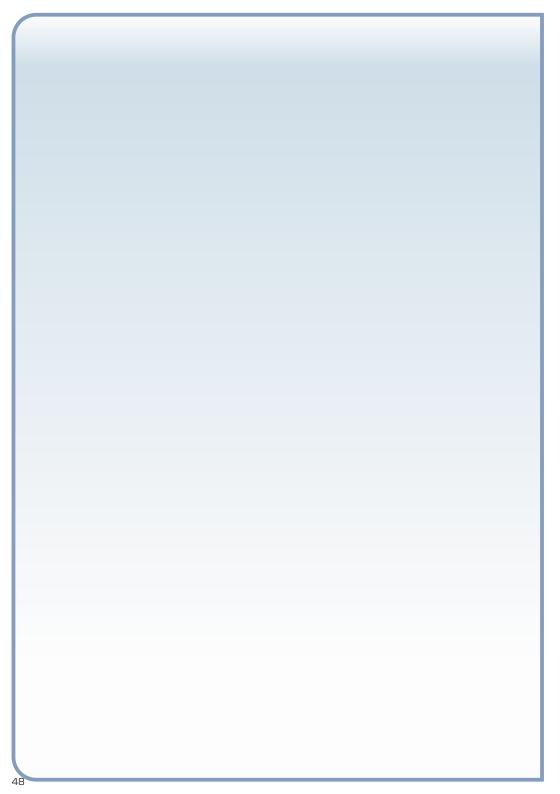
Since 2017, she is a member of the CELSA Research Fund Evaluation Committee (Pharmaceutical Science, Leuven), and since 2007 she has been involved in the European Pharmacopoeia Commission as a member of the Experts and Working Party (Excipient performance).

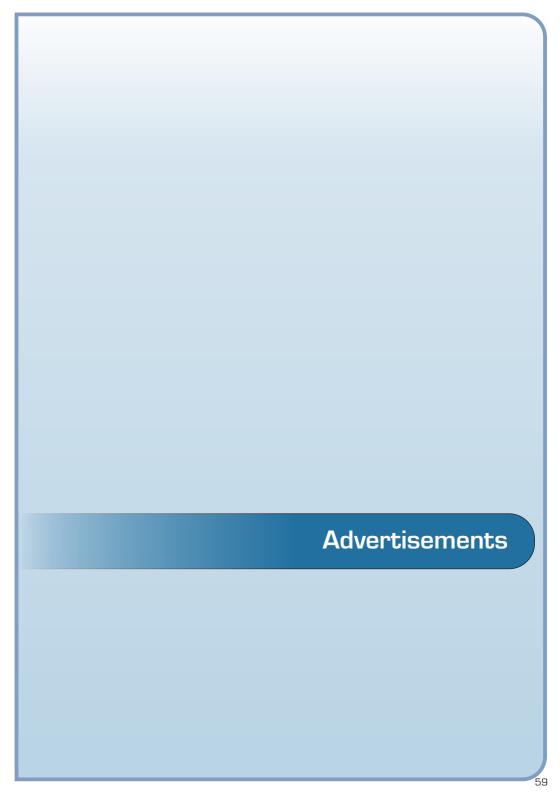
She has supervised 17 Ph.D. students and is currently the supervisor of 3 Ph.D. students.

Since 2005 she has been the Responsible Editor of the journal Acta Pharmaceutica Hungarica, and since 2019 she has been Editor-in-Chief of the journal. She is a member of the editorial board of several international journals (International Journal of Pharmaceutical Investigation, International Journal of Nanomaterials, Nanotechnology and Nanomedicine, Pharmaceutics, and an Associate Editor of the Heliyon Pharmaceutical Science, Pharmacology and Toxicology section.

In 2003 she was awarded the Excellent Academic Student Educator of Semmelweis University, in 2006 the Hungarian Research Award of Sanofi-Aventis, and in 2007 the Outstanding Researcher Award of the Aesculap Foundation. In 2011 she was awarded the Hugonnai Vilma Medal of Semmelweis University, and in 2014 the Kempler Kurt Memorial Medal of the Hungarian Society for Pharmaceutical Sciences. In 2020 she received the Excellent Ph.D. Teacher Award of Semmelweis University. In 2022 she was awarded the Officer's Cross of the Hungarian Order of Merit, and the Richter Gedeon Medal of the Semmelweis University.

zelko.romana@semmelweis.hu





Semmelweis University

H-1085 Budapest, Üllői út 26. Hungary

Over 250 years of tradition, innovation and excellence

Semmelweis University's history started more than 250 years ago, when Hungarian queen Maria Theresa added a faculty of medicine to the University of Nagyszombat in 1769. Semmelweis University is the oldest medical school in Hungary still in operation today. With its 6 faculties and as a university specialising in health sciences, it occupies a prestigious place in Hungarian medical higher education. Its main commitment is based on the integrity of education, research and healthcare, which make Semmelweis University an internationally renowned centre of knowledge.

Worldwide Recognition

Semmelweis University ranks among the top 250 universities in the world according to the Times Higher Education Rankings 2023. It is among the top 250 universities in pharmaceutical education in the QS Ranking 2022. The university and its predecessor institutions have issued more than 100,000 diplomas so far. The degrees are accepted in numerous countries around the world, and the university is listed in the World Health Organisation's World Directory of Medical Schools.

Education in three languages

In the academic year 2022/2023, Semmelweis University has celebrated the 40th anniversary of launching its international medical training. German and English language programmes have been available at the Faculty of Medicine, Dentistry and Pharmaceutical Sciences for over three decades. German language programmes have been run at Semmelweis University since 1983, while the English language programme was foundedin1989. Almost a third of the nearly 14,000 students enrolled at the six faculties of Semmelweis University are international students. They come from 110 countries of five continents. The ratio of international students is the highest at the Faculty of Medicine, where they outnumber Hungarian students. 48% of the student body at the Faculty of Dentistry is also international. In addition, Semmelweis University was among the first in Europe to introduce international campus training. Its programmes include the medical programme in Germany, the physiotherapy master's programme in Switzerland and the health manager master's programme in Slovakia.

Excellence in all six faculties

The Faculty of Medicine, the Faculty of Dentistry and the Faculty of Pharmaceutical Sciences are the largest training institutes in their fields, and the Faculty of Health Sciences is the country's leading higher education institution training healthcare professionals. The Faculty of Health and Public Administration operates with a multidisciplinary approach on the boundary of natural and social sciences. Andra's Peto Faculty is the cradle of conductive education and is the only accredited conductor training institution in the world.

Outstanding scientific results

Semmelweis University is a regional centre of excellence in science and innovation in the field of life sciences. As a biomedical institution, the approach of translational research is dominant, but also basic research serves the prevention and treatment of diseases. The diversity and broad spectrum of the university's RDI activities is illustrated by the more than 300 research groups, a wide range of research areas and the intensive scientific publication activity. Numerous research groups publish regularly in internationally recognised and highly ranked scientific journals.



79999

Top healthcare provider

The university is one of the largest health care institutions in Hungary today, handling 2.7 million cases each year. It has nearly 40 departments distributed among the 4 main clinical centres. The university covers the health care needs of approximately 6,4 percent of the Hungarian population, treating over 200,000 patients each month. The university clinics are practical training sites and patient care is carried out on the highest level as it has several departments catering for patients in critical condition or requiring complex treatment. Cutting edge technology enables the establishment of the most accurate diagnosis, like in the case of organ transplantations, and certain procedures are available only at the university.

http://semmelweis.hu/english/

https://www.facebook.com/semmelweisuniversity

https://www.linkedin.com/school/semmelweisuniversity

https://twitter.com/semmelweishu

https://www.youtube.com/semmelweisuniversity

https://www.instagram.com/semmelweis_egyetem/

EMMELWEIS NAC FÜLÖP

Everyone on Earth deserves access to better health.

Having a presence in 138 countries on six continents, ACG is now the world's largest integrated supplier of inputs for manufacturing oral solid dosage products and services. We provide hard-shell capsules, barrier packaging materials, pharmaceutical manufacturing machinery, and fully integrated track and trace solutions.

ACG Capsules

Medicine is only as good as how well it's delivered.

With 'reliability' at the centre of all we do, ACG has a hard-shell gelatine and HPMC capsule solution for almost every application. Plus, our customisation options are virtually limitless.

ACG Engineering

Medicine is only as good as how well it's manufactured.

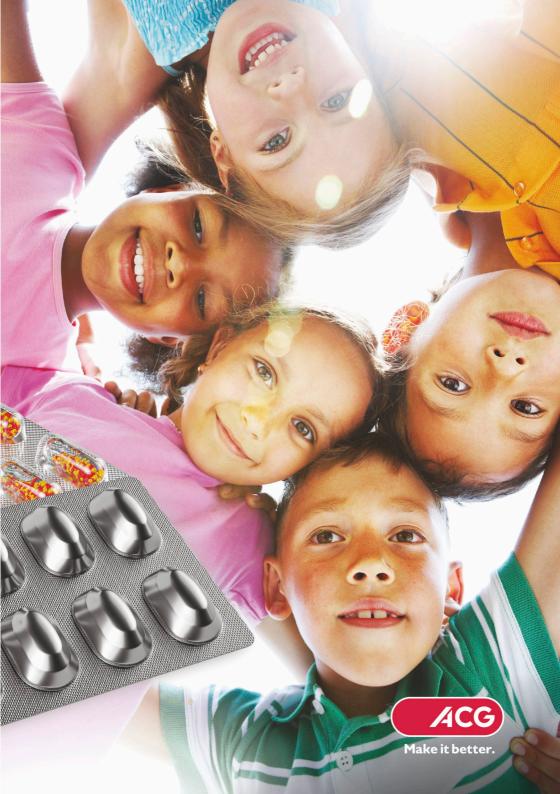
ACG provides a full spectrum of oral dosage manufacturing equipment. Our global design team takes a customerled approach, and we're renowned for exceptional after-sales service.

ACG Packaging Materials

Medicine is only as good as how well it's protected.

We supply the world's largest range of both film and foil barrier materials, with almost everything produced in-house for greater quality control. Expert advice is the key to your perfect solution.





ACG is the world's most integrated provider of oral dosage products and services.















Blister packing





Vision inspection





Cartoning









Impressive performance Unmatched value

Now you can afford your first choice



What is the Velocity LFQ HR-DIA platform?

Thermo Scientific™ Velocity label-free quantitation (LFQ) high-resolution (HR)-DIA platform — our exclusive unmatched DIA solution for quantitative proteomics is now available at a more affordable price. We provide an award-winning standard for quantitative accuracy, precision and data completeness for deep proteome coverage. You choose the mass spectrometer that is right for your research. Both the Thermo Scientific™ Orbitrap Exploris™ 240 and Thermo Scientific™ Orbitrap Exploris™ 480 mass spectrometers are outstanding options for DIA analysis.

High-throughput high-resolution data-independent acquisition workflow for accurate label-free quantitation



Are you ready to learn more about our DIA promotion?

Go to thermofisher.com/DIAValue to get the details.





thermo scientific

For Research Use Only, Not for use in diagnostic procedures, © 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified, FL002089S-EN 0423S



Rethink what is possible Orbitrap Astral mass spectrometer

Realize the promise of proteomics at scale to better understand biology and disease mechanisms with the novel technology of the Thermo Scientific™ Orbitrap™ Astral™ mass spectrometer. Powered by the synergy of the high resolution quadrupole mass filter, Thermo Scientific™ Orbitrap™ mass analyzer and the novel Thermo Scientific™ Astral™ mass analyzer, this revolutionary new instrument achieves unsurpassed performance with industry leading usability. The combination of these three mass analyzers enables the rapid acquisition of exceptional quality high resolution accurate mass (HRAM) data with high sensitivity and dynamic range. Expect whole proteome coverage at a depth of 12,000 proteins in an hour, the sensitivity to accurately and precisely quantify over 3,000 proteins from 80 single cells in a day and the throughput to analyze over a million protein groups across 180 samples in a day.

- Faster throughput identify over 8,000 proteins with and 8-minute injection-to-injection cycle
- Deeper coverage unlock near whole-proteome depth of coverage with the identification of 12,000 proteins in 1 hour from a single-shot experiment
- Higher sensitivity increase throughput and depth of coverage with higher sensitivity by identifying over 5,000 proteins from 130 pg of HeLa at a rate of 80 samples per day
- Accurate and precise quantitation achieve accurate and precise quantitation with a large dynamic range for label-free Quantitation (LFQ) using Data Independent Acquisition (DIA) and achieve faster throughput and deeper coverage with multiple quantitation using Tandem Mass Tags (TMT)

These ground-breaking capabilities empower you to comprehend the dynamic, temporal and spatial complexity of biology.





Do you also expect the best solution?

DISCOVER the BEST DSC, TGA, SDT, DVS, DMA and Rheometer systems EVER designed.

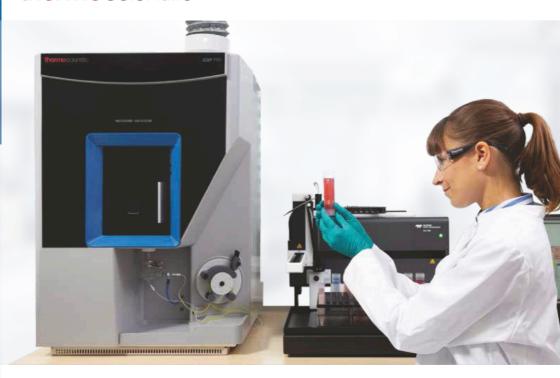
Choose the best service for:

- Research and Discovery
- Drug Formulation and Development
- Manufacturing, Production and Quality Control
- Scale up and Engineering





thermoscientific



iCAP PRO ICP-OES and iCAP PRO X ICP-OES

Deliver robust, uncomplicated trace elemental analysis for your laboratory with the Thermo Scientific iCAP PRO ICP-OES and Thermo Scientific iCAP PRO X ICP-OES systems. These systems offer fast start-up, easy-to-use software and incredible speed, providing multi-element detection technology far superior to that of single-element AAS.

ICAP PRO XP ICP-OES

Analyze high-matrix trace elemental samples with sensitive multi-element detection and meet your data requirements with the optimal performance of the Thermo Scientific iCAP PRO XP ICP-OES. Rugged on all fronts, this system needs surprisingly little bench space or user maintenance.

ICAP PRO XPS ICP-OES

Experience high-speed analysis of your trace elemental samples with the Thermo Scientific iCAP PRO XPS ICP-OES. It meets your specific regulatory requirements with unmatched throughput and versatility.



Find out more at thermofisher.com/icp-oes

Thermo Fisher

For Research Use Only. Not for use in diagnostic procedures. © 2020 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. BR44428-EN 0320C













We research, we innovate, we care. Since 1901

Dissolution Testing

Classic6 and Elite8 dissolution baths



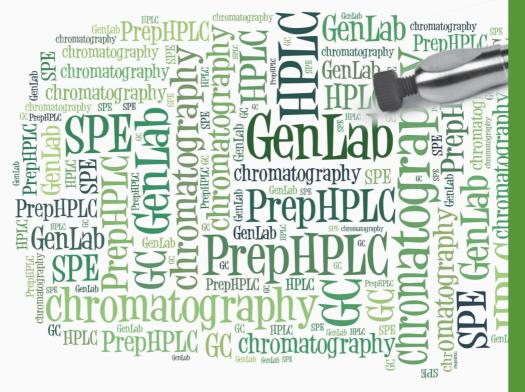
CD14 comparative dissolution tester

Protocol Manager software



Manufacturer: Teledyne Hanson Research www.teledynehanson.com

Albania, Austria, Bosnia and Herzegovina, Bulgaria, Croatia, the Czech Republic, Hungary, Moldova, Montenegro, North Macedonia, Poland, Romania, Serbia, Slovakia, Slovenia www.ablelab.com





Minden, ami kromatográfia

H-1119 Budapest, Hadak útja 41.

Tel.: +36 (1) 206-2455

Fax: +36 (1) 206-2451

Web: www.gen-lab.hu E-mail: info@gen-lab.hu

VisionSafety Cap

Brings you safety and comfort into your laboratory.





WHY CHOOSE ELECTROSPINNING?

From biomedical applications to high-performance textiles and filtration systems, electrospinning offers unparalleled versatility and customizability. This cutting-edge technology allows you to create ultrafine fibers with precise control, unmatched by traditional manufacturing methods. Electrospun nanofibers offer enhanced material properties, increased surface area, and improved mechanical strength, providing you with a competitive edge in your research area. spincube electrospinners are the key solutions for the development and small scale production of nanofiber matrices and scaffolds applying the wide range of natural and unnatural polymers. Nanofibers

NANOFIBERS IN THE HEALTH INDUSTRY

In the modern health industry, nanofibers have emerged as remarkable game-changers. These ultrafine structures, with diameters in the nanometer range, are revolutionizing the medical and pharmaceutical technologies with their diverse applications. From regenerative medicine to drug delivery, nanofibers hold immense potential for transforming patient care. By mimicking the extracellular matrix, nanofiber-based scaffolds promote tissue regeneration and wound healing. Their high surface-area-to-volume ratio and fine-tunable

polymer composition allows for precise interactions at the cellular level, enabling targeted and controlled drug delivery. Additionally, functionalized nanofibers show promise as antimicrobial agents in combating infectious diseases. Although nanofibers may play a crucial role in personalized and effective healthcare solutions, their formulation presents a distinct set of challenges that must be overcome. spincube and spincube Pro* electrospinners are designed to meet your challenges in nanofiber research..













spincube

The spin**cube** and spin**cube** Pro* electrospinners are designed to address the challenges of nanofiber research, offering tailored solutions for your needs.

* Available for pre-order



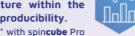
With high voltage capabilities of up to 40 kV and enhanced safety features, it is safe for users of all levels of expertise.



Experience unparalleled convenience with quick and tool-free changes of collectors and emitters, and template projects in spinstudio.



Continuously control* and monitor humidity and temperature within the cabinet for enhanced reproducibility.



Utilize the spinstudio software to design experiments, analyze, compare, and share experimental data effortlessly.



Enjoy flexible and precise precursor feed options from glass or disposable syringes with multiple syringe pumps.



Reduced dead volume allows small sample quantites with the innovative HydroDrive system.



Observe jet formation remotely with industrial grade imaging system.



Control processes remotely from the spinstudio application.



Widen your research opportunities by exploring our range of available accessories, carefully designed to cater to your unique needs and maximize the potential of your spin**cube** electrospinner.

spin**cube** is capable of producing a diverse array of materials, including randomly oriented nanofibers, oriented nanofibers, core-shell nanofibers, and spherical nanoparticles.

ATF Xtend

Fully Automated
Dissolution Testing System



Dissolution. 100% Unattended.

The new ATF Xtend™-Worlds most compact, USP compliant fully automated dissolution testing system. Perform a series of 100 % unattended dissolution runs including media preparation, vessel filling and self-cleaning of the system.



Solutions for Pharmaceutical Testing



SOTAX AG Nordring 1 4147 Aesch Switzerland

Phone: +41 61 487 54 54 Email: sales@sotax.com

www.sotax.com



CE 7smart Flow-Through Dissolution Testing System



Flexible. Precise. Predictive.

The CE 7smart flow-through dissolution tester allows you to see differences in your formulations that paddle and basket methods simply wont show. Widely recommended for poorly soluble, MR / ER, and low dose products, it is also frequently used for IVIVC studies and a growing range of novel dosage forms.





Solutions for Pharmaceutical Testing

SOTAX AG Nordring 1 4147 Aesch Switzerland

Phone: +41 61 487 54 54 Email: sales@sotax.com www.sotax.com





Agilent dissolution systems



708-DS Specifications

Condition	Performance may vary depending on environmental conditions (temperature, humidity, altitude, etc.)				
Evaporation	Less than 1% evaporative loss under specific conditions				
Ambient temperature	5 °C to 40 °C				
Humidity (non-condensing)	Not more than 80% RH				
	Voltage	Current 708-DS (operating)	Current Wide Input Range Heater (operating)		
Requirements	90-250V, 50-60 Hz 115 V, 60 Hz	2.5-1.0A 2.0 A	13.0-4.5A 10.0 A		

	230 V, 50 Hz	1.0 A	5.0 A		
	Speed Range	Speed Accuracy	Speed Selection	Shaft Material	
Spindle	10-250 RPM	±1% over 25 RPM ±2% 10-25 RPM	Via touch screen	Stainless steel	
Bath	Temperature Range		Probe Accuracy		
	Ambient +5 to 55 °C		±0.1 °C		
Sampling	Manifold option available for automated sampling				
Display	LCD with integral touch screen				
Spindle shaft material	Stainless steel				
Drive unit lift	Manual or motor drive				
Dimensions	67.31 cm (w) x 67.95 cm (operating h) / 99.06 cm (clearance h) x 76.2 cm (d)				
	26.5 in. (w) x 26.75 in. (operating h) / 39 in. (clearance h) x 30 in. (d)				
Weight	54.4 kg (120 lb) machine dry with vessels and paddles				
Ontional features	Manual or motorized drive unit lift, Dosage Delivery Module (DDM), Auto Sampling,				

AutoTemp, resident sampling cannulas, handheld temperature probe, printer

Presented by: Novolab

Optional features

2045 Törökbálint Hosszúrét utca 1. www.novolab.hu info@novolab.hu

rra D. Durham, Genevieve C. Van de ner, Sheher Banu Mohsin, and feng Wu

Agilent, Santa Clara, CA, USA





Introduction

Targeted LC/TQ Workflow for Multi-Omics

Comprehensive targeted proteomics, metabolomics, and lipidomics methods have been developed for multi-omic pathway discovery and quantification of biomarkers. Multi-omic studies enable analysis of metabolic pathway perturbations, which can provide insight into:

A) Therapeutic mode(s) of action B) Off-target effects

C) Precision medicine development, efficacy correlation and cohort subgroups toxicity

Pseudo-Discovery With LC/TQ

These methods aim to measure a significant proportion of pathway relevant analytes with an LC/TQ. This takes advantage of the TQ performance in finding biomarkers which a HRAM untargeted platform may miss.

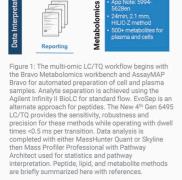
- · Sensitivity at attomole level on column
- Precision 0.5-fold change may be used with increased precision
- Linearity across 5-6 orders of magnitude
- · Throughput with automation
- Annotation completed with TQ database
- Ease of use

Agilent is combining hardware, consumables, methods, and support to transfer polar metabolite, lipid, and peptide methods. Figure 1 describes the hardware and methods used for this workflow.



盟 🚨 🙉

Data Analysis



Experimental

Multi-use Hardware for a Multi-Omic Dataset

Automated preparation of cell and plasma samples can be performed using the Bravo Metabolomics Workbench.\(^12\) Manual extraction protocols are available, although automation improves reproducibility, reducing variation by -50%.\(^2\) Using a reproducible HILLO method and database, over 500 polar metabolites can be profiled with the Infinity II BioLC and the new \(^1\) Gen 6495 LD/TQ.\(^3\) The speed of the 6495 allows for both positive and negative mode analysis in the same injection with reproducible peak areas even for low dwell times (Figure 3). This is impactful when trying to measure hundreds of biomarkers in the same injection. The same LC/TQ can measure over 700 lipids across 44 different classes with a reproducible C18 method- annotated for isomers. For protein digestion, an AssayMap Bravo may be used prior to peptide quant analysis with the same LC/TQ hardware and the MRM Proteomics products.\(^1\) If a project is sample limited (<1 ug protein) and low flow is needed, then an EvoSep one system with an Agilent nanoESI source may be used. This setup has proven robustness and reproducibility for low flow peptide analysis.\(^1\) For all three methods, chromatographic specificity provides the ability to reproducibly monitor hundreds of analytes

Results and Discussion

Reproducible and Transferable Metabolite, Lipid and Peptide Methods.

The lipid method is semi-quantitative and proven to be reproducible over large cohorts of plasma samples (3000+ samples) et its eyer transferable with similar performance across different labs (Figure 3).

Peptide quant methods are enabled using MRM

Peptide quant methods are enabled using MRM proteomics products. These cover 375 mouse plasma peptides and other products for other matrices are available. Data shown here shows amol sensitivity for mouse plasma peptides on this solution (Figure 2).



Figure 2: Sensitivity of 125 peptides in mouse plasma matrix. 74% LLOQ under 50 amol (on column) and 49% LLOQ under 10 amol (on column).

For an MRM method that has absolute quant, 375 mouse plasma peptides require 2250 transitions for 3 transition per peptide and internal standard. This methodology pushed the dwell time to <1 ms per transitions at times but the reproducibility is still very high. RSDs <30% for 95% of the peptides.





Figure 4 (above): An intra-lab study using the NIST 1950 plasma standard was conducted. 4 different states collected data with the same NIST extract. RSDs of the different lipids are reported here. The majority of lipids had <20% RSDs. And the 4 labs reported similar performance proving transferability.

Results and Discussion

New 4^{th} Gen 6495 LC/TQ is Sensitive, Fast, and Precise.

The metabolomics method and database can be used for a range of projects from discovery workflows of all 500 metabolites, to custom profiling of 200-300 analytes from plasma or cell samples, to quantitative analysis of a few key analytes of interest with fmol levels of detection in matrix.³

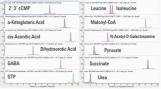


Figure 5: Analyte diversity in the HILIC LC/TQ database for metabolomics. 500+ metabolites in positive and/or negative mode with annotated RTs.

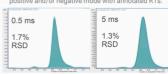


Figure 6: The New $4^{\rm th}$ Gen 6495 LC/TQ can measure transitions as fast as 0.5 ms with excellent precision even in complex matrix. Here, 0.5 ms and 5 ms dwell times are tested with plasma matrix (n=6). At the 0.5 ms dwell time for cis-aconitic acid the RSD is 1.7% (A). When dwell time is increased to 5 ms, the RSD improve slightly to 1.3% (B). This hardware feature is how we can measure more analytes per injection for pathway profiling methodologies.

Conclusions

Discover Impactful Pathway Information with Multi-Omic Studies Using Easily Transferable Methods.

- Agilent 1290 Infinity II BioLC is configured for all three methods on the same system.
- The New 4th Gen 6495 LC/TQ is robust, highly sensitive, very fast and easy to maintain enabling a pathway screening approach for labs looking for biological insights.
- Agilent and our partners at MRM Proteomics can provide transferable methods for 500+ metabolites, 700+ lipids, and 375 mouse plasma peptides.

References

1 Van de Bittner, GC et al. An Automated Dual Metabolite + Lipid Sample Preparation Workflow for Mammalian Cell Samples. Agilent Application Note 5994-5065EN. 2022.

2 Sartain, M et al. Enabling Automated, Low-Volume Plasma Metabolite Extraction with the Agilent Bravo Platform. Agilent Application Note 5994-2156EN. 2020.

3 Yannell, K et al. An End-to-End Targeted Metabolomics Workflow. Agilent Application Note 5994-5628EN. 2023.

4 Wu, L. Peptide Quantification in Plasma the Agilent 6495 Triple Quadrupole LC/MS Coupled with the Agilent 1290 Infinity II LC System. Agilent Application Note 5994-2285EN. 2020.

5 Wu, L. Robust and Reproducible Protein Quantification in Plasma using the Evosep One and the Agilent 6495 Triple Quadrupole LC/MS. Agilent Application Note 5994-1928EN. 2020.

6 Huynh, K et al. A Comprehensive, Curated, High-Throughput Method for the Detailed Analysis of the Using Plasma Lipidome. Agilent Application Note 5994-3747EN. 2021.

DE96861348

Digital dissolution testing

The DT 950 Series

for the requirements of today

and the challenges of the future



powered by digital embedded technology





ERWEKA

100% USP/EP compliant



Intuitive user interface with the new TestAssist for easy dissolution testing



Upgradeable at any time



USP 1, 2, 5 and 6

ERWEKA – Magyarország Kft.

2030 Erd Onto u. 22. Hungary erweka@erweka.hu +3623 523 797



Sample preparation workstation



Manufacturer: accroma labtec Ltd. www.accroma.com

BULGARIA • THE CZECH REPUBLIC • HUNGARY • POLAND ROMANIA • SERBIA • SLOVAKIA www.ablelab.com





Society for Pharmaceutical Dissolution Science (SPDS)



VISION

To be one of the most prominent professional body focusing on Dissolution Science among the Pharmaceutical Industry and Academia



To dissipate the science & advancement taking place in the field of dissolution related to clinical application and methods

SPDS Flagship Events

Disso India - International Conference on Dissolution Science and Applications which promotes the, advancement in the field of Dissolution Science, introduction of new technology, innovation & various aspects of Dissolution Testing and its applications

Dissolution Research Presentations International (DRPI) - a unique platform for researchers from academia and industry to showcase their research in field of dissolution science, technology and applications

Registered Office:

Society for Pharmaceutical Dissolution Science 7, Prabhat Nagar, Near 24 Carat, SV Road, Jogeshwari West, Mumbai - 400102. Email: contact@spds.in

SPDS - US Chapter 2400 Computer Drive Westborough, MA 01581 E-mail: info@spds.us

evertise on every level

to craft science and technology solutions in life science

Supelco. Analytical Products

Milli-Q_®

Sigma-Aldrich

BioReliance.

Pharma & Biopharma Manufacturing & Testing Services

SAFC.

Pharma & Biopharma Raw Material Solutions

Millipore.

Preparation, Separation, Filtration & Monitoring Products





Merck has brought together the world's leading Life Science brands, so whatever your life science problem, you can benefit from our expert products and services.

To find out how the Life Science Business of Merck can help you work, visit SigmaAldrich.com/advancinglifescience

#howwesolve

The life science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Merck, the vibrant M, Milli-Q, Millipore, SAFC, BioReliance, Supelco and Sigma-Aldrich area my crademarks of Herck Koad, Damsdad, Genary or reademarks of Herck Koad, Damsdad, Genary of their respective owners. Detailed information on trademarks is available via publicly accessible resources. © 2018 Merck Koad, Darmstadt, Germany and/or its diffilest. All Rights Reserved.



Biophysical characterization solutions

Technologies and expertise to accelerate bioscience research and pharmaceutical development



- Particle size
- Particle concentration
- Surface charge
- Stability assessment
- Particle count
- Aggregation analysis





PCT Ipari, Szolgáltató és Kereskedelmi Kft. H-9200 Mosonmagyaróvár Juhar u. 10, Tel: +3696237199, e-mail:pct@pct.hu, web: www.pct.hu



EXPLORE PHARMACEUTICAL SOLUTIONS



Research and discovery



API development



Pharmaceutical formulation development



Pharmaceutical manufacturing and quality control



In vitro bioequivalence (IVBE)



Analytical instrument qualification



Morphologi 4-ID



Mastersizer 3000



NanoSight Pro



Zetasizer range



MicroCal PEAQ-ITC



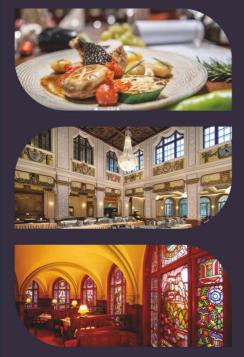
MicroCal PEAQ-DSC Automated







+36 46 331 411 | info@hotelpalota.hu www.hotelpalota.hu







MicroNIR™ Handheld and Process Spectrometers

One product line, one solution for all your process control requirements

VIAVI MicroNIR™ spectrometers are designed for one purpose: to help you improve the quality and reduce the cost of your products. With models and accessories to suit every stage of pharmaceutical manufacturing, full GMP compliance, and low total cost of ownership, MicroNIR instruments are ready and able to take you where you want to go.

- Use the handheld, wireless OnSite-W at the loading dock for raw material identification and qualification (RMID)
- Use the USB-powered PAT-U for real-time monitoring of drying, granulation, tableting, and coating
- Use the compact, wireless PAT-W on a tumble blender for a rotation-by-rotation readout of blend uniformity

MicroNIR Pro software, a complete, easy-to-use chemometric modeling suite, is included with every instrument and supports compliance with USP 1856 and EP 2.2.40 standards.

Contact your local MicroNIR reseller today for more information.

