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12th European Biosimilars Congress

April 15-16, 2019
Berlin, Germany



SCIENTIFIC PROGRAM

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12th European Biosimilars Congress

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AGENDA

Title: Reinvestement opportunities to enhance patient care

Anusha Patel
Kettering General Hospital, Kettering, England

Anusha graduated in 2008 with a Masters of Pharmacy at Kings College London and completed her post graduate training in various hospitals around London. Following obtaining a Diploma in Medicines Management from the London School of Pharmacy, she specialised in Trauma and Orthopaedics pharmacy at UHL for a number of years. She then took on a homecare role at Kettering which has evolved into the current position. Current roles are split between an Embedded Pharmacist for NHSE, a High Cost Drugs Pharmacist for the local CCG and Regional Homecare Lead for Trusts in the East Midlands.

Title: Ogden syndrome—malformation, infantile lethality and nt-acetylation protection

ANIL BATTA
HEAD, DEPTT.OF BIOCHEMISTRY, GOVT.MEDICAL COLLEGE, AMRITSAR

Dr. Anil Batta is presently Head and senior consultant of Medical Biochemistry in Govt.Medical College, Amritsar affiliated to Baba Farid University of Health Sciences. He did his M.B.B.S. and M.D. in Medical Biochemistry from Govt. Medical College, Patiala in 1984 and 1991, respectively. His research interest is mainly in clinical application especially cancer and drug de-addiction. He has supervised more than 25 M.D., M.Sc. and Doctorate researches and published more than 100 international research papers.

Title: Demand for biogas: State of the art and future perspective

Abdeen Omer
ERI
UK

Abdeen Mustafa Omer (BSc, MSc, PhD) is an Associate Researcher at Energy Research Institute (ERI). He obtained both his PhD degree in the Built Environment and Master of Philosophy degree in Renewable Energy Technologies from the University of Nottingham. He is qualified Mechanical Engineer with a proven track record within the water industry and renewable energy technologies. He has been graduated from University of El Menoufia, Egypt, BSc in Mechanical Engineering.

SPEAKER SLOTS AVAILABLE

Title: Trad-Mcn in Tradescantia pallida for evaluation of urban atmospheric air quality

Aline do Nascimento Rocha
National Research Center, Egypt

Researcher in Entomology and Biodiversity Conservation at Federal University of Grande Dourados (UFGD). Master in General Biology/Bioprospecting also by UFGD. Works with bioindicators and plant anatomy. He holds a bachelor's degree in biological sciences from the State University of Mato Grosso do Sul (2014), where he obtained experience in the field of zoology, with emphasis on entomology (animal behavior), also worked on the following topics: pedagogical practices.

Title: Chemometrics in biosimilarity and stability assessment; analytical review

Basma M. Eltanany
Cairo University, Egypt

Dr. Basma Eltanany; Assistant professor of Analytical Chemistry and instrumental analysis at Faculty of Pharmacy, Cairo University , Egypt. She is a post-doc reasearcher at the same faculty. Basma has been awarded the BSc in pharmaceutical sciences (2006) and her MSc in Analytical Chemistry (2012). She got the PhD degree in Analytical Chemistry (2016). She has published number of articles in refreed journals and prticipated in national and international conferences.

Title: Human Papillomavirus Infection in genital Women in four regions of Senegal

El Hadji Seydou Mbaye,
Germany

Dr. El Hadji Seydou Mbaye was born in 1978 in Kaolack a region of Senegal. During 2008-2013, he persued his PhD in Biology and Human Pathologies with the collaboration of the International Agency for Research on Cancer (IARC) /WHO, Lyon (France); 2006-2007 : Master of Life and Health, Specialty Biology of microorganisms, Virology in Louis Pasteur University of Strasbourg (France); 2005-2006 : Master of Life and Health

SPEAKER SLOTS AVAILABLE

Title: Single use technology based biopharma manufacturing facility design and operations; From a CMO perspective

Nataraj Vedapuri,

Syngene international ltd, India

Nataraj Vedapuri has expertise in Biologics GMP Manufacturing Operations, Cell culture GMP Large scale (2000 Lit) facility design, Scale up and Technology transfer. Have Strong academic knowledge with B. Tech (Chemical Engineering), M. Tech (Biotechnology) and MBA (Operations Management) degree

Title: Paradigm shift in discovery of new generation antibodies & their Biosimilars via Path breaking innovation Radha 108 (Receptol)

Pawan Saharan
Kheda Satellite
Amul Dairy, India

Dr. Saharan has MS in Life Sciences (JNU); Ph.D in medicine (WVU) & Post Doc. (Stanford University).He has several International Publications / Presentations including in Top Scientific Journal Nature from the age of 21.

Title: Impact of product heterogeneity on product biological activity and stability in the context of Bio-therapeutics

Ravish Patel,

India

Ravish Patel completed a PhD in biotechnology from Niram University and a Master's degree in Microbiology from University of Mysore, Dr. Ravish Patel started his career at the Intas pharmaceutical, Ahmedabad as Research associate in 2007. He quickly advanced from a Research associate to his current position as Manager- Quality at Epygen Biotech, Mumbai. The company is engaged in development and manufacturing of Bio-therapeutics.

SPEAKER SLOTS AVAILABLE

Title: Blockchain transformation in healthcare

Samer Ellahham,
Cleveland Clinic
Abu Dhabi, UAE

Samer Ellahham belongs to a clinical department. And he is from Abu Dhabi, UAE.The blockchain is positioned to be the next disruptive technology in health care.

Title: Biosimilars: Stability and quality considerations

Samia A. Tawfik,
Cairo University,
Egypt

Samia Ali; Demonstrator of Analytical Chemistry and instrumental analysis at Faculty of Pharmacy, Cairo University, Egypt. She is a junior researcher at the same faculty. She has been awarded the BSc in pharmaceutical sciences (2013). She has published number of articles in refereed journals and participated in national and international conferences. She is going to complete her MSc by the end of 2019 and she pursues her scientific passion for completing her BSc abroad. Her current research interests include separation sciences, spectrophotometry and potentiometry.

Title: Towards safety of oral anti-cancer agents, the need to educate our pharmacists

Sanaa Mekdad
Saudi Arabia

Sanaa Mekdad is belongs to a pharmaceutical department and has done research in Anti cancer angents. She is from Saudi Arabia.

SPEAKER SLOTS AVAILABLE

Title: Estimation of causal equivalence effects in clinical bioequivalence/biosimilar studies in the presence of intercurrent events: Noncompliance and missing data

Wanjie Sun
USA

Wanjie Sun is currently a senior mathematical statistician at CDER of FDA. Prior to joining FDA, Wanjie worked at GWU as a lead research scientist and a PI/co-PI for over ten years, and she also worked in pharmaceutical industry for a couple of years. Wanjie received her PhD in Biostatistics from GWU. Wanjie has over 40 publications in statistical, medical, and pharmacy journals.

Title: Biosimilar assessment: Quantitation of antibody variants and pharmacokinetic studies using peptide mapping LC-MS analysis

Jane Xiao
USA

Jane (Xiaoyao) Xiao received her PhD in Analytical Chemistry from University of Wales Swansea, UK. Jane Xiao is currently a co-founder and Senior Director in Biologics Characterization at Axcel BioPartners. Prior to that, she served as Director at Oncobiologics, Head of a proteomics lab at Johnson & Johnson and Senior Scientist at Merck. For the last 15 years she has worked for the pharmaceutical industry leading analytical method development for protein characterization, biomarker development in early phase clinical trials, biosimilar development for similarity assessment and comparability assessment

Title: Comparative anti-angiogenesis study between Allicin nanoparticle and normal Allicin from Garlic (Allium Sativum Linn)

Shafeeque K* and Hashim KM
India

Shafeeque K* and Hashim KM Uwin Life Sciences, Malappuram, India. Comparative Anti-Angiogenesis Study between Allicin Nanoparticle and Normal Allicin from Garlic.

SPEAKER SLOTS AVAILABLE

Title: Quality, non-clinical and clinical considerations for biosimilar monoclonal

Hasumati Rahalkar
India

Hasumati Rahalkar manages consulting firm which she founded in year 2012. As a director of the company, she is responsible for general management of regulatory and GMP projects. She plays crucial role in timely advise to clients, development of expertise within company and for the clients.

Title: Children and cerebral palsy: The hopeful clinical and neuro-imaging impacts of joint therapy

Khajik Sirob Yaqob
Iraq

Khajik Sirob Specializes in a Child's Nutrition and Growth with Interest in Pediatric Neurology, Associate Membership of the RCPCH, Membership of Oxford University Hospitals, Member of the American Academy of Nutrition and Dietetics, Member of Kurdistan Pediatric Society, Iraq.

Title: ENDOLIFT and Ultherapy® for the best face, neck and body non-surgical lifting

Dell'Avanzato Roberto
Italy

Dell'Avanzato Roberto is Specialist in Surgery with an University Master in Aesthetic Medicine and Surgery; Professor of Laser and Laser Assisted Liposuction, San Marino University (San Marino); University Diploma in Laparoscopic Surgery, Louis Pasteur University of Strasbourg France.

SPEAKER SLOTS AVAILABLE

Title: Quantification of Polysorbats: Characterization, Quantification in final formulation and monitoring of their

Steven Alexander Watt
Germany

After studying molecular biology at the Bielefeld University and graduating with a PhD in genetics and molecular biology in 2005, Dr. Steven Watt was granted a position as assistant professor at the department of proteome and metabolome research.

Title: Recent developments in patent law in the area of biosimilars in Europe

James M. Ogle
UK

JAMES M. OGLE, PhD is a Partner of Hoffmann Eitle (Munich). Dr. Ogle graduated in biochemistry from Regensburg University in 2000 and obtained his PhD in 2004 at the University of Cambridge with V. Ramakrishnan on research closely related to the latter's Nobel Prize on ribosome structure. With Ramakrishnan, Dr. Ogle published major papers and reviews on that topic in Science, Cell and the Annual Review of Biochemistry.

Title: The potential utility of aqueous extract of stevia rebaudiana Bertoni in adjunct with metformin in treating diabetes mellitus

Abdel-Azim Assi
Egypt

Abdel-Azim Assi Department of Pharmacology1 Faculty of Medicine and Department of Pharmacognosy2 Faculty of Pharmacy, Assiut University, Egypt

SPEAKER SLOTS AVAILABLE

Title: Evaluation of an inverse molecular design algorithm in a model binding site

Grigoriadis J.
Greece

Ioannis Grigoriadis has completed his PharmacistD at the age of 24 years from Aristotle University of Thessaloniki. He is the scientific director of Biogenea Pharmaceuticals Ltd, a premier biotechnology personalized cancer vaccination service organization.

Title: Children and cerebral palsy: The hopeful clinical and neuro-imaging impacts of joint therapy

Marek Swierczynski
Poland

Marek Swierczynski has completed his PhD and postdoctoral studies from the Silesian University. He is Professor of Law at University of Cardinal Stefan Wyszynski in Warsaw (Poland), member of the Polish Ministry of Health Council "Together for Health" and consultant to the Council of Europe (CDCJ).

Title: ENDOLIFT and Ultherapy® for the best face, neck and body non-surgical lifting

VeselinDickov
Serbia

Prof. dr Veselin Dickov spec. MD PhD DIRECTOR , Institute for the health protection of students .

SPEAKER SLOTS AVAILABLE

Title: Sample Size in Biosimilar Drug Product Development antibody development

Shein-Chung Chow
USA

Dr. Chow is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and the Editor-in-Chief of the Biostatistics Book Series at Chapman and Hall/CRC Press of Taylor & Francis Group. He is Fellow of the American Statistical Association (ASA) and an elected member of the ISI (International Statistical Institute).

Title: Near-field enhancement SNOM - a forgotten directly higher resolving technique than stochastic ones

Gerd Kaupp
Germany

Gerd Kaupp has completed his PhD at the age of 24 years from Würzburg University and postdoctoral studies from Iowa State University, Lausanne University, and Freiburg University. He held a full-professorship till 2005 in Oldenburg Germany.

SPEAKER SLOTS AVAILABLE

DAY 1
Monday, 15th April

08:30-09:00 **Registrations**

09:00-09:30 **Introduction**

09:30-09:50 COFFEE BREAK

09:50-11:50 Meeting Hall 01 **KEYNOTE LECTURES**

11:50-13:10

MEETING HALL 01	MEETING HALL 02
Talks On: Current Challenges in Developing Biosimilars	**Talks On:** Analytical Strategies for Biosimilars and Intellectual Property Rights
Biopharmaceuticals development	Biosimilars multimodal techniques
Quality by Design for Biologics and Biosimilars	Biosimilars bioanalytical methods
Implimentation of the BPCI Act	Bioassay for comparability and potency testing
Advertising, promotion and labelling essentials	Biosimilars LC/MS analysis for discovery, preclinical and clinical programs
Unique considerations for biologics	Biosimilars GMP protein analysis
Comparability for biologics	Biosimilars electrophoresis

13:10-13:15 GROUP PHOTO

13:15-14:00 LUNCH BREAK

14:00-16:00

MEETING HALL 01	MEETING HALL 02
Talks On: Biological Medicine and Emerging Biosimilars in Therapeutics	**Talks On:** Innovative Clinical Approach in Biosimilars and Biosimilars Research Pipeline
Advances in biological products	Biosimilars clinical trials
Biological drugs	Clinical PK/PD studies
Generic biological drugs	Toxicological studies
Biologics in cancer	Risk management and quality affairs
Biologics in autoimmune disease	Future of next generation biosimilars

16:00-16:20 COFFEE BREAK

MEETING HALL 01 (16:20-17:00)	MEETING HALL 01 (17:00-18:00)
Young Researchers in Pharmaceutical Sciences	Workshop

DAY 2
Tuesday, 16th April

09:00-10:30 Meeting Hall 01

KEYNOTE LECTURES

10:30-10:50 COFFEE BREAK

10:50-12:50

MEETING HALL 01	MEETING HALL 02
Talks On: Regulatory Updates on Biosimilars & Biosimilars Development in Markets	**Talks On:** Biosimilars Approval to Biogenerics in Clinical Practice
Licensing of biosimilars	Biotechnologic drug
BLA filing for biosimilars	Monoclonal antibody
Regulatory prospects of BRIC countries	Fusion protein
Biosimilars USA	Biologic drug
Biosimilars Europe	Anti–tumor necrosis factor

12:50-13:35 LUNCH BREAK

13:35-15:55

MEETING HALL 01	MEETING HALL 02
Talks On: Biopharmaceutical Informatics & Consequences of Brexit on Biosimilars	**Talks On:** BCS and IVIVC Based Biowaivers & Globalization of Biosimilars
Applications of computation in biologic drug development	BCS biowaivers
Physics-based molecular modelling	Preclinical and clinical testing for oral drug delivery
Protein sequence-structural contexts and degradation reaction mechanisms	Waiver for In vivo bioavailability or bioequivalence
Brexit- Pros and Cons to European pharma market	Global impact of biosimilars over generics
Post Brexit changes in biosimilars regulation in UK	Economic aspect towards biosimilars
Fate of biosimilars clinical trials in UK	Biosimilars in global market

15:55-16:15 COFFEE BREAK

MEETING HALL 01 (16:15-17:00)	MEETING HALL 01 (17:00-18:00)
Poster Presentations	Workshop

Organizing Committee Members



Andras Guttman

Sciex Separations, USA



Cecil Nick

PAREXEL, UK



Christoph Volpers

Michalski Hüttermann & Partners, Germany



David Ebsworth

Vifor Pharma Ltd, Switzerland



Dominic Seitz

Simon-Kucher & Partners, Germany



Fiona M Greer

SGS Life Sciences, Switzerland



Francois-Xavier Frapaise

Biosimilars Consultant, France



Kamali Chance

BioSciencesCorp, USA



Parastoo Azadi

Complex Carbohydrtae Research Center - University of Georgia, USA

PAST AFFILIATES

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Andras Guttman
Sciex Separations, USA

Fiona M Greer
SGS Life Sciences, Switzerland

Francois-Xavier Frapaise
Biosimilars Consultant, France

Parastoo Azadi
Complex Carbohydrtae Research Center - University of Georgia, USA

Cecil Nick
PAREXEL International, UK

Dominic Seitz
Simon-Kucher & Partners, Germany

David Ebsworth
Vifor Pharma Ltd, Switzerland

Sakae Tsuda
National Institute of Advanced Industrial Science and Technology, Japan

Emile Van Corven
Bioceros, Netherlands

Thomas Kofoed
Alphalyse A/S, Denmark

R Helena Bustos-Cruz
Universidad de La Sabana, Colombia

M. Carme Parés Santilari
European Bio Immune(G)ene Medicine Association, France

Kurt R Karst
Hyman, Phelps & McNamara, P C, USA

Kamali Chance
BioSciencesCorp, USA

Roberto Valenti
DLA Piper, Italy

Theo Christie
National Institute for Health Research, UK

Archana Shubhakar
Ludger Ltd, UK

Fatemeh Torkashvand
Pasteur Institute of Iran, Iran

Roberta Bursi
InsilicoTRIALS, Italy

Victor Tsetlin
Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry RAS, Russia

Padma Priya Anand Baskaran
ReeLabs Pvt. Ltd., India

Eraldo Martins Guerra Filho
Recife Center for Advanced Studies and Systems, Brazil

Oleksandr Kukharchuk
ReeLabs Pvt. Ltd., India

Tsachi Shaked
Elcam Drug Delivery Devices, Israel

Menachem Zucker
E3D Elcam Drug Delivery Devices, Israel

Mohammed H Alwan
Al Nahrain University, Iraq

PAST AFFILIATES

PAST AFFILIATES

Logean Q Al Karam
Al Nahrain University, Iraq

Thomas Zahel
Exputec GmbH, Austria

Yazan Shaban
Hikma Pharmaceuticals, Jordan

Cecil Nick
PAREXEL International, UK

Pavel Vítámvás
Crop Research Institute, Czech Republic

Anna Shaliutina-Kolesova
University of South Bohemia Ceské Budejovice, Czech Republic

Hamdi Uysal
Ankara University, Turkey

Hana Ujcikova
Institute of Physiology-Czech Academy of Sciences, Czech Republic

Peter Nilsson
KTH-Royal Institute of Technology, Sweden

Peter Nilsson
KTH-Royal Institute of Technology, Sweden

Sara Motta
National Research Council, Italy

Patrícia Sampaio Tavares Veras
Gonçalo Moniz Research Center- FIOCRUZ, Brazil

Patricia Renard
University of Namur, Belgium

Alex Bayes
Biomedical Research Institute Sant Pau, Spain

Mario Looso
Max Planck Institute for Heart and Lung Research, Germany

Nadine Bongaerts
Delft University of Technology, Netherlands

Lydia Siragusa
Molecular Discovery Limited, UK

Thomas Schneider
Philip Morris International, Switzerland

Miguel Quintela-Fandino
Spanish National Cancer Research Center, Spain

Andreu Soldevila Fabrega
LeanBio, Spain

Alastair Waugh
3P Biopharmaceuticals, Spain

Carles Celma Lezcano
Kymos Pharma Services, Spain

Tiziana Bonaldi
European Institute of Oncology, Italy

Maria De Angelis
University of Bari Aldo Moro, Italy

Jasmina N Jovanovic
School of Pharmacy, UK

Huseyin Cimen
Yeditepe University, Turkey

Stefanie Wienkoop
University of Vienna, Austria

PAST AFFILIATES

PAST AFFILIATES

Tamar Geiger
Tel Aviv University, Israel

David Sheehan
University Cork College, Ireland

Martine Cadene
Centre de Biophysique Moléculaire, France

Claudine S Bonder
University of South Australia, Australia

Fuad Fares
University of Haifa, Israel

Eunjoo Kim
Daegu Gyeongbuk Institue of Science and Technology (DGIST), South Korea

Jaime Jacqueline Jayapalan
University of Malaya, Malaysia

Serhiy Souchelnytskyi
Qatar University, Qatar

Vadim Govorun
Federal Research and Clinical Center of Physical-Chemical Medicine of Federal Medical Biological Agency, Russia

Akira Imaizumi
Ajinomoto Co., Inc., Japan

Amilcar Perez-Riverol
Sao Paulo State University, Brazil

Mohamad Khairi Zainol
Universiti Malaysia Terengganu, Malaysia

Hasni Arsad
Universiti Sains Malaysia, Malaysia

Carlos Eduardo A Souza
Cisne University, Brazil

Diogo Ribeiro Demartini
Laboratorio de Proteinas Toxicas UNIPROTE-MS Centro de Biotecnologia – UFRGS , Brazil

Jamal Alruwaili
Vice Dean Faculty of Applied Medical Sciences Northern Border University Arar, Saudi Arabia

Nadeem A. Kizilbash
Northern Border University, Saudi Arabia

Chin Chiew Foan
University of Nottingham, Malaysia

Jianshe Zhang
Changsha University, China

John F Cipollo
Center for Biologics Evaluation and Research-USFDA, USA

Wendy Sandoval
Genentech, Inc. South San Francisco, USA

Xuequn Chen
School of Medicine, Wayne State University, USA

Alan J. Tackett
University of Arkansas for Medical Sciences, USA

Euro Biosimilars **Glimpses**





















Berlin Attractions

















