



UWE GUDAT
FRESENIUS KABI
SWISSBIOSIM GMBH
Head of Safety, Biosimilars
GERMANY



STEINAR MADSEN
NORWEGIAN MEDICINES
AGENCY
Medical Director
NORWAY



RODEINA CHALLAND CHALLAND BIOSIMILAR CONSULTING LTD. Director UNITED KINGDOM



TAMAL RAHA
INTEGRATED BIOPHARMA
& PHARMA SOLUTION
FOUNDER
INDIA



OMAR ALI UNIV. PORSTMOUTH Visiting lecturer value based pricing & innovative UNITED KINGDOM



FIONA GREER SGS Life Sciences Global Director, Biopharma Services Development UNITED KINGDOM



CECIL NICK
PAREXEL
Vice President
UNITED KINGDOM



BEATRIX METZNER BOEHRINGER INGELHEIM Head of Global Tech RA GERMANY



REENITA DAS FROST & SULLIVAN Transformational Health Partner and S V President UNITED STATES



ANNA AILLERIE
GEDEON RICHTER
Head of Commercial Operations, Biotechnology
SWITZERLAND



DAIRINE DEMPSEY OPEN ORPHAN DAC CEO/CMO IRELAND



JAKOB LANGE YPSOMED AG Account Director SWITZERLAND



HAZEL GORHAM
PRA HEALTH SCIENCES
Senior Director, Clinical Pharmacology and Biosimilars Development – Scientific Affairs
UNITED KINGDOM



M. CÉU MACHADO INFARMED President PORTUGAL



JOANNA BROUGHER
BIOPHAMA LAW GROUP,
PLLC
Owner & Principal
UNITED STATES



HELDER MOTA FILIPE INFARMED Former Vice-President PORTUGAL



BRYAN KIM SAMSUNG BIOEPIS Vice President of Business Development KOREA



ERIN FEDERMAN MYLAN Head of Biologics, Europe GERMANY



SWITZERLAND

MICHAEL MUENZBERG COMPARATIVE OUTCOMES GROUP Independent Consultant



ANDREU SOLDEVILA LEANBIO Founder SPAIN



On 22 & 23 March 2018, Porto will host the 2nd BioTech Pharma Summit: Biosimilars & Biologics 2018. This year's flagship event will gather top EU, US, Asia and global regulators, officials, healthcare actors as well as industry leaders, to foster open exchange and debate on the role of the biosimilars & biologics medicines sector.

Participating at this conference provides the unique opportunity to meet the leaders of biosimilars in one place, to inform yourself about the latest tools, services, and challenges, and to advertise your solutions in this dynamic and complex field.

Join the conversations in Porto and be a part of the future.





Thursday, 22-March // DAY 1

08:00 Registration and Welcome Coffee

08:30 Opening Ceremony: Maria do Céu Machado President at INFARMED

MORNING SESSIONS CHAIRMAN> CECIL NICK

I. EVOLUTION, LATEST TRENDS AND FUTURE OF BIO-**SIMILARS & BIOLOGICS**

08:45 CASESTUDY Totality of evidence: Why Sherlock Holmes Likes Biosimilars.

A Bayesian approach to the Biosimilar Evidence

- Why we speak of "totality of evidence"
- >> Integrating evidence across domains
- The difference between probability and likelihood
- What we can learn from looking in the rear view

UWE GUDAT Head of Safety, Biosimilars at Fresenius-Kabi Swiss BioSim

09:20 Speed Networking

Innovative approach to maximize networking capabilities through two minute periods, where delegates can meet their peers and exchange business cards before rotating to the next company representative.

09:40 CASESTUDY Present on the past/future of Biosimilars - what's your take?

> MICHAEL MUENZBERG Former Medical Director Biosimilars Europe at Amgen. Member at Comparative **Outcomes Group**

10:20 Morning Coffee & Networking Break

GEDEON RICHTER

11:00 CASESTUDY Challenges and opportunities in development of Biosimilars: Global Perspective

- Exhaustive information about new products, untapped geographies, recent developments, and investments in the biosimilars market
- New guidance from FDA to help manufacturers develop more treatment options

ANNA AILLERIE Head of Commercial Operations Biotechnology Business Unit Gedeon Richter Plc.

II. REGULATORY LANDSCAPE & PATENT PROTECTION

11:40 CASESTUDY The Current State of the PLAN GROUP PLLC BPCIA and the Anti-Patent Climate

- Overview of the BPCIA Patent Dance and recent court decisions
- » Review of inter partes review (IPR) procedures and anti-patent climate
- Examine challenges to biosimilar market entry, including, constitutional challenges, sovereign immunity, anti-trust issues, and current legislations

JOANNA BROUGHER Owner & Principal at BioPhama Law Group, PLLC

12:20 CASESTUDY Regulatory approaches to PAREXEL Biosimilars (EU, FDA and Globally)

» BEU vs. USA; Japan; China; RoW

CECIL NICK Vice President at PAREXEL Consulting

13:00 Business Lunch

AFTERNOON SESSIONS CHAIRMAN> REENITA DAS

14:00 CASESTUDY Biosimilars Interchangeabili-👳 ty and Extrapolation



» Current Biosimilar interchangeability and extrapolation issues

- » Key factors in Biosimilar interchangeability and extrapolation
- » Challenges in new guideness

RODEINA CHALLAND Director at Challand Biosimilar Consulting Ltd.

14:40 CASESTUDY Biosimilars: contribution for the sustainability of health systems

> HELDER MOTA FILIPE Former Vice-President IN-FARMED (National Authority of Medicines and Health Products)



III. INVESTMENTS, BUSINESS MODELS AND DEVEL-**OPING PARTNERSHIPS**

15:20 CASESTUDY The growth opportunities for biosimilars in Asia

- » Growth scenario of the biosimilars market in APAC
- » Key factors driving the market and barriers the need to be addressed
- » Key market segments to look out for, key trends and regulatory aspects
- » key market participants involved, actors affecting the biosimilars market in the different regions of APAC

REENITA DAS Transformational Health Partner and Senior Vice President at Frost & Sullivan

16:00 Coffee-Break

16:30 BIOEPIS

CASESTUDY Perspective on biosimilars **SAMSUNG** market development in US, EU and Asia

> BRYAN KIM Vice President, Business Development at Samsung Bioepis

GISESSIUM Biosimilars and emerging markets

HAZEL GORHAM Senior Director, Biosimilars Development at PRA Health Sciences

17:30 PANELDISCUSSION Progress in the regulatory landscape for biosimilars Panelists:

> >> Hazel Gorham, UK; Helder Mota Filipe, PT; Rodeina Challand, UK

MODERATED BY CECIL NICK, VP Parexel

18:00 Chairman's Closing Remarks

19:30 Taylor's Port Wine Cellars Visit & Gala Dinner at the Taylor's Restaurant

Friday, 23-March // DAY 2

08:30 Registration and coffee

08:50 Opening Address with **Andreu Soldevila**

MORNING SESSIONS CHAIRMAN> ANDREU SOLDEVILA

IV. METHODS & ANALYTICAL STRATEGIES FOR BIO-**LOGICS AND BIOSIMILARS**

09:00 CASESTUDY Biologics, Biosimilars Orphan Drugs - an Introduction

DAIRINE DEMPSEY CEO, Open Orphan DAC

09:40 WORKSHOP Critical Analytical Charac-

- » Comprehensive characterization of multiple batches of the target molecule to determine the exact structure, post-translational modifications and variability of quality attributes to allow establishment of QTTP and development of Analytical Similarity Assessment
- » Comparative data for the biosimilar alongside the originator is required to demonstrate biosimilarity. These data include both structural and functional activities
- » Analytical strategies for primary and higher order structure determination will be discussed particularly for antibodies where their size and complexity requires LC/MS/MS approaches
- Orthogonal analytical techniques: requirements for "finger-print like" assessment, utilising both conventional and emerging technologies

FIONNA GREER Life Sciences Global Director, Biopharma Services Development at SGS

Boehringer Ingelheim

10:50 CASESTUDY Analytical Comparability of **Biologics and Biosimilars**

- » Differences in the comparability assessment
- » Assigning criticality to quality attributes Statistical approaches
- » Justifying differences in critical quality attributes BEATRIX METZNER Head of Global Tech RA bei Boehringer Ingelheim

11:30 CASESTUDY Innovative clinical approach BPS in biosimilars

- » Early Clinical Development findings
- » An Innovative Approach to the Formulation of Biobetters
- » Next generation biosimilars

TAMAL RAHA Founder at Integrated Biopharma & Pharma Solution

12:10 CASESTUDY From biosimilar approvstatens al to biogenerics in clinical practice

- » Attitudes and acceptance in clinical practice
- » Uptake in clinical practice
- » Nor-Switch study and other clinical trials
- » Switching and interchangeability

STEINAR MADSEN Medical Director at Norwegian Medicines Agency

13:00 Business Lunch

AFTERNOON SESSIONS CHAIRMAN> OMAR ALI

V. BIOSIMILARS DEVELOPMENT & INNOVATION

14:00 CASE TIMEY Injection Devices for Biosimi-

YPS@MED lars: Advantages of Platform Products

- » Overview of devices for self-injection Devices for biosimilar applications
- » Custom-made devices vs customized platform prod-
- » Development of customized platform products Usability for platform products

JAKOB LANGE Account Director at Ypsomed AG

VI. BIOLOGICALS & BIOSIMILARS: ADDRESSING THE NEEDS OF PATIENTS AND PAYERS

14:30 CASESTUDY Payer Perspectives on Value Added from Biosimilars

- Fiscal overview ON Payers perspectives on **Biosimilars**
- Government drivers on Biosimilars and how payers are implementing this
- How Payers are aligning biosimilars with innovative parent brands to streamline patient care settings
- Physician loyalty [brand v biosimilar and biosimilar v biosimilar and how this affects formulary uptake
- >> What value offerings from biosimilars resonate with payers and formulary decison

OMAR ALI Former Former Adviser for NICE Adoption & Impact Programme Reference Panel

15:00 STRATEGY SPEECH Biosimilars:

Mylan Importance of Patient Voice in Ensuring Uptake

ERÍN FEDERMAN Head of Biologics, Europe at Mylan

15:30 Coffee-Break

16:00 PANELDISCUSSION Perceptions and Perspectives on Biosimilars

The pros and cons of industry-funded vs publically-funded patient support programs and the need for tools and education to support informed decision making by patients about biosimilars.

Panelists: Erin Federman, DE; Tamal Raha, IN; Steinar Madsen, NO

MODERATED BY OMAR ALI. Former Adviser for NICE Adoption

16:30 Chairman's Closing Remarks and







UWE GUDAT FRESENIUS KABI SWISSBIOSIM GMBH Head of Safety, Biosimilars GERMANY

Uwe Gudat received his medical degree from the University of Marburg. He is licensed in internal medicine and diabetology as a sub-speciality, training under Michael Berger in Düsseldorf.

He joined the pharmaceutical industry in 1995 with Eli Lilly and since then has held positions at Hesperion/Actelion, Novartis and Merck Serono. In this time he has led global clinical development teams, served as global medical brand director, led clinical teams for in-licensing due-diligence and managed clinical-trial review, first in man transitions and product safety assessments. Currently he is Head of Safety of the Merck Serono Biosimilars Unit. He has published a number of scientific papers in the field of diabetes and is currently on the editorial advisory board of Applied Clinical Trials.



STEINAR MADSEN
NORWEGIAN MEDICINES
AGENCY
Medical Director
NORWAY

Dr. Steinar Madsen is medical director at the Norwegian Medicines Agency. He has been working with generic substitution since it was introduced in Norway in 2001 and with biosimilars since 2006. He is member and previously chairman of the committee for generic substitution at the Agency. Dr. Madsen is also engaged in the drug information service, with a special interest in the safe and cost-effective use of drugs. He is a specialist in internal medicine and cardiology and works part time as a consultant in cardiology.



CECIL NICK
PAREXEL
Vice President
UNITED KINGDOM

Vice President (Technical), at PAREXEL Consulting has been working in regulatory affairs and clinical development for over 30 years; for over 25 years he has focused on biological medicines. Cecil Nick has particular expertise in monoclonals and biosimilars, having worked on over 20 such programs, engaged in over 50 interactions and meetings with regulatory agencies in the EU, US, Canada, Australia, Mexico, Brazil and supported 6 submissions in the EU and US including the first monoclonal biosimilar to be approved in the EU and US. Cecil has been working in Regulatory Affairs since 1979. He was on the editorial panel of SCRIP Clinical Research and has authored many articles on regulatory and clinical development issues.



DAIRINE DEMPSEY
OPEN ORPHAN DAC
CEO/CMO
IRELAND

Dr. Dempsey is the co-founder of the Dublin-based EU pharmaceutical company specialised in bringing orphan drugs to EU patients. With over 15 years experience in the pharmaceutical industry, she previously held the role of Vice President, Strategic Regu latory Affairs at ICON plc, a global clinical research organisation running clinical trials and providing a variety of pharmaceutical services to medical industries worldwide. From 2009 to early 2015 she worked as pharmaceutical consultant with The Compliance Group with responsibility for pre- and post-marketing regulatory affairs and pharmacovigilancee, while ledding the establishment of the pharmaceutical products regulatory authority in Bahrain.



Founding Director of M-Scan, contract analytical laboratories specializing in biopharmaceutical characterization. She is now Global Director, Biopharma Services Development, SGS Life Sciences. Following a Ph.D. in Protein Biochemistry, she joined M-Scan to estab lish and direct biologics characterization services. With over 35 years experience, she has been involved with a diverse range of biotechnology products, both novel and biosimilar and consults to companies throughout the world. She is regularly invited to give presen tations and workshops at international meetings. In 2016 she was named in the Medicine Makers "Power List - Top 100 influencers".



RODEINA CHALLAND CHALLAND BIOSIMILAR CONSULTING LTD. Director UNITED KINGDOM

B.Sc., Director, Challand Biosimilar Consulting, over 25 years of experience in healthcare, cancer research and pharmaceutical industry across a wide range of roles including developing and implementing clinical development strategies for biosimilars at Hospira Inc. as Director of Clinical Projects and Head of Clinical Operations in the EU. Was the lead in the development of Hospira's first biosimilar, for the EU and the US programs. Was also the company's representative in several EMA consultations with regard to the development of the biosimilar guidelines and a member of the European Biopharmaceutical Group. Experience in study design and regulatory agency discussions (Europe, US, Japan, Australia, Singapore and S. Korea).





MICHAEL MUENZBERG COMPARATIVE OUTCOMES GROUP Independent Consultant SWITZERLAND

Dr. Michael Muenzberg is currently working as an independent Consultant for Biosimilars and Biotech related topics. He was born in Austria and educated in Austria, Canada and Sweden. Licensed as Doctor of Nuclear Medicine and has 20 years' experience in Pharmaceutical In dustry, working as local as well as global Medical Manager/Director for Serono, Novartis, Amgen, Roche, Sandoz International Biopharmaceuticals and Merck Serono Biosimilars.

His recent position was Medical Director Biosimilars EU at Amgen Europe, responsible for the launch of pipeline Biosimilars in Oncology and Inflammatory Diseases.



HAZEL GORHAM PRA HEALTH SCIENCES

Senior Director, Clinical Pharmacology and Biosimilars Development – Scientific Affairs

UNITED KINGDOM

Dr Hazel Gorham has 26 years of experience in both academia and the pharmaceutical research/industry across a wide range of roles. She also has 8 years of experience in all aspects of biosimilar development including formulating clinical development plans, study design (Phase I and Phase III) and regulatory agency discussions both at national and regional levels.

Dr Gorham is experienced in all aspects of clinical trial project management having worked in both large and small pharma companies; she has managed the conduct of multiple Phase I through IV clinical trials and post-marketing studies across different geographical regions and therapeutic areas She is placed within the clinical pharmacology group of PRA Health Sciences that comprises an international group of scientists whose aim is to maximize the product development success of PRA's clients.



JOANNA BROUGHER BIOPHAMA LAW GROUP, PLLC Owner & Principal UNITED STATES

Joanna is a patent attorney who focuses her practice on all aspects of services related to patents in the life sciences. Has experience counseling clients on the Hatch-Waxman Act and is monitoring developments involving biosimilars under the Biologics Price Competition and Inno vation Act. Also an Adjunct Lecturer at the Harvard T.H. Chan School of Public Health and the Editor-in-Chief of the Journal of Commercial Biotechnology. In 2013, published a book called Intellectual Property and Health Technologies: Balancing Innovation and the Public's Health which ex amines the relationship between patents and public health in the context of medical technologies.



MYLAN
Head of Biologics, Europe
GERMANY

Erin Federman is Head of Biologics, Europe for Mylan, a senior-level, award-winning strategic marketer and problem solver with over 20 years sales and marketing experience across multiple industries and geographies. She has led strategic marketing initiatives for a broad range of biotech, pharmaceutical and technology products, from early development through launch and LOE with a particular focus on launch excellence, patient advocacy and market access. Specifically, she has led the launch preparation and roll-out of 9 new medical devices (global) and 3 pharmaceutical assets (2 global, 1 EU). Erin has worked for such leading healthcare focused organiza tions as Boehringer Ingelheim, Pfizer, Smiths Medical, and Fujifilm SonoSite. She has lived and worked in the U.S., Italy, the United Kingdom and Germany.



PORTUGAL

Maria-Céu Machado (MD, PhD) is the President of the Executive Board of INFARMED (Portuguese Medicines Agency), Full Professor of Pediatrics at the Faculty of Medicine at Lisbon University, Vice-President of the Federation of European Academies of Medicine and Member of the National Council of Ethics for the Life Sciences. She is an Expert Consultant of the Portuquese Health Plan 2016-2020. Prof Machado was High Commissioner for Health (2006-2011) in Portugal, Director of the Department of Pediatrics and Clinical Director of the University Hospital Santa Maria in Lisbon, President of the Nacional Committee for the Children and Adolescents Health and President of the Pediatrics Medical Association.



HELDER MOTA FILIPE INFARMED Former Vice-President PORTUGAL

Prof. Helder Mota Filipe is a member of the Executive Board at INFARMED (National Authority of Medicines and Health Products), he has a degree in Pharmaceutical Sciences and a PhD in Pharmacology from the Faculty of Pharmacy of the University of Lisbon and is Associate Professor of Pharmacology and Therapeutics (Faculty of Pharmacy of the University of Lisbon). Vice-President and President of Infarmed, IP. and Member of the Executive Board of INFARMED. Member of the Management Board of the European Medicines Agency. Member of the Health Technology Assessment Network.

Also a member of the Pharmaceutical Committee (EC). Specialist in Regulatory Affairs by the Pharmacists Association. Member of the Ethics Committee for Clinical Investigation. Member of the Committee on Medicines for Human Use (CHMP, EMA).



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BRYAN KIM SAMSUNG BIOEPIS

Vice President of Business Development

KOREA

Mr. Bryan Kim is VP of Business Development with Samsung Bioepis. He has 20 years of global experience in healthcare / pharmaceuticals, having lived and worked in US, Europe and Asia. Mr. Kim managed emerging mar kets Asia business for Boehringer Ingelheim. Previously, served as a management consultant with Booz & Co where he advised Fortune 500 companies, before assuming various commercial leadership roles with Pfizer. He began his career as a business development manager for Intel Corporation in Silicon Vallev.



REENITA DAS Frost & Sullivan

Transformational Health Partner and S V President

UNITED STATES

Reenita Das is an industry expert with +25 years of healthcare marketing and consulting experience which include engaging with global clients and start ups to develop and implement growth strategies. She is a passionate visionary, futurist, innovator and thought leader working towards changing healthcare. Das currently serves as Transformational Health Partner and Senior Vice President and is the first woman Partner at Frost & Sullivan. In ad dition, she is the Founder of the Corporate GLOW (Growth and Innovation of Women) program.



BEATRIX METZNER BOEHRINGER INGELHEIM Head of Global Tech RA GERMANY

Dr. Beatrix Metzner worked since 2000 at MediGene AG, Germany as Senior Scientist and later as Senior CMC Project Manager. In 2005 she started at Merck KGaA, Germany. In 2007, moved to Global Regulatory Oncology where she has been working as Dir. Global Regulatory Oncology, responsible for global regulatory strategy of biological products. Metzner started working for Boehringer-Ingelheim as Director CMC Strategy and Tech RA responsible for CMC regulatory strategy of new biological entities and biosimilars at Boehringer Ingelheim. Since 2016 she acts the Head of Global Tech RA



OMAR ALI UNIV. OF PORSTMOUTH Visiting lecturer value based pricing & innovative

UNITED KINGDOM

Omar has been working as the Formulary Advisor for Surrey & Sussex Healthcare NHS Trust for over 15 years, sitting on the regional Joint Drugs & Therapeutics Committee as well as the CCG/Commissioning Prescribing Clinical Network. Lecturer at UCLH Pharmacy Programme and was both Lecturer & Examiner on Independent Prescribing V300 Course at the University of Surrey. Lecturer at the Univ. Portsmouth, is an Editorial Content Adviser to Guidelines, since recently he is Associate Editor to the Canadian Journal of Population Therapeutics & Clinical Pharmacology.



TAMAL RAHA
INTEGRATED BIOPHARMA
& PHARMA SOLUTION

Founder INDIA

Tamal has a PhD from University of Calcutta and post-doctoral experience at University of California (San Diego, USA), IISc Bangalore and University of Massachusetts Medical Centre. Tamal has rich experience in biopharmaceutical de velopment and regulatory strategy having undertaken extensive work in Biologics and Biosimilar product development, process development (CMC), non-clinical and clinical development strategy, comparability stutdies, technology trans fer, global regulatory, CTD modules and analytical characterization.



ANDREU SOLDEVILA

Vice President of Business Development

SPAIN

Dr Andreu Soldevila is the founder and CEO of Leanbio and Co-founder and CEO of Syna therapeutics, companies dedicated to Biotherapeutics. Leanbio is a CDMO founded in 2014 dedicated to both New Biologic entities and Biosimilars. Syna Therapeu tics is a Biotherapeutics Developer, founded in 2017 and currently has two products in the pipeline. Andreu Developed as a professional in the field of Biotechnology for the last 20 years, moving from initial applied research to CMC regulatory activities, holding Bioanalysis Head of department at a multinantional company, Head of R&D in a CMO and current CEO positions.



JAKOB LANGE YPSOMED AG Account Director

SWITZERLAND

Jakob is an Engineer and Materials Scientist by training with an MSc degree in Chemical Engineering from the Royal Institute of Technology in Stockholm, and a PhD in Polymer Science from the Swiss Federal Institute of Technology in Lausanne, Switzerland. He has published over 30 peer-reviewed papers on medical devices, packaging materials and polymers and is a regular contributor to technical and scientific conferences. He has held different positions at Yp somed, from Marketing and Sales as well as in R&D Project Management. Currently acts as Account Director in M&S Delivery Systems.



ANNA AILLERIE GEDEON RICHTER

Head of Commercial Operations, Biotechnology

SWITZERLAND

Anna Aillerie has for 20 years been involved with strategic marketing, global launch management and portfolio management for well-known companies like Lipha, Merck KgaA, Merck Generics, Mylan, Lupin and Gedeon Richter. Anna holds a Master of Sciences in Pharmaceutical and Healthcare Marketing from the University Paris VI, and is currently responsible for developing biosimilar commercial activities in her role as Head of Commercial Operations, Biotechnology at Gedeon Richter.



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- 🕅 Rua do Choupelo, 4400-088 Vila Nova de Gaia
- www.the-yeatman-hotel.com











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