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2018

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THE FUTURE OF BIOTECH MEDICINES

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« I enjoyed the conference, which I felt was just the right size and with the right people in it. It was a very open, interactive forum for all of us and provided us an opportunity to speak out or subject related thoughts, concerns and get perspectives from other subject experts. »

SAMIR KULKARNI
ASSOCIATE VICE PRESIDENT, PRODUCT DEVELOPMENT AND STRATEGIC PROGRAM MANAGEMENT
INTAS PHARMACEUTICALS

« I congratulate you on a high quality conference. I was genuinely impressed. I would have loved to stay longer. »

UWE GUDAT
HEAD OF SAFETY. BIOSIMILARS
MERCK SERONO

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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, health-care actors as well as industry leaders, to foster open exchange and debate on the role of the bio-similars & 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.

KEY PRACTICAL LEARNING POINTS

- Interchangeability strategy in Biosimilar clinical trial
- Biosimilar development in emerging markets
- CMC Analytical Comparability: Methods & Strategies for Biologics, Biosimilars & Biobetters
- Prognosis for the Global Biologics market in an era of transformative new technologies
- Critical Analytical Characterization Steps for Biosimilarity Assessment
- Process Development for Biosimilars - Industry challenges
- Biosimilars development and impact on clinical practice
- Biosimilar approval to biogenerics in clinical practice
- Pricing and reimbursement considerations for Biosimilars
- Commercial challenges and opportunities - strategies to develop Biosimilars & Biologics
- Developing successful business models in Biosimilar product development
- Understanding the current regulatory approval standards
- Injection Devices for Biosimilars: Advantages of Platform Products

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MEET THE SPEAKERS

BRYAN KIM
SAMSUNG BIOEPIS
Vice President of Business Development
KOREA

Bryan Kim is Vice President of Business Development with Samsung Bioepis, where he oversees strategic partnerships and growth initiatives. He has 20 years of global experience in healthcare/pharmaceuticals, having lived and worked in US, Europe and Asia. Most recently, Mr. Kim managed emerging markets Asia business for Boehringer Ingelheim. Previously, he 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 Valley.

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 as CMC Project Manager. In 2007 she moved to Global Regulatory Oncology where she has been working as Director Global Regulatory Oncology until November 2013 responsible for global regulatory strategy of biological products. Beatrix started working for Boehringer-Ingelheim, Germany as Director CMC Strategy and Tech RA responsible for CMC regulatory strategy of new biological entities (NBEs) and biosimilars at Boehringer Ingelheim. Since July 2016 she acts the Head of Global Tech RA.

TAMAL RAHA
INTEGRATED BIOPHARMA & PHARMA SOLUTION
Founder
INDIA

Tamal has Rich experience in biopharmaceutical development and regulatory strategy. Extensive work in Biologics and Biosimilar product development, process development (CMC), non-clinical and clinical development, comparability studies, technology transfer, global regulatory, CTD modules and analytical characterization.
He has led product registration in EU, South Asia, South East Asia, MENA, Latin America, Brazil, and Mexico. He has also successfully negotiated product development strategies and registration with global regulatory agencies like US FDA and EMA (both national level and with central agency).

ROMAN IVANOV
BIOCAD
Vice President, Research & Development
RUSSIA

Roman Ivanov is Vice President, R&D, of biotechnology company BIOCAD. Prior to joining BIOCAD, Roman conducted scientific research in the field of molecular immunology at the Hematology Department of Utrecht University Medical Centre in the Netherlands. Roman was responsible for development of the first rituximab, trastuzumab and bevacizumab biosimilars marketed in Russia. Currently he supervises clinical development of several other biosimilars and next-in-class biologics as well as non-clinical studies of multiple innovative products developed by BIOCAD.

REENITA DAS
FROST & SULLIVAN
Transformational Health Partner and Senior Vice President
UNITED STATES

Reenita Das is an industry expert with +25 years of healthcare marketing and consulting experience. Currently serves as Transformational Health Partner and Senior VP and is the first woman Partner at Frost & Sullivan. In addition, she is the Founder of the Corporate GLOW (Growth and Innovation of Women) program. Das works on futuristic forecasts and understanding the place of healthcare 20 years from today. Additionally, she works on best practices and mapping of core capabilities, understanding of emerging markets and the challenges of the complex business scenario of healthcare.

FRANÇOIS-XAVIER FRAPAISE
F.-X. FRAPAISE CONSULTING
Principal
UNITED STATES

Dr. Francois-Xavier Frapaise, M.D has over 35 years of international drug development, strategic planning and marketing experience at major pharmaceutical companies including Sanofi, Bayer, Boehringer, Merck and Abbott; he has hold multiple C-level positions (CSO,C-MO,CEO) in different Pharmacos in the US and Europe. Until recently ,he was heading Clinical Development, Medical Affairs and Pharmacovigilance at Merck KGaA Biosimilars Division; he has extensive experience of biosimilars development acquired at Boehringer-Ingelheim and Pfenex); he now runs a consulting business, based in Paris.

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, Sweden and a PhD in Polymer Science from the Swiss Federal Institute of Technology in Lausanne, Switzerland. He has written and published more than 30 peer-reviewed papers on medical devices, packaging materials and polymers and is a regular contributor to technical and scientific conferences.

ANNA AILLERIE
LUPIN LTD
Former Director, Commercial Biosimilars
SWITZERLAND

MEET THE SPEAKERS

ROHIT NAMBISAN
TREATO; NEUROLEX DIAGNOSTICS
SVP Product Strategy & Partner Integration; Product Advisor
UNITED STATES
Rohit's interests lie at the intersection of healthcare and technology. As the SVP, Product Strategy & Partner Integration at Treato, he manages Product & Innovation portfolio through bridging technological solutions and market need. Additionally, he is the Product Advisor to NeuroLex Dx, a startup developing voice-based diagnostics for mental health disorders. Rohit was the VP & Head of Product at Prognos, a healthcare AI & Data Analytics company focused on diagnostic data solutions for Life Sciences, Payers & Diagnostics companies.

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 Innovation 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 examines the relationship between patents and public health in the context of medical technologies.

UWE GUDAT
MERCK SERONO
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.

RODEINA CHALLAND
CHALLAND BIOSIMILAR CONSULTING LTD.
Director
UNITED KINGDOM
B.Sc., Director, Challand Biosimilar Consulting Ltd., 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 both 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 (EBG). Experience in all aspects of biosimilar development including study design and regulatory agency discussions (Europe, US, Japan, Australia, Singapore and S. Korea).

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 including almost 10 years in the national regulatory authority for medicines, she previously held the role of Vice President,Strategic Regulatory Affairs at ICON plc, a global clinical research organisation running clinical trials and providing a variety of pharmaceutical services to the medicines and medical device industries worldwide. From 2009 to early 2015 she worked as a 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.

FIONA GREER
SGS
Life Sciences Global Director, Biopharma Services Development
UNITED KINGDOM
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 establish 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 presentations and workshops at international meetings. In 2016 she was named in the Medicine Makers "Power List – Top 100 influencers".

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.

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WHO TO ATTEND

CHIEF EXECUTIVES, EXECUTIVE DIRECTORS, VICE PRESIDENTS, HEADS AND TEAM LEADERS AND MANAGERS INCLUDING:

- Biologics/Biotechnology/ Biogenerics
- Biopharmaceuticals
- Legal Affairs
- Intellectual property
- Pricing and Reimbursement
- Clinical Immunology
- Regulatory Compliance
- R & D
- Preclinical and Clinical Development
- New Product Development
- Quality Affairs/ Quality Control
- Principal Scientist
- Pharmacovigilance
- Chief Scientific Officer
- Drug Safety & Risk Management
- Health Economics
- Process Control and Analytical
- Technologies
- Business Development
- Commercial Affairs
- Marketing & sales
- Legislation and Policy Advice
- Business Development
- Manufacturing
- Drug and Safety Assessment
- Market Strategy
- Regulatory Affairs

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Thursday, 22-March // DAY 1

08:00 Registration and Welcome Coffee

08:30 Opening Ceremony

I. EVOLUTION, LATEST TRENDS AND FUTURE OF BIOSIMILARS & BIOLOGICS

08:40 FRESENIUS KABI **CASESTUDY** Totality of evidence: Why Sherlock Holmes Likes Biosimilars.

A Bayesian approach to the Biosimilar Evidence Base

- 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 mirror.

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.

10:30 Morning Coffee & Networking Break / One-on-one meetings

11:00 LUPIN PHARMACEUTICALS, INC. **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 Director, Commercial Biosimilars EMEA at Lupin Pharmaceuticals

II. REGULATORY LANDSCAPE & PATENT PROTECTION

11:40 BIOPHARMA LAW GROUP PLLC **CASESTUDY** The Current State of the 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 PAREXEL **CASESTUDY** Regulatory approaches to Biosimilars (EU, FDA and Globally)

- BEU vs. USA; Japan; China; RoW

CECIL NICK Vice President at PAREXEL Consulting

13:00 Business Lunch

14:00 CBC **CASESTUDY** Biosimilars Interchangeability 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.

III. INVESTMENTS, BUSINESS MODELS AND DEVELOPING PARTNERSHIPS

14:40 FROST & SULLIVAN **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

15:20 **CASESTUDY** Perspective on biosimilars market development in US, EU and Asia

SAMSUNG BIOEPIS

BRIAN KIM Vice President, Business Development at Samsung Bioepis

16:00 Coffee-Break

16:30 **CASESTUDY** Impact that biosimilars make on availability of biologicals on ROW markets

BIOCAD Biopharmaceutical Company

» Unmet medical need for affordable biologic drugs on emerging markets

» Factors that define fast market penetration of biosimilars on emerging markets

» Case studies of successful biosimilar launches on emerging markets

Regulatory and market trends for biosimilars on emerging markets

Bio-betters and next-in-class products as alternatives to biosimilars

ROMAN IVANOV Vice President, Research & Development at BIOCAD

17:10 **PANELDISCUSSION** The implementation of biosimilars in the market

» Global debate on naming of biosimilars

» What can we expect as we moving closer to 2020?

» Partnerships play in the development of biosimilars

Moderated by the Chairman

17:30 Chairman's Closing Remarks

20:00 Gala Dinner

Friday, 23-March // DAY 2

08:30 Registration and Coffee

08:50 Opening Address from the Chairman

IV. METHODS & ANALYTICAL STRATEGIES FOR BIOLOGICS AND BIOSIMILARS

09:00 **CASESTUDY** The Need For Biosimilars

» The unsustainable growth in the medicines budget around the globe

» The pipeline of biologics driving future growth

» Biologics entering new therapeutic areas

» Life-cycle management of biologics

» Affordability, access and improved outcomes arising from biosimilars

DAIRINE DEMPSEY CEO, Open Orphan DAC

09:40 **WORKSHOP** Critical Analytical Characterization Steps for Biosimilarity Assessment

SGS

» Biosimilar development requires initial 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 the Quality Target Product Profile (QTTP) and development of the Analytical Similarity Assessment Plan

» Subsequently, comparative data for the biosimilar side-by-side with 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 which address regulatory requirements for "finger-print like" assessment, utilising both conventional and emerging technologies, will be reviewed.

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

10:20 Coffee & Networking Break

11:00 **CASESTUDY** Analytical Comparability of Biologics and Biosimilars

Boehringer Ingelheim

» 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

11:40 **CASESTUDY** Innovative clinical approach in biosimilars

BPS

» Early Clinical Development findings

» An Innovative Approach to the Formulation of Bio-betters

» Next generation biosimilars

TAMAL RAHA Founder at Integrated Biopharma & Pharma Solution

12:20 **CASESTUDY From biosimilar approval to biogenerics in clinical practice**

Statens legemiddelverk

» 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

V. BIOSIMILARS DEVELOPMENT & INNOVATION

14:00 **CASESTUDY Injection Devices for Biosimilars: Advantages of Platform Products**

YPSOMED SELFCARE SOLUTIONS

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

JAKOB LANGE Account Director at Ypsomed AG

14:40 **CASESTUDY Biosimilars and patient centricity**

» Patient Centricity
» The emerging role of "Digital Health" in Biosimilares (EUPATI, PCORI)
» Pre-launch activities: Patient support programs and the target indications (oncology vs auto-immune disorders).

FRANÇOIS-XAVIER FRAPAISE Principal at F.-X. Frapaise Consulting

15:20 Coffee Break

16:00 **CASESTUDY Patient reported clinical algorithms, efficacy, & preference for Biosimilars & Biologics**

treato

ROHIT NAMBISAN VP Product Strategy & Partner Integration at Treato & Product Advisor at Neurolex Diagnostics

16:40 Chairman's Closing Remarks and End of the BioTech Pharma Summit

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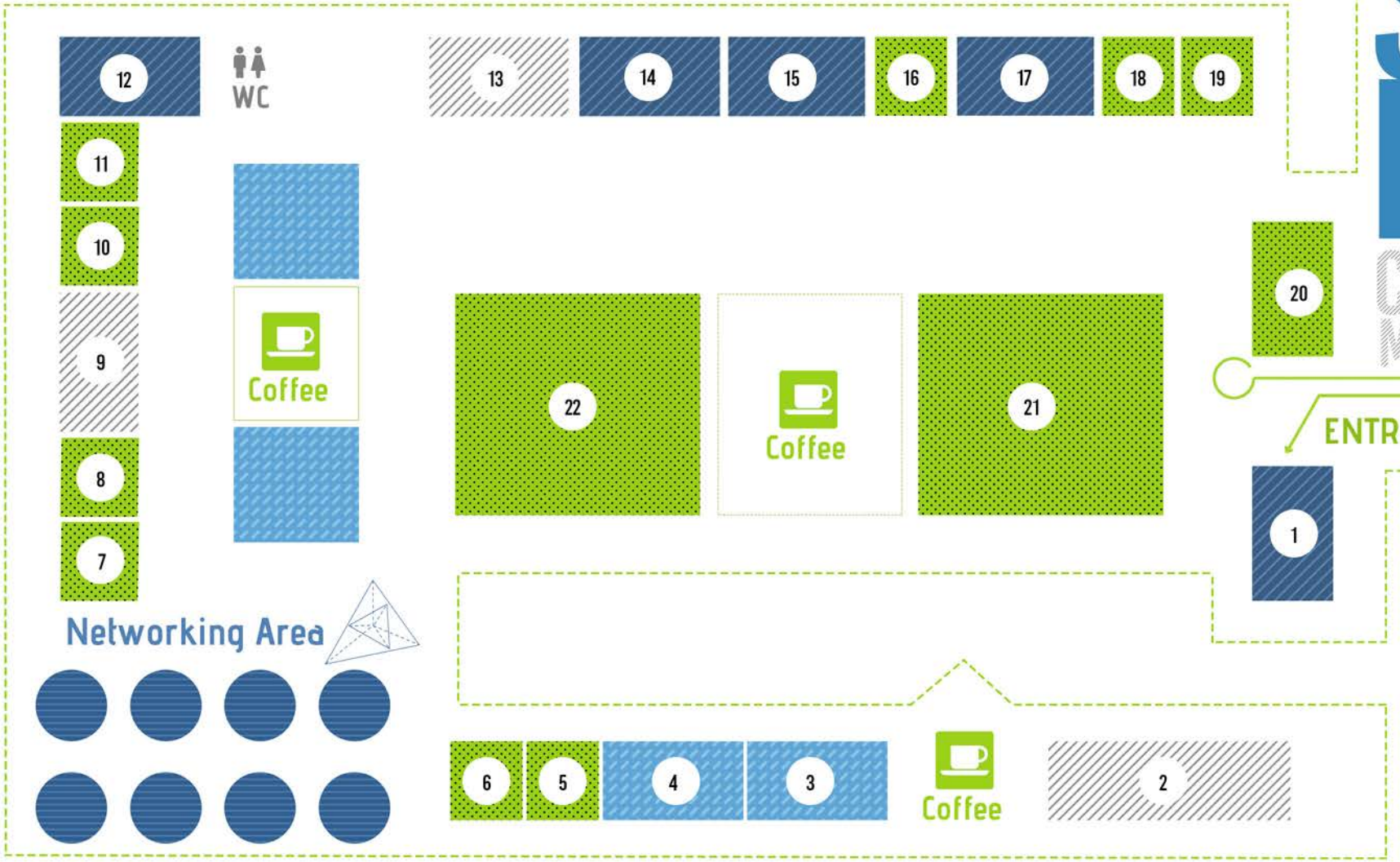

YOU WILL MEET:

• Chief Scientific Officers • Chief Development Officers • Vice Presidents of Antibody Engineering • Vice Presidents Research & Development • Directors of Discovery • Lab Heads • Senior Scientists of Analytical Development • Senior Research Scientists • Senior Principal Scientists • Professors of Bioengineering

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