11 OCT

Starts at 08:00am CEST

Radisson Blu Hotel Zurich Airport

CHECK OUT OUR **STRATEGY DINNERS** On Pages 6,7 and 8

LIMITED SPACE ONLY **BOOK NOW**

Proventa International's 4th Annual

BIOMANUFACTURING STRATEGY MEETING EUROPE 2022

*Looking into the **Multimodal** → **Scalable** → **Adaptable** Bioprocessing Facility of the Future*

QMS | QbD | PAT | Upstream | Downstream | Industry 4.0 | GMP | Biologics | Automation | Facility of the Future

Featuring Industry Leaders and Decision Makers

Lars Nieba
Chief Executive Officer and Chief Technology Officer
Nordic Nanovector

Uwe Buecheler
Senior Vice President, Head of Business Units, Biopharmaceuticals
Boehringer Ingelheim

Lorenz Rindisbacher
Senior Director, Head of Site Quality
CSL Behring

Nora Eifler
Director DSD Project Managment CH, Drug Substance Development Biologics
Novartis

Christoph Herwig
Full Professor - Senior Advisor Bioprocess Technology
Tu Wien

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DataHow AG

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Click here to find out what our clients think about our ***STRATEGY MEETINGS!***

Don't miss THIS INTIMATE FORMAT where senior leadership discuss the biggest challenges facing the industry!

Visit our website for future events →

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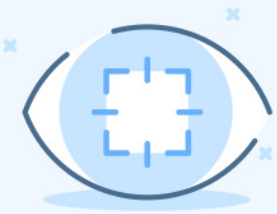
PROVENTA INTERNATIONAL

Proventa International's Strategy Meetings are a completely unique experience.

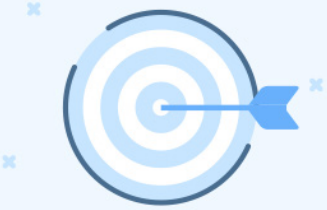
BIOMANUFACTURING STRATEGY MEETING EUROPE 2022 | 11 OCT

Our Vision



To be a platform for creating life-saving therapies and to facilitate the creation of a completely patient centric pharmaceutical industry.

Our Mission



By encouraging key leaders and their companies to put the patient at the very heart beat of every innovation. Sharing valuable insights and strategies to assist in the discovery, development and commercialisation of life saving therapies.

Our Unique Meeting Format

ROUNDTABLE DISCUSSIONS

These interactive and informal discussion groups are the hallmark of the meeting. The brightest minds in the industry are brought together in 60-minute sessions that enable participants from all over the world to share ideas, challenges and lessons learned.

PERSONALISED AGENDA

Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time spent is focused and well-utilised.

INNOVATIVE SOLUTIONS

The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.

STRATEGIC NETWORKING

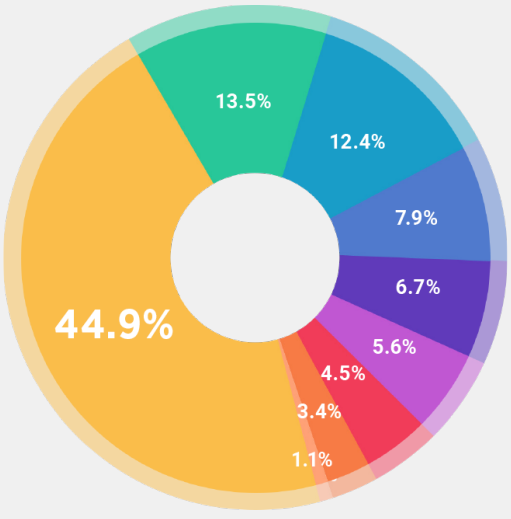
Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances to make lasting connections that benefit you.

BIOMANUFACTURING is continuing to evolve for the Life Sciences Industry through its shift and focus into more advanced biologic therapies such as Covid vaccine, cell & gene therapies, amongst others. Transitioning, whether through initiative or involuntarily from current advanced regulatory or select automation state to full automation, in preparation for Industry 4.0 is a reality that biotech companies and pharmaceuticals should face head-on.

WHY should you attend THIS MEETING?

- The topic discussions on how to align QMS with different global regulatory policies provide the participants an opportunity to gain vital information needed to attain quality-compliant products across countries.
- The shared challenge on raw material deficiency serves as a catalyst for the biomanufacturing key players to collectively resolve this matter. Gain pointers on how to effectively navigate digital transitions and automation leading to Bioprocessing 4.0
- Learn from case studies and success stories of other pharmaceuticals and biotech companies in establishing a manufacturing system in new modalities and achieving process excellence
- Obtain practical guide in interacting with CMOs to productively communicate and execute the organisation's manufacturing goals
- Discover innovative ways to attain flexibility in manufacturing conducive to future market demands
- Develop industry solutions and solve immediate challenges on upstream and downstream processing, quality & analytics (QMS, QbD, PAT), Bioprocessing 4.0/digital transformation, new modalities manufacturing, and flexible manufacturing
- Collaborate with different solution providers to discover the latest tools or techniques to amplify manufacturing excellence

SENIORITY OF ATTENDEES



- Director Level
- Department Head
- Other
- C-level
- Academia
- Scientist
- President / VP
- Team Lead
- Manager

Facilitator Faculty

Uwe Buecheler
Senior Vice President, Head of Business Units, Biopharmaceuticals
Boehringer Ingelheim

Nora Eifler
Director DSD Project Managment CH, Drug Substance Development Biologics
Novartis

Christoph Herwig
Full Professor - Senior Advisor Bioprocess Technology
Tu Wien

Lars Nieba
Chief Executive Officer & Chief Technical Officer
Nordic Nanovector

Lorenz Rindisbacher
Senior Director, Head of Site Quality
CSL Behring

HOW HAS OUR Strategy Meetings Benefit The Life Science Industry

> *It was an excellent experience I really enjoyed the format. I like the fact that it was a relatively small group, so very open discussion, people were sharing very direct and open way."*
>
> **Thibaud Stoll** - *Senior Vice President, Head Global Biotech Manufacturing & Development*, **Merck**

> *We're basically touching the needs of the industry, to understand where we are going in the future and there are many people and senior position in industry that can advise and share their knowledge and their approaches which helps you then to decide yourself which path you know going forward future."*
>
> **Kurt Reichen** - *VP, Technical Operations*, **PaxVax Berna GmbH**

WHO SHOULD ATTEND?

- Chief Executive Officers
- Senior Vice Presidents
- Executive Vice Presidents
- Vice Presidents
- Global Heads
- Directors
- Executive Director

RESPONSIBLE FOR:

- Quality
- Quality Operations
- Biomanufacturing Operations
- Quality Risk Management
- Process Research & Development
- Bioprocess R&D
- Validation Manufacturing Science & Technology
- Process Design
- Technical Operations
- Product Supply
- Quality Assurance
- Quality Compliance

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Hamilton Process Analytics offers complete measuring solutions for Biotech & Biopharma process applications in R&D, Pilot Scale and GMP production, such as intelligent sensors for pH, dissolved oxygen and CO2, conductivity, viable and total cell density. Our products are characterized by innovative features, proven quality and outstanding performance, backed by over 30 years of engineering and manufacturing expertise.

VISIT WEBSITE

Established in 2016 in Shenzhen, China, **Cheerland Biotechnology (CLB)** aims to become a leading biologics CDMO provider in the world. Led by an international team with extensive industry experiences, CLB provides global biopharma clients with top-line equipment including the first 15kL bioreactor in China, robust process design, and compliance with cGMP standards and global regulatory requirements. We also offer our clients flexibility in payment through forming joint ventures or Dedicated Bioreactor leasing. Our mission is to make biomedicine affordable and accessible to worldwide patients through technological innovations and large-scale commercial production. Cheerland Biotechnology, the World's Local CDMO.

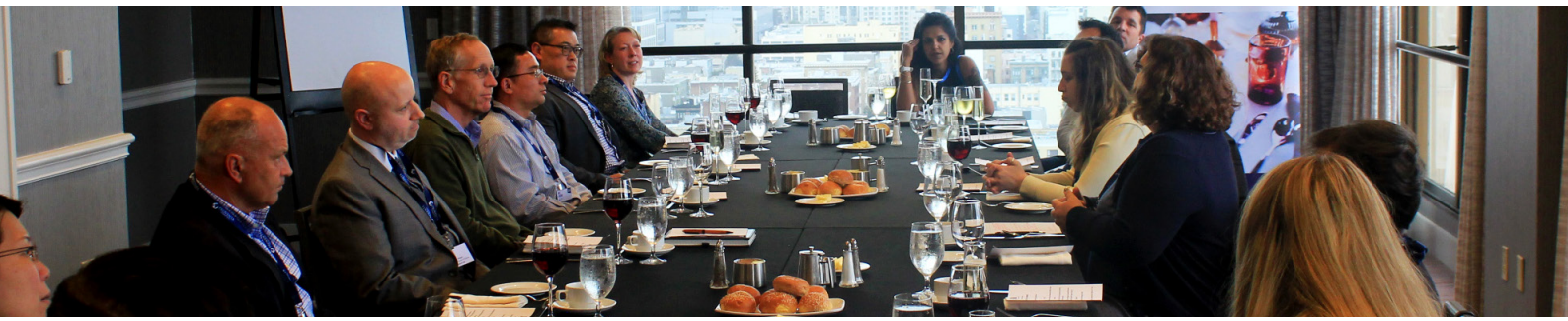
VISIT WEBSITE

DataHow is a spin-off company from ETH Zurich focusing on industry 4.0 software for the pharma and chemical industry. DataHow's model-based software solutions are used to support decision taking and automation for manufacturing of complex products, e.g. biopharmaceutical drugs.The central element of DataHow's digital technology is the combination of engineering know-how and cutting-edge machine learning techniques. The company's value proposition is to substantially reduce resources in process development and risks in manufacturing. Since creation in 2017, more than 10 of the largest 20 big pharma companies are using DataHow's technology. The DataHow team of 45 team members operates on three continents. By 2026 DataHow targets to be a central service and product provider of industry 4.0 technology for biopharma manufacturing.

VISIT WEBSITE

Optimal Industrial Technologies has more than 30 years' experience in the automation and optimisation of control and data management systems for the pharmaceutical, biotech and life science industries. Our PAT Knowledge Management software platform, synTQ®, enables real-time process monitoring and the control of critical quality attributes, non-invasively, to facilitate Quality by Design (QbD) via Process Analytical Technology (PAT). The demands being placed on manufacturers in relation to production costs, product quality and business sustainability is ever increasing. We strive to deliver measurable improvements in these target areas.

VISIT WEBSITE



Global Sponsorship Opportunities

Proventa's end-to-end consulting division gather real-time business intelligence on the industry's **needs, challenges, budgets** and **investment areas**. We combine this information with your specific needs to enhance your business development strategy. With the wealth of intel we provide, Proventa guarantees tangible results for your business within twelve months of the event.

For Sponsorship Opportunites please contact:
SPONSORSHIP TEAM: info@proventainternational.com | +44 (0) 2070961222

How it Works?

BIOMANUFACTURING STRATEGY MEETING EUROPE 2022

11 OCT

Real insights are shared in conversations, not lectures. That's why our unique **roundtable** format guarantees real learning and ensures you only attend discussions that deliver value to you.

Join as many as four roundtable discussions, each with up to 20 other subject experts, networking with top-level peers in an informal, relaxed and sociable environment.

Simply follow the steps below to select your roundtable discussions and we'll create your own personalised agenda for the day:

01

EXPLORE THE FULL AGENDA

Select which roundtable discussions you would like to join. Our sessions are divided among 4 themed tracks for easy selection - you can choose to join any session you like.

02

COMPLETE YOUR SCHEDULING FORM

Select your preferred roundtable discussion for each time slot. We will send this form out via email a few weeks before the event - be sure to get your first choice by completing the form quickly.

03

ENJOY YOUR PERSONALISED EXPERIENCE

Join your selected roundtable sessions on the day. We will give you your personalised agenda containing the time and room assignments of your chosen roundtable discussions so you won't miss it.

Agenda at a Glance

Biomanufacturing Strategy Overview 11th of October, 2022 – Radisson Blu Hotel Zurich Airport

	TRACK 1	TRACK 2	TRACK 3	TRACK 4
TIME CEST	QUALITY & ANALYTICAL (QMS, QBD, PAT)	UPSTREAM/ DOWNSTREAM PROCESSING	BIOPROCESSING 4.0/DIGITAL TRANSFORMATION	NEW MODALITIES
08:00 - 08:30	REGISTRATION AND WELCOME			
08:30 - 09:00	OPENING KEYNOTE PRESENTATION An overview of biologics supplies also in light of the pandemic challenges and emergence of multiple new biologics modality			
09:00 - 10:00	Aligning Quality Systems With Evolving Global Health Authority Expectations	Exploring The Latest Revolution In Upstream Processing For Flexibility And Cost-Effectivity Leading To Higher Yields	Pharma 4.0: How To Effectively Integrate Advanced Process Control Based on Digital Twins Combined With Process Analytical Technology For Real-Time Release Testing (RTRT)	Addressing The Challenges In Manufacturing New Biologic Modalities: Viral Vectors, ADCs, RNA, and Cell Therapies To Build A Viable Commercial Production
10:00 - 10:20	NETWORKING / 1-1 MEETINGS			
10:20 - 10:40	NETWORKING / 1-1 MEETINGS			
10:40 - 11:00	NETWORKING / 1-1 MEETINGS			
11:00 - 12:00	Embracing The Best Strategy To Mitigate Risk And Achieve Product & Process Consistency In Place Of External Conditions Such As The Pandemic, Changing Regulations, Or Other Unseen Constraints	Looking Into Highly-Effective Tools And Techniques To Maximise Quality Output In DSP Processing	Exploring The Opportunities To Build A Cost-Effective GMP Cloud Computing Without The Need To Sacrifice Data Integrity	Understanding The Crucial Part Of Biomanufacturing To Lessen The Cost Of Advanced Therapies
12:00 - 13:00	NETWORKING LUNCH			
13:00 - 13:30	KEYNOTE PRESENTATION			
13:30 - 13:50	NETWORKING / 1-1 MEETINGS			
13:50 - 14:10	NETWORKING / 1-1 MEETINGS			
14:10 - 14:30	NETWORKING / 1-1 MEETINGS			
14:30 - 15:30	Integrating New Concepts On Real-Time/ Batch Release, Virtual Management And Quick Quality Decisions	Escalating Biologics/Candidate Development Through Intensified Cell Culture Process	Dissecting The Use Of Single-Use Technology In Large Scale Production Of Biological Products	Squaring the circle' – how to get fast to the clinic with nearly final product quality
15:30 - 16:30	DRINKS & CANAPES RECEPTION			

ADAPT IDEATIONS

IN PARTNERSHIP WITH:

PROVENTA INTERNATIONAL

DATE

Monday, 10th October 2022

VENUE

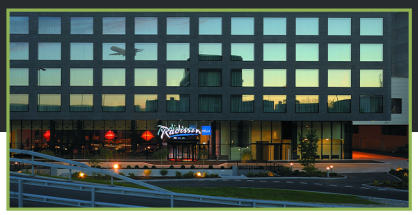
Radisson BLU

Radisson Hotel Zurich Airport

STRATEGY DINNER

The global pandemic has been a major disruptive force of change putting forth the critical role of data analytics; can Active Tracking replace Passive Tracking to achieve this goal today?

The global pandemic has been a major disruptive force of change while additional dynamics around data driven decision making bring pressures to adopt end to end visibility. These dynamics underline the mission-critical role of data capture and analytics to further improve effectiveness for all organizations in the supply chain. The question now is, what will it take to replace the older passive tracking manual intensive ecosystems within cold chain & bio-pharma to fully automated cloud based active tracking solutions without impacting the budget and operational overhead. And what is the relationship between technology, smart packaging, and the supply chain movers to adopt innovation at the speed of progress.



KEY TOPICS OF DISCUSSION

- What is the definition of Active Tracking vs. Passive Tracking
- The impact today of Active Tracking and the intrinsic value it brings over current non-connected solutions
- The importance of collaboration between smart packaging, innovative technology, and the symbiotic relationship to cold chain distribution
- What does advanced analytics mean to your decision making and are you ready to integrate at governing level to transform monitoring
- The market says by 2025 50% of all global supply chain will be utilizing Active tracking in some capacity, do we agree 2025 is realistic sooner/later
- What will be the largest hurdle to overcome, budgets or change management

KEY OPINION LEADERS

Jody Radoff — CRO, Adapt Ideations
An 18 year business development expert from leading global sales organizations across multiple industries brings his strategic leadership to Adapt Ideations. Jody has driven world class teams driving revenues into the 100's of million. As an honors graduate with a BA in Communications and Journalism from the University of Arizona, Jody is driven and through his strong work ethic is empowered to drive results through actions allowing business goals to be greatly achieved. As CRO, Jody is responsible for Adapt Ideations U.S. and EU expansion and providing oversight to global sales operations. Jody is dedicated to listening to our clients and connecting with them to assist them in reaching their company's goals & visions.

Prashanth Dharawath — CEO (Co-Founder), Adapt Ideations
With a degree in Aerospace Engineer from IIT Bombay, Powai (Mumbai, India), Prashanth is one of the co-founders of Adapt Ideations. Apart from heading the Asia Operations for Adapt Ideations, Prashanth has in-depth knowledge of Narrowband Internet of things technology, Industrial Robotics and Self-Driving vehicles. Aeromodelling and embedded systems design are his favorite hobbies.

Anirban Gupta — Director (Co-Founder), ANZ
Anirban has a strong background in IT & leadership roles across the FMCG and supply chain solutions sector. Anirban is a Harvard Business School alum having completed his executive MBA specialising in leadership and innovation. His experience and knowledge led him to form Adapt Ideations with Prashanth & Sai and has enabled Adapt Ideations to become what it is today.

Paul Della Villa — Director Digital Solutions Cold Chain Technologies (Global Leader of Cold Chain Packaging and Covid-19 Vaccine Packager), Cold Chain Technologies
Head of global new innovation solutions for Cold Chain Technologies. Paul is central to CCT's innovative packaging solutions to revolutionize cold chain management. An MBA graduate with 15+ Years of experience delivering quality results in the cold chain industry. Extensive experience in the international business arena specializing in new utilizing IOT and SAAS technologies to bring new products to market and developing business strategies around these technologies.

ABOUT ADAPT IDEATIONS

Adapt Ideations is a leading innovator of asset tracking and monitoring solutions designed for the global Cold Chain and Bio-Pharmaceutical industry. Their mission is to design and build tailored, vertically-integrated asset intelligence solutions for regulated industries to enable greater visibility, asset intelligence and compliance helping simplify everyday asset management through automated technology. With innovation at the forefront of their solutions, we tackle challenges that matter and we're doing it with diverse teams of amazing people all over the world. Adapt Ideations works with a range of clients globally in the U.S, Europe, Asia, ANZ, and the APAC region.

CONTACT Genelyn Amorillo ga@proventainternational.com +1 (617) 4315492 ext 327 www.proventainternational.com

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STRATEGY DINNER

"Smart PAT" (PAT = Process Analytical Technology).

Biopharmaceutical manufacturing is a notoriously complicated process. A major challenge in this process is the product itself - particularly for biologics manufacturing. Proteins are highly complex molecules with many closely related, but functionally different, variants., These realities can make analysis and control difficult. Traditional quality control methods are over-reliant on lab work for process sampling and analytics: often, labs, their location, capacity and the costs associated with them act as bottlenecks. Improving quality controlprocesses requires a true disruption of the traditional in-lab work with an advancement to smart quality control. Smart quality control shifts quality and performance monitoring to the shop floor to enable in-line monitoring, automated process control, and real-time release. This is achieved through harnessing cutting-edge technologies to realize increased cost-efficiencies throughout the supply chain.

Attendees will be able to address these issues and the innovations solving them, such as:

- New real-time measurement technologies that overcome the challenges of durability, specificity, and speed to measure PAT Critical Process Parameters and Key Performance Indicators during the process.
- Progressing digitalization to enable innovative process analytics (soft sensors), advanced process control (e.g. digital twin simulation), preventative maintenance, and asset management.

AGENDA

17:15–18:00	REGISTRATION, NETWORKING & COCKTAILS
18:30-19:00	WELCOME AND INTRODUCTION
19:00-20:00	ROUNDTABLE DISCUSSION **Title: Smart, connected and controlled: The new bioprocesses.** **Speaker:** Martin Mayer, Business Development Smart Engineering Services & Digitalization at ZETA GmbH • Digitalization and Smart Sensors for Bioprocesses • Use of measurement data for process optimization and closed loop control in operations • FDA take on ML / Advanced Process Control • Learnings and outlook
20:00-20:45	DINNER
20:45-21:45	ROUNDTABLE DISCUSSION **Title: Of plasmids, proteins and viral vectors: (soft) sensors for the production of novel biopharmaceutical modalities.** **Speaker:** Prof. Dr. Thomas Villiger, Prof. of Bioprocess Technology at University of Applied Sciences Northwestern Switzerland (FHNW) • Advantage of using simple and robust mechanisms over complicated mathematical models • Applying soft sensor triggered fed-batch platform for plasmid and protein production • Utilizing product quality control by biocapacity measurements in continuous cell culture processes • Discussing the capabilities and limitations of Raman spectroscopy
21:45-22:00	CLOSING REMARKS AND COFFEE

11TH OCTOBER 2022
TUESDAY

Radisson BLU HOTEL, ZURICH AIRPORT

Zurich Airport,
8058, Switzerland

Key Opinion Leaders

Prof. Dr. Thomas Villiger
Prof. of Bioprocess Technology
University of Applied Sciences Northwestern Switzerland (FHNW)

Thomas Villiger received his Msc and PhD in Chemical and Bioengineering from ETH Zurich. He gained more than a decade of industrial experience in bioprocess development and manufacturing at Merck, Novartis and Biogen. Since 2019, he is head of the Bioprocess Technology Laboratory at the University of Applied Sciences Northwestern Switzerland (FHNW) in Muttenz, Basel. His research focuses on upstream and downstream processes for antibodies, viral vectors, and other complex biologics, with particular emphasis on the application of process analytical technologies and data science tools to develop new manufacturing strategies, intensify processes, and control product quality.

Martin Mayer
Business Dev Smart Engineering Services & Digitalization
ZETA GmbH

Martin Mayer studied industrial engineering and business at the Technical University Graz. During his career a wide variety of senior roles from business development, research and development responsibility to general management challenged his skills within more than 15 years of interesting international work.
Within that time he was responsible for a number of projects in chemical industry, Pulp and Paper as well in biotech/ biopharma industry mainly in the field of digitization, data management, data analytics and model based optimization (DoE). Within the last years the growing awareness for digitalization topics within the pharma industry in combination with the harmonization activities (ICH Q8-Q12) have formed excellent boundary conditions for the establishment of new products and services, not only in the manufacturing sector, but especially in the field of R&D (Data Management in R&D, advanced control strategies for conti processes,...). Within ZETA he is responsible for business development in the field of Smart Engineering Services and Digitalization. Martin Mayer is member of the Steering Commitee for the Plug&Produce activities within the ISPE Pharma 4.0 program.

Contact Details:
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www.proventainternational.com

STRATEGY DINNER

Seamless global strategy for NCE development and API supply chain by optimizing technology, providing collective expertise, and reducing the delivery time and cost – an unmet need

The "heart of drug development" is to employ innovative technologies and collaborations across the globe, to assemble a powerful Drug Development Engine to accelerate candidates from drug discovery, PRD, scale-up through commercialization. The best way to increase the valuation of drug discovery and development pipeline and company's portfolio is to accelerate their milestones, reduce costs while maintaining quality. Today's CDMO industry is lacking a unique collective expertise in one place, utilizing ground-breaking technologies for the synthesis of architecturally complex molecules that can intercept any molecule, at any stage of development. Ultimately the know-how of phase appropriate execution, 'shaving' months off the development cycle time and a "one stop shop" of delivery of entire CMC management is an unmet need.

OCT 12
WEDNESDAY

Radisson Blu

Radisson Blu Hotel Zurich Airport

AGENDA	
17:00 - 18:00	Registration, Networking & Cocktails
18:00 - 18:15	Welcome & Introductions Swapan Bhattacharya, *Managing Director*, TCG Lifesciences Pvt. Ltd. Sanjoy Kumar Mahanty, Ph.D, *Vice President & Head of Business Development-NA*, TCG Lifesciences Pvt. Ltd.
18:15 - 19:15	Roundtable Discussion on: Big Pharma training with Biotech mentality to "Accelerate Molecules to Medicines" • Solving complicated CMC problems for NCEs adopting "First Time Right" techniques for First in Human studies • Reducing timelines by utilizing optimized "Drug Development Engine" • Leveraging innovative technologies embedded in Process Research and Development for API • Utilization of dynamic cost structure model • Tapping global resource pool • US management oversight operation • 24 hr/day for solving problems and deliveries • Smooth tech transfer for API in a global setting • Implementing collective expertise of globally based scientists, scientific project managers and engagement with client-based approach • Maintaining transparency and IP protection Joseph D. Armstrong, III, Ph.D, *COO*, TCG GreenChem, Inc. (NJ & VA, USA)
19:15 - 20:30	Dinner
20:30 - 21:30	Roundtable Discussion: Continue the topic Big-Pharma training with Biotech mentality to "Accelerate Molecules to Medicines" Subho Roy, Ph.D, *Vice President - Business Head*, Clinivent Research Pvt. Ltd, A 100% subsidiary of TCG Lifesciences
21:30 - 22:00	Closing Remarks, Coffee & Cognacs Vishal Rajput, Ph.D, *Vice President, Business Development*, TCG Lifesciences Pvt. Ltd. Dr. Gopal Sirasani, *Associate Vice President*, TCG GreenChem

KEY OPINION LEADERS

Swapan Bhattacharya - *Managing Director*, TCG Lifesciences Pvt. Ltd.

Swapan Bhattacharya is the Managing Director of TCG Lifesciences (TCGLS) and is responsible for the executive leadership and overall management of the company. He co-founded TCGLS in 2001 and has taken the Company to a global leadership position in the research services space. He is also a key member of the Governing Council of the TCG Centers for Education and Research in Science and Technology, a not-for-profit institute in the process of spawning multiple centers of excellence in the frontier fields of translational neuroscience and oncology, AI and quantum computing. He has been associated with the TCG Group since 1995 and has spearheaded the group's investments in India and its entry into life sciences domains from 1998. His professional career has spanned across the globe for about 40 years. Prior to joining the Group, he has held positions with PaineWebber Inc. as Senior Vice President and as Consultant to the US Nuclear Regulatory Commission. Over the years, he has held leadership committee positions in US India Business Council, FICCI, AMCHAM and Assocham; several board positions; and received excellence awards. He holds a bachelor's degree in engineering from the Indian Institute of Technology, Kharagpur, a master's degree from the Virginia Polytechnic Institute and State University, U.S.A and an MBA from Kellogg School of Management, Northwestern University, U.S.A. He received the Lester Cunningham Award for academic excellence at Northwestern.

Sanjoy Kumar Mahanty, Ph.D - *Vice President & Head of Business Development-NA*, TCG Lifesciences Pvt. Ltd.

Dr. Sanjoy Kumar Mahanty is part of the core business development, account management, marketing & sales team in the USA. Dr. Mahanty has twenty-five years of expertise in scientific research, and extensive leadership experience in drug discovery & development process. Dr. Mahanty has been associated with TCG Lifesciences for over eight years. He has been highly successful in penetrating CRO/CDMO markets globally, and proven track-record in establishing the new business, and maintaining existing clients. He holds a bachelor's degree from Utkal University, and a master's of sciences (MSc) & PhD degree in Biochemistry from Jawaharlal Nehru University, New Delhi, India. Dr. Mahanty completed his Post-Doctoral Research Experience from Harvard Medical School, Boston, and University of North Carolina, Chapel Hill, USA. He has eighteen co-authored peer reviewed publications including one in the highly reputed journal CELL, one book chapter, and ten shared patents to his credit.

Joseph D. Armstrong, III, Ph.D - *COO*, TCG GreenChem, Inc. (NJ & VA, USA)

Dr. Armstrong is a high energy scientific and executive leader with 28 years of experience at Merck & Co., Inc. in Process Research, Formulation Development and Project Management with deep knowledge and experience of all drug discovery and development processes to support IND to NDA filings. As the Merck Preclinical Integration Lead (Process R&D, Formulation R&D, DMPK, Safety Assessment, and Clinical Supplies) for the merger with Schering Plough, created a multidisciplinary organization that leveraged development knowledge to accelerate identification of Preclinical Candidates and their rapid entry into the clinic and beyond. He led the cross-functional team that filed the drug Januvia™ for the treatment of type II diabetes in less than 4 years by executing new green and sustainable technologies and strategies. He led the Process R&D Team that discovered the novel asymmetric hydrogenation process for the preparation of Sitagliptin, the active ingredient in Januvia™ . This team received the Thomas Edison award, the EU IChemE Aztra-Zeneca Award for Green Chemistry and Engineering and the US Presidential Green Chemistry Challenge Award.

Subho Roy, Ph.D - *Vice President - Business Head, Clinivent Research Pvt. Ltd*, A 100% subsidiary of TCG Lifesciences

Dr. Subho Roy Joined the group in 2002 and has been one of the key leadership members responsible for the growth of the company. He holds a Ph.D degree from Indian Institute of Chemical Technology, working with Dr. A.V.Rama Rao, on synthesis of natural products of biological importance and subsequently spent few years at the University of Kansas, Lawrence, USA, working with Dr. Gunda Georg for his post-doctoral studies. He has more than 20 years of Industrial experience of progressing small molecules coming out of R&D through various phases of development and taking them all the way to commercialization. He is a specialist in new process development, optimization and various other aspects of CMC. Dr. Roy has several publications to his credit and holds several European and US patents. He has played a key role in conceptualizing and designing of the manufacturing facility, "Clinivent Research Pvt. Ltd.", a 100% subsidiary of TCG Lifesciences, which has successfully completed US FDA inspection.

Vishal Rajput, Ph.D - *Vice President, Business Development*, TCG Lifesciences Pvt. Ltd.

Dr. Vishal Rajput holds Masters in Chemistry from IIT Roorkee, he is a Ph.D in Medicinal Chemistry from CDRI Lucknow, and a Post Doctorate from Lund University, Sweden and University of Alberta, Canada. He also holds PG diploma in patent Law from NALSAR Law University, Hyderabad. He is a seasoned techno-commercial professional with experience in Pharma/Life science Industries spans across Business Development (CDMO), API-Sales, Project and Portfolio Management and in R&D from top-tier pharma and biotech companies like Syngene Intl Ltd. Merck and Sigma-Aldrich etc. His last assignment was with Shilpa Medicare Ltd. as Head of Global CDMO Business- Drug Substance and Drug Product. He also has cross value chain expertise and Business Development experience covering discovery, development and manufacturing services for small and large molecules (ADC, NCE, Carbohydrates, Polymer and peptide) API for global Innovator and Generic companies.

Dr. Gopal Sirasani - *Associate Vice President*, TCG GreenChem

Dr. Gopal Sirasani is the Associate Vice President of TCG GreenChem. He is responsible for key account management, marketing, and sales operations. He has been highly successful in establishing new business collaborations between biotech companies and TCG GreenChem/TCG Lifesciences. Dr. Sirasani is heavily involved in tracking the customer projects for CMC development, in terms of route scouting, process development, scale-up operations and cGMP/non-GMP campaigns to deliver for preclinical and clinical needs of the clients. Dr. Sirasani received his bachelor's in Chemical Technology, Masters in Drugs and Pharmaceuticals, Ph.D. in Synthetic Organic Chemistry at Temple University, Philadelphia, and Post-Doctoral training at Harvard University. In total, he has 18 years of academic and industrial experience.

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Event Day

OPENING KEYNOTE PRESENTATION

8:30 – 9:00 CEST

An overview of biologics supplies also in light of the pandemic challenges and emergence of multiple new biologics modality

Uwe Buecheler
Senior Vice President, Head of Business Units Biopharmaceuticals
Boehringer Ingelheim

ABOUT THE SPEAKER

Uwe Buecheler, joined Boehringer Ingelheim (formerly Dr. Karl Thomae GmbH) in 1991. During his time at Boehringer Ingelheim he held different positions in Biopharmaceuticals in CMC Development and Regulatory Affairs, Biopharma Operations, Biological Safety and Quality. In 2006 he was appointed site head for the Boehringer Ingelheim site in Biberach, Germany and thereafter 2010 got responsible for global Biopharmaceuticals Operations including sites in Germany, Austria, USA and China. In 2016 he took over the responsibility for the Biopharma Business Unit responsible for the growing BioXcellence TM contract manufacturing business as well as supplies of Biopharmaceuticals to Boehringer Ingelheim Human Pharma. From March 2022 Uwe acted as a Senior Advisor Biopharmaceuticals to the Board of Managing Directors of Boehringer Ingelheim. Uwe Buecheler, has conducted his Ph. D. in Molecular Biology at the University of Heidelberg and the Cancer research Center in Heidelberg. Prior to joining Boehringer Ingelheim he worked at Roche (former Boehringer Mannheim site in Penzberg). He has been awarded Professor h.c. at the University of Ulm, is chair of the Biopharma Cluster South Germany and member of various Advisory boards and (Bio-) Pharmaceutical Industry Associations.

END OF OPENING KEYNOTE

Event Day

TRACK 1:
QUALITY & ANALYTICAL (QMS, QBD, PAT)

Building Quality into products is the end-goal of every manufacturing process. The successful integration of QbD and PAT in the Quality Management System amidst challenging time is the focus of discussions in this track.

9:00 – 10:00 CEST

ROUNDTABLE 1:
Aligning Quality Systems With Evolving Global Health Authority Expectations

- Adopting methods to track new quality regulations across the globe
- Approaches undertaken by pharmaceutical and biotech companies in dealing with new guidelines, procedures, and regulatory trends in the EU, U.S. and rest of the world regions
- Identifying possible pitfalls in product excellence when dealing with heterogeneous global requirements

Lorenz Rindisbacher
Senior Director, Head of Site Quality
CSL Behring

ABOUT THE SPEAKER

Lorenz Rindisbacher has a PhD in General Microbiology from the University of Bern. Following postdoctoral studies in the U.S. and in Switzerland in various areas of molecular parasitology, biotechnology, molecular virology and bio-artificial organs, he held site and corporate quality and safety functions at the vaccine development and manufacturing company Berna Biotech/Crucell for over ten years. He subsequently joined Merck KGaA, as the Site Quality Head at Merck Serono's Biotech manufacturing site in Aubonne, Switzerland and as Merck Biopharma's divisional Head of Biotechnology Quality. Since June 2017, he is the Site Quality Head at CSL Behring AG, overseeing quality and compliance of human plasma products manufactured in Bern, Switzerland.

END OF TRACK 1

TRACK 2:
UPSTREAM AND DOWNSTREAM PROCESSING

Raw materials shortage, batch failures, and inconsistencies in the raw materials output are some of the common challenges in bioprocessing that continually confront the industry. Sessions discussing the techniques and tools to amplify yields, minimise batch fails, and the latest innovations in upstream and downstream summarises this track.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Exploring the Latest Revolution In Upstream Processing For Flexibility And Cost-Effectivity Leading To Higher Yields

- Determining factors in scaling the upstream process
- Defining the facility of the future in terms of increasing and prospective product portfolio
- Leverage the latest techniques and technologies to create a flexible and cost-effective upstream system

Lars Nieba
Chief Executive Officer & Chief Technical Officer
Nordic Nanovector

ABOUT THE SPEAKER

Dr. Lars Nieba is CTO at Nordic Nanovector, an innovative Biotech company in the field of Radio Immunotherapeutics. He has 20 years of leadership experience in the development of multiple pharmaceutical product candidates and innovative technologies, at Bayer and F. Hoffmann-La Roche Ltd.. He held leadership roles in technical development, manufacturing and clinical operations, he also was interim CEO of Nordic Nanovector. Dr Nieba gained a PhD from the Max-Planck-Institute for Biochemistry, Munich, and Institute for Biochemistry at the University of Zürich; and an executive MBA from the University of St. Gallen, Switzerland.

END OF TRACK 2

TRACK 3:
BIOPROCESSING 4.0 / DIGITAL TRANSFORMATION

With the progressing automation of the manufacturing process, achieving bioprocess 4.0 is not a far-fetched concept, afterall. This track discusses the strategies by which data-driven processing could further the industry alongside other innovations in the biomanufacturing realm.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Pharma 4.0: How To Effectively Integrate Advanced Process Control Based on Digital Twins Combined With Process Analytical Technology For Real-Time Release Testing (RTRT)

- **The business case:**
  - — Batch failures resulting in an average of $1-2B loss annually for large biotech and pharmaceutical companies. Understand how Pharma 4.0 can help to solve current manufacturing challenges
  - — Discuss the pros and cons of moving from a process-driven to data-driven manufacturing capabilities
  - — Identify key elements to enable RTRT, such as deployment of predictive analytics and digital twins
- **The technological needs:**
  - — Evaluate the industry's current level of preparedness to go full automation
  - — Determine practical strategies suitable to implement Pharma 4.0 in manufacturing using a well-built, organisation-wide digital transformation roadmap
  - — Understand factors to consider in choosing the appropriate data-driven software

Christoph Herwig
Full Professor – Senior Advisor Bioprocess Technology
Tu Wien

ABOUT THE SPEAKER

Christoph Herwig, bioprocess engineer from RWTH Aachen, worked in industry in the design and commissioning of large chemical facilities prior to enter his interdisciplinary PhD studies at EPFL, Switzerland in bioprocess identification. Subsequently he positioned himself at the interface between bioprocess development and facility design in biopharmaceutical industry. Since 2008, he is full professor for biochemical engineering at the Vienna University of Technology. The research area focuses on the development of data science methods for integrated and efficient bioprocess development along PAT and QbD principles for biopharmaceuticals. In 2013 he founded the company Exputec, which is now part of Körber Pharma, pioneering data science software solutions for the biopharma life cycle.

END OF TRACK 3

Event Day

TRACK 4:
NEW MODALITIES

As the manufacturing industry moves into sophistication, introduction of novel modalities at a rapid phase on advanced and biological therapies and products, give an unprecedented manufacturing paradigm. This section aims to address some of these pressing issues.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Addressing The Challenges In Manufacturing New Biologic Modalities: Viral Vectors, ADCs, RNA, and Cell Therapies To Build A Viable Commercial Production

- Enumerate the recurrent challenges encountered in producing Viral Vectors, ADCs, RNA, and Cell Therapies and their cause
- Discuss industry options in finding solutions to the manufacturing hiccups of each new biologic modalities mentioned
- Recognise the role of CDMOs in achieving process excellence in producing these new therapeutic methods

Uwe Buecheler
Senior Vice President, Head of Business Units, Biopharmaceuticals
Boehringer Ingelheim

ABOUT THE SPEAKER

Uwe Buecheler, joined Boehringer Ingelheim (formerly Dr. Karl Thomae GmbH) in 1991. During his time at Boehringer Ingelheim he held different positions in Biopharmaceuticals in CMC Development and Regulatory Affairs, Biopharma Operations, Biological Safety and Quality. In 2006 he was appointed site head for the Boehringer Ingelheim site in Biberach, Germany and thereafter 2010 got responsible for global Biopharmaceuticals Operations including sites in Germany, Austria, USA and China. In 2016 he took over the responsibility for the Biopharma Business Unit responsible for the growing BioXcellence TM contract manufacturing business as well as supplies of Biopharmaceuticals to Boehringer Ingelheim Human Pharma. From March 2022 Uwe acted as a Senior Advisor Biopharmaceuticals to the Board of Managing Directors of Boehringer Ingelheim. Uwe Buecheler, has conducted his Ph. D. in Molecular Biology at the University of Heidelberg and the Cancer research Center in Heidelberg. Prior to joining Boehringer Ingelheim he worked at Roche (former Boehringer Mannheim site in Penzberg). He has been awarded Professor h.c. at the University of Ulm, is chair of the Biopharma Cluster South Germany and member of various Advisory boards and (Bio-) Pharmaceutical Industry Associations.

14:30 – 15:30 CEST

ROUNDTABLE 3:
Squaring the circle' – how to get fast to the clinic with nearly final product quality

- How to identify CQAs early?
- How to set specifications for new modalities smartly?
- 'Fit for purpose' quantity & quality
- Virus and HCP removal – lessons learned from viral vectors

Nora Eifler
Director DSD Project Managment CH, Drug Substance Development Biologics
Novartis

ABOUT THE SPEAKER

Nora Eifler joined Novartis in 2007 as a Lab Head for DSP Development in Biotechnology, Basel. She has held positions of increasing responsibility within Biologics since, including Technical Project Leader for early phase biologics projects, and the cross-functional role of training lead for Technical R&D. After her role as Product Steward at ESO MS&T Biopharm Sandoz, where she was responsible for CPV implementation and continuous improvement for the commercial biosimilar Binocrit (EPO), Nora re-joined Technical R&D as Technical Project Leader for NCEs in 2015. For six years, she was leading early and late phase CMC teams for the development of parenteral and topical projects. For more than one year, Nora has been leading the group of DS project leaders, working in all development phases. Nora studied Biology at the University of Heidelberg, Germany. She holds a PhD in biophysics from the Biozentrum Basel, Switzerland, on high resolution electron microscopy of membrane proteins. Nora has three children and enjoys spending as much time as possible outdoors with her family.

END OF TRACK 4

END OF Biomanufacturing Strategy Meeting Europe 2022

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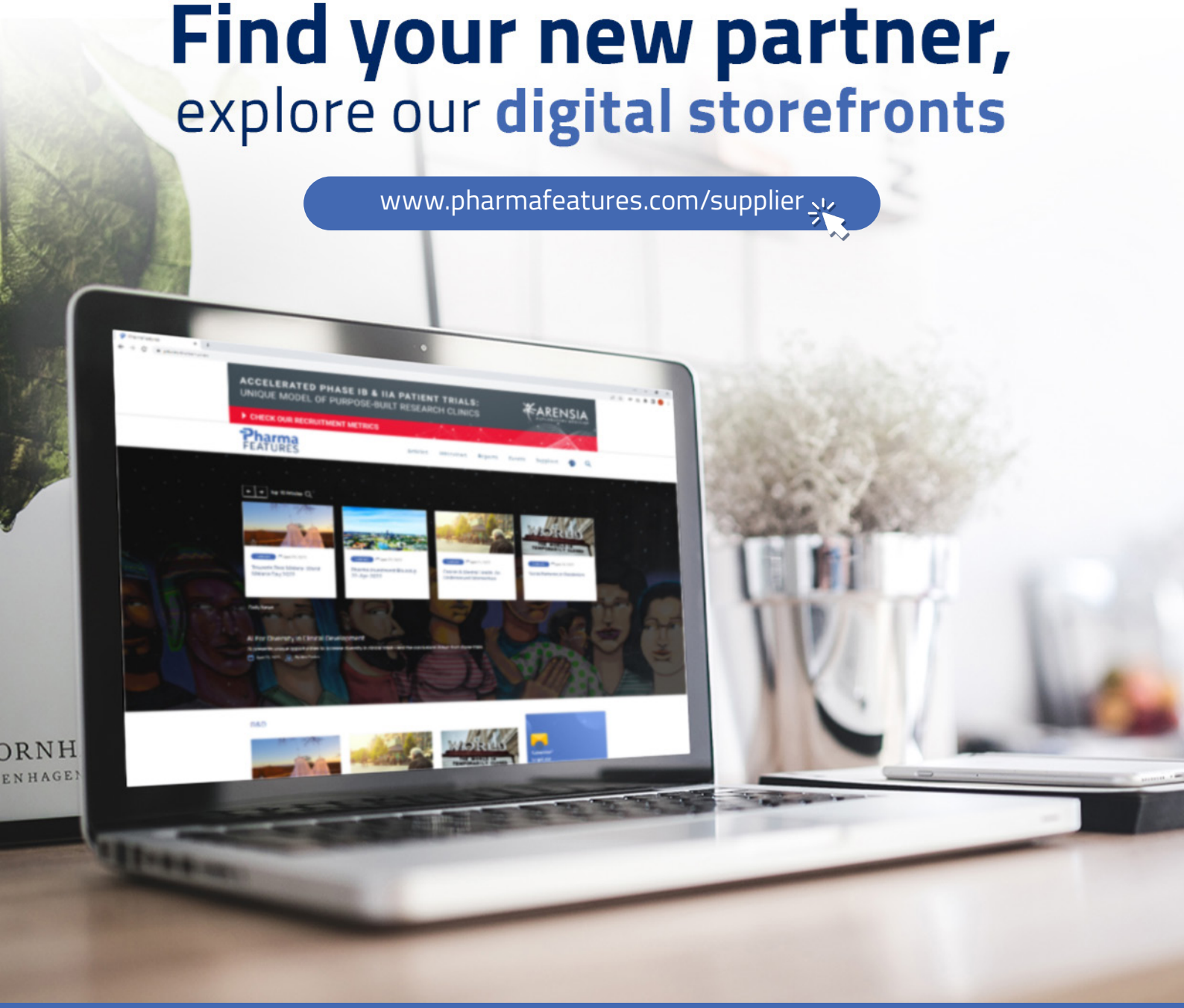

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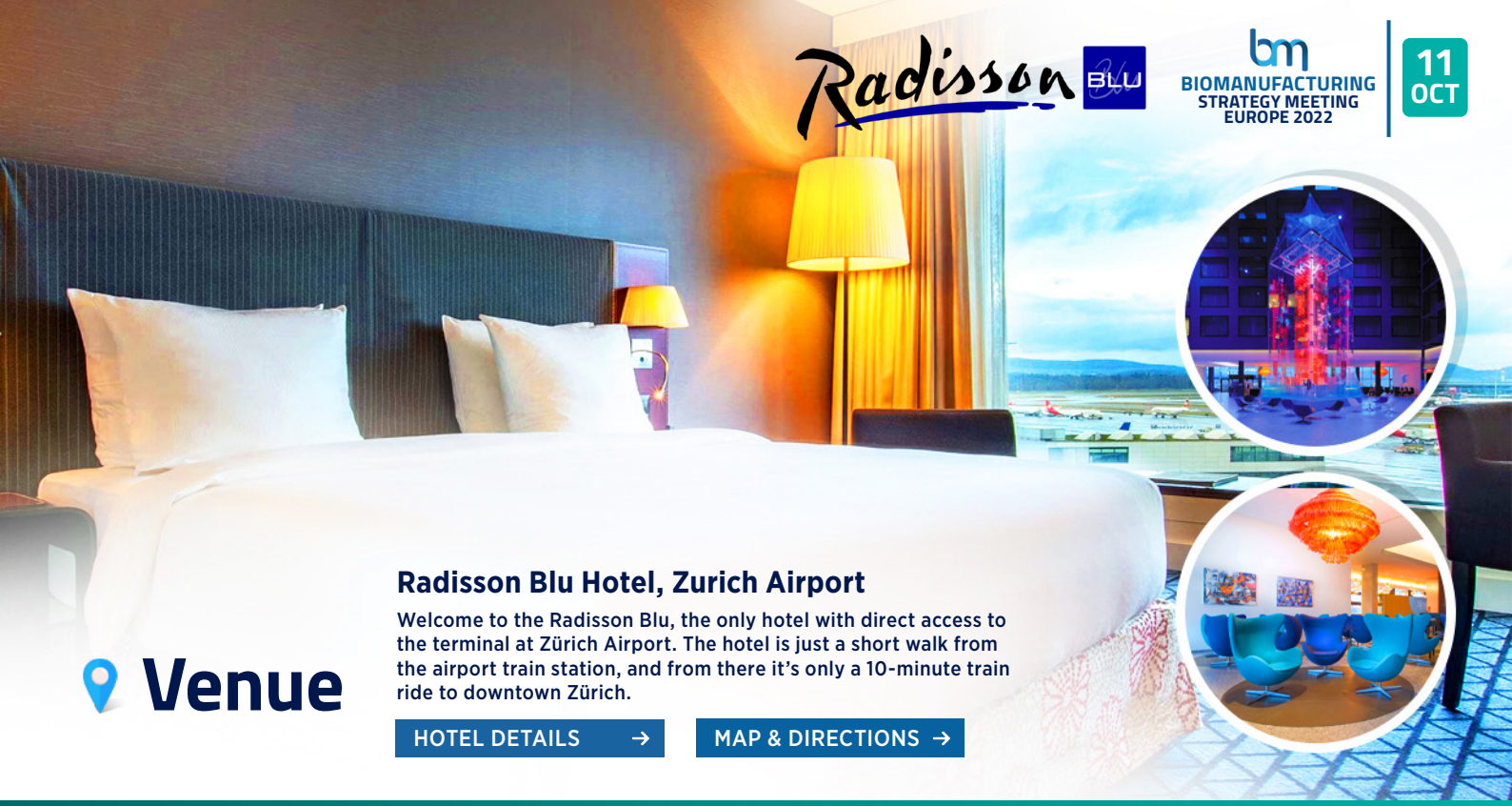

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11 OCT

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HOTEL DETAILS →

MAP & DIRECTIONS →

OUR FACE-TO-FACE MEETING IN OCTOBER & NOVEMBER 2022

Strategy Meeting Zurich and Boston

Zurich - Europe

OCT 10 MON — CLINICALOPERATIONS
Clinical Operations Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 10 MON — CLINICALTRIALSUPPLYCHAIN
Clinical Trial Supply Chain Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 11 TUE — BIOMANUFACTURING
Biomanufacturing Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 11 TUE — CELLANDGENETHERAPY
Cell & Gene Therapy Strategy Meeting 2022
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OCT 12 WED — REGULATORYAFFAIRS
Regulatory Affairs Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 12 WED — CHEMISTRYMANUFACTURINGCONTROL
CMC Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

OCT 13 THUR — MEDICINALCHEMISTRY
Medicinal Chemistry Strategy Meeting 2022
Radisson Blu Hotel Zurich Airport

Boston/Cambridge MA - US East Coast

NOV 08 TUE — ONCOLOGY
Oncology Strategy Meeting 2022
Le Meridien Cambridge

NOV 09 WED — CLINICALOPERATIONS
Clinical Operations Strategy Meeting 2022
Le Meridien Cambridge

NOV 10 THUR — REGULATORYAFFAIRS
Regulatory Affairs Strategy Meeting 2022
Le Meridien Cambridge

NOV 14 MON — DRUG DISCOVERY BIOLOGY
Drug Discovery Biology Strategy Meeting 2022
Le Meridien Cambridge

NOV 15 TUE — MEDICINALCHEMISTRY
Medicinal Chemistry Strategy Meeting 2022
Le Meridien Cambridge

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