12 OCT

Starts at 08:00am CEST

Radisson Blu Hotel Zurich Airport

CHECK OUT OUR STRATEGY DINNER On Pages 7

LIMITED SPACE ONLY BOOK NOW

REGULATORY AFFAIRS & CHEMISTRY, MANUFACTURING, & CONTROLS STRATEGY MEETING EUROPE 2022

The premier meeting for European Regulatory Affairs and CMC professionals

Featuring Industry Leaders and Decision Makers

Anna Löfgren
Vice President, Head of Global Quality
SOBI

Elisa Gomez-Reino Garrido
Senior Director, International Expansion, Global Regulatory and Quality
Alexion Pharmaceutical

Tamas Szolyak
Director Global Regulatory Science & Portfolio Management
Gedeon Richter

Dhananjay Jer
Director, Drug Product, Manufacturing and Supply
Fresenius Kabi

Andrea Casazza
Global Head, Chemistry, Manufacturing & Controls
Chiesi Farmaceutici S.p.A

Tarita Qveflander
Global Head, Strategic Sourcing
Sobi - Swedish Orphan Biovitrum AB

Urszula Ścieszko-Fic
Regulatory Intelligence Head
Gedeon Richter

OUR SPONSORS

ESKO BRAND SOLUTIONS · ASPHALION · Lumanity · SK pharmteco · DIATHEVA Bringing Research to Application · LAURUS Labs Knowledge . Innovation . Excellence · aragen · Raffles PharmaTech 莱佛士 · AGC Pharma Chemicals · Selvita · aspen API

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

Visit our website for future events →

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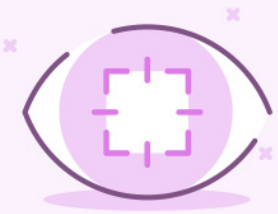
PROVENTA INTERNATIONAL

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

REGULATORY AFFAIRS & CHEMISTRY, MANUFACTURING, & CONTROLS STRATEGY MEETING EUROPE 2022

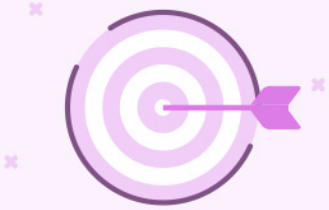
12 OCT

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.

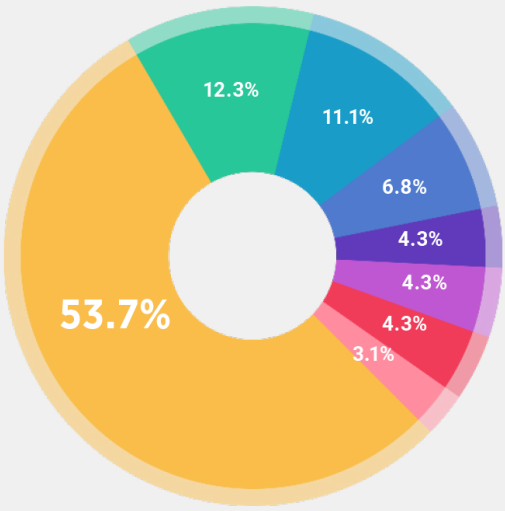
In the face of a rapidly changing regulatory landscape, the regulatory teams of pharmaceutical and medical devices companies are under constant pressure to adapt to evolving regulatory requirements, global COVID-19 health crises, and fast-moving advanced technologies. Responding to the change, doing more with less resources and time while mitigating the risk and enhancing compliance at the utmost level has never been more important to the regulatory teams. In this 5-track series of REGULATORY STRATEGY MEETING **(RIM/Data Management > Regulatory Operations/Regulatory Strategy > Medical Devices > Labeling, Artwork, Regulatory Content Management > Regulatory Submissions)**, we will deep dive into the critical areas of Regulatory Affairs that will help elevate collaboration to achieve new heights in giving patients faster access to approved therapeutics.

The journey to develop a product, move it towards health authority approval and eventual commercial success can be a long and arduous process. In conjunction, obstacles may impede this journey and risk a product development team's ability to reach their destination such as pharmaceuticals being denied approval due to the quality of the product and the manufacturing process failing to meet sufficiently high standards. Join the CMC STRATEGY MEETING and address the need to create and implement CMC strategies that ensure the product is high-quality, safe, effective and consistent, as well as approaches to expedite drug development to bring even more products to market.

Why this strategy meeting is a MUST ATTEND FOR YOU AND YOUR TEAM!

- Gain scientific understanding through product and process development to lifecycle expectations for global regulatory CMC submissions
- You will be better equipped to streamline approval and deliver uninterrupted product supply chains in the drug development process
- Evaluating current industry best practices in overcoming obstacles and seizing opportunities in CMC industry
- Address the increasing regulatory complexity in the development and manufacturing for worldwide markets, pandemic medicines, and new technologies

SENIORITY OF ATTENDEES



Facilitator Faculty

REGULATORY AFFAIRS & CHEMISTRY, MANUFACTURING, & CONTROLS
STRATEGY MEETING EUROPE 2022

12 OCT

Simon Cavanagh
Business Development Executive
ESKO

Beatriz Goñi
Regulatory Affairs Manager
Asphalion

Klara Dalmay
Director, RA International
PTC Therapeutics

Krisztian Fodor
Head of Global Regulatory Leads
Gedeon Richter

Elisa Gomez-Reino Garrido
Senior Director, International Expansion, Global Regulatory and Quality
Alexion Pharmaceutical

Anna Löfgren
Vice President, Head of Global Quality
SOBI

Koen Nauwelaerts
Regulatory Policy and Innovation Lead
Bayer

Urszula Ścieszko-Fic
Regulatory Intelligence Head
Gedeon Richter

Tamas Szolyak
Director Global Regulatory Science & Portfolio Management
Gedeon Richter

Samuel Baron
Director of R&D
SK biotek Ireland an SK pharmteco

Andrew T. Phillis
Chief Business Officer
Raffles Pharmatech

Andrea Casazza
Global Head, Chemistry, Manufacturing & Controls
Chiesi Farmaceutici S.p.A

Tarita Qveflander
Global Head, Strategic Sourcing
Sobi - Swedish Orphan Biovitrum AB

Tomaso Guidi
Head of Formulation and Process Development Unit - GTD Global Technical Development,
Chiesi Farmaceutici S.p.A

Dhananjay Jere
Director, Drug Product, Manufacturing and Supply
Fresenius Kabi

WHO SHOULD ATTEND?

- Chief Executive Officers
- Chief Medical Officer
- Chief Scientific Officer
- Senior Vice Presidents
- Vice Presidents
- Executive Directors
- Global Heads
- Directors
  Executive Director

RESPONSIBLE FOR:

- Cell Therapy
- Cell Engineering
- Biotherapeutics
- Regenerative Medicine
- Immune Deficiencies
- CART
- Cellular Immunotherapy
- Supply Chain
- Manufacturing
- AAV
- Lentivectors
- TCR Cell Immunotherapies
- mRNA/DNA
- CRISPR/CAS
- Regulatory Affairs
- CMC
- Safety & Compliance
- Quality Assurance/Compliance
- Labeling Management & Compliance
- RIM & Data Management
- Regulatory Operations

HOW HAS OUR Strategy Meetings Benefit The Life Science Industry

> *"I think the roundtable meeting format was very interesting and really encouraged a lot of participation by all of the participants and sharing of ideas and and much more so than any kind of lecture format would have."*
>
> **Adrian Dana** - *Vice President, Global Patient Safety and Risk Management*, Alnylam

> *"The one-to-one meeting is very good. It was an interesting experience, it felt a little bit like speed dating, I never done that before. It worked well, you had a chance to connect with someone for a good conversation."*
>
> **Richard Schaaf** - *Vice President, Technology & Operations*, Commonwealth Informatics

Our Sponsors

Co-host Sponsors

SK pharmteco specializes in the commercial and clinical production of APIs, Advanced Intermediates, Registered Starting Materials and Key Building Blocks. Our offerings include process R&D, analytical method development and stability, scale-up and optimization, validation and commercial production of small molecules as well as extensive Adeno-Associated Virus (AAV) and Lentiviral vector development and cGMP production capabilities. Our global operations include 7 cGMP manufacturing and development facilities across the US, Korea, Ireland and France. We also operate dedicated analytical services facilities. We have a strong record of environmental, health, and safety performance. All our plants have been successfully audited by global regulatory agencies including the FDA (US), EMA (Europe), PMDA (Japan), & MFDS (Korea). Extensive technology toolbox and ~1,000 m^3 of global small-molecule capacity plus 5,000 m^2 of viral vector facilities.

VISIT WEBSITE

DIATHEVA is an Italian leading contract development and manufacturing organization for the biopharmaceutical, biotech and medical devices industries. DIATHEVA's aspiration is to improve the quality of life and health of patients through its R&D pipeline of highly technological and innovative biologic therapeutics in oncology and infectious diseases areas. With our expertise in the biopharmaceutical field, we provide fully integrated and personalized services that range from process development to large scale production of biopharm products. DIATHEVA holds a state-of-the art GMP production facility authorized by EMA to produce and release biological APIs for preclinical and Phase I/II clinical studies. Our capabilities include:

- Expression system & cell line development and optimization
- Process Development and scale up
- Biophysical Characterization
- GMP APIs Release
- Production and characterization of master and working cell banks
- Analytical Development, Qualification, Validation
- Microbial cGMP Manufacturing
- ICH – Compliant Stability Programs

We work to ensure to our customers an acceleration for drugs to enter clinical trials.

VISIT WEBSITE

AGC Pharma Chemicals is an innovative Global Contract Development and Manufacturing Organization (CDMO), based in Spain and Japan, manufacturing small molecule Active Pharmaceutical Ingredients (APIs) and intermediates. Our purpose is to provide pharmaceutical companies with reliable, high-quality chemical compounds while fully complying with cGMP and EHS regulations. We offer agile and cost-efficient manufacturing processes and services, including fluorination. The result is our standing as a leader in this technology.

VISIT WEBSITE

Trusted partner for integrated Contract Development and Manufacturing Services
Laurus Synthesis is a leading Contract Development & Manufacturing Organization (CDMO) with a solid track record in supporting drug development and manufacturing programs of global pharmaceutical and biotech companies. Our state of the art facilities in India (Hyderabad and Visakapatnam) and experienced scientific teams have been supporting our customers for over 10 years in meeting the challenges in drug development programs from early phase development to commercial manufacturing. We are part of Laurus Labs — a Fortune 500 India company and one of India's largest and fast-growing pharmaceutical companies. Being part of Laurus Labs helps us leverage the power of rapid, elastic scale and remain consistently dependable.

VISIT WEBSITE

Founded in 2011, **Raffles PharmaTech** supports innovative pharmaceutical clients globally with custom small molecule contract development and manufacturing of drug substances. As a CDMO, we specifically offer services in route discovery, process development, optimization, scale-up, and cGMP manufacture of advanced intermediates (KSMs, RSMs) and API for all stages of development from early discovery (grams), pre-clinical, clinical, (kgs) through commercial ton quantities. With ~400 employees, Raffles operates two sites in Guangdong, China, an R&D site in Pingshan made up of 6,000 m^2 of synthesis and analytical development lab space and a 7-acre cGMP manufacturing site located in Dayawan Bay which was opened in 2021 with modular trains, ranging from 50L-5,000 L reactor sizes and capabilities in, cryogenics/high-temperature, hydrogenation equipment including Hastelloy, and two kilo scale facilities cGMP and non-cGMP. We have containment facilities to operate up to OEB3/4 control.

VISIT WEBSITE

Aragen Life Sciences (formerly, GVK BIO), is a leading R&D and manufacturing solutions provider for the life sciences industries worldwide. It offers end-to-end integrated or standalone solutions for small and large molecules. Established in 2001, the Company operates through a network of sites located globally with a team of 3000+ scientists and 450+ PhDs. Its expertise and experience have enabled over 450 customers in advancing their research programs from discovery through commercialization. Aragen's innovative mindset, infrastructure, flexible business models have enabled us to serve large pharma, biotech, agrochemical, animal health and performance chemical industries globally. Visit www.aragen.com for more details.

VISIT WEBSITE

Selvita was established in 2007 and currently employs over 900 professionals, of which over 40% hold a PhD degree. The Company research sites are located in Krakow (HQ) and Poznan, Poland, as well as Zagreb, Croatia. Selvita's international offices are located in Cambridge, MA, and San Francisco Bay Area, in the U.S., as well as in Cambridge, UK. Selvita provides state-of-the-art analytical services supporting pharmaceutical and biopharmaceutical companies at various stages of drug development and CMC processes by providing contract laboratory services for testing. We have a diverse analytical instrumentation and expertise portfolio, allowing us to meet varied demands, including testing of starting materials, drug substances, intermediates, and final products of small and large molecules. Selvita complies with GMP and GLP requirements to meet the highest industry standards.

VISIT WEBSITE

At **Aspen API**, we develop and manufacture high quality Active Pharmaceutical Ingredients to improve patients' lives worldwide. With quality, compliance, collaboration, and partnership at our core, we continuously strive to improve and provide the ultimate solutions for our customers. Sustainability is extremely important at Aspen API. We want to preserve this world for generations to come, therefore, we aim to minimize our carbon footprint. We use green technology and green solvents in our chemical processes where possible and strive for more environmentally friendly alternatives.

VISIT WEBSITE

Esko, part of the Danaher group, is the worldwide market leader within packaging and labelling software for workflow automation, quality assurance and online collaboration. Esko packaging and labeling management solutions helps pharmaceutical and life sciences companies manage their packaging preproduction specifications, regulatory content and artwork portfolio in a compliant and secure way, helping raise productivity, reduce time-to-market, lower costs, expand business and improve profitability. Esko offers a common online communications platform that: • Provides security and control • Enforces compliancy (GMP compliant) • Creates and maintains an audit trail of all activities • Brings control to the graphics and content process • Helps each department & function manage their tasks and approval management process proactively.
Company Website: https://www.esko.com/en/solutions/brand-solutions/webcenter

VISIT WEBSITE

Asphalion is an International Scientific and Regulatory Affairs consultancy, with offices in Barcelona, Madrid, Amsterdam and Munich. Our Regulatory Affairs, CMC, Technical and Scientific Writing teams offer comprehensive support to Pharma, Biotech and Medical Devices companies. We assist our clients in phases ranging from early development, throughout registration, until marketing and post-commercialization. Our consultants are experts in their field and are in direct contact with EU agencies (EMA and NCAs) for the development and implementation of new regulatory standards.

VISIT WEBSITE

Lumanity is a global company supporting the industry in the Development, Medical, Real Word Evidence, Commercial, Market Access, Pricing and Marketing areas. The clinical and regulatory team is composed of skilled scientific and regulatory consultants that deliver distinctive approaches to fulfill the complex business needs of the industry. Blending scientific expertise and business acumen, Lumanity integrates strategy, support, and analysis for regulated products to provide results-driven solutions with superior outcomes. Our experts have worked with the US FDA, European Health Authorities and agencies in the rest of the world. They have expertise in the fields of Rx and OTC medicines, medical devices, herbals, cosmetics and food supplements. With over 20 years of experience, our clinical and regulatory experts can support your European and global plans with: • Product regulatory, clinical and development strategies • Key Health Authority meetings (Scientific Advice, Oral Explanation, ...) • Regulatory submissions with EMA and EU Health Authorities (Briefing Package, ODD, CTA, MAA, ...) • Merger & Acquisitions (product & company Due Diligences, Competitive Landscape, ...) • Label compliance and claims support
Company Website: https://lumanity.com/solutions/medical-strategy-communications/

VISIT WEBSITE

How it Works?

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 6 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

Regulatory Affairs & CMC Strategy Overview 12th of October, 2022 – Radisson Blu Hotel Zurich Airport

	TRACK 1	TRACK 2	TRACK 3
TIME CEST	RIM AND DATA MANAGEMENT	REGULATORY OPERATIONS & REGULATORY STRATEGY	LABELLING, ARTWORK, REGULATORY CONTENT MANAGEMENT & REGULATORY SUBMISSION
ROOM ►	Luzern	St. Gallen	Uri
08:00 - 08:30	REGISTRATION AND WELCOME		
08:30 - 09:00	OPENING KEYNOTE PRESENTATION A Comprehensive View and Vision of the Future: Exploring the Current Regulatory Landscape and Learning Outcomes from the COVID-19 Pandemic		
09:00 - 10:00	Best Practices to Create and Maintain a Global Dossier to Support Global Submissions While Handling Effectively the Local Regulatory Requirements and Diverse Authority Questions	Accelerating Development, Registration, Submission, and Market Tracking Of Globally Unified Products and Create Profound Synergy Among Global Regulatory Authorities And Pharmaceutical Industry	Structured content management as a strategically important tool to drive the transition from paper to electronic labelling information for patients and HCPs
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 SOLUTION	How to overcome RIM challenges from a regulatory perspective ASPHALION		
12:00 - 13:00	NETWORKING LUNCH		
13:00 - 13:30	ESKO BRAND SOLUTIONS	KEYNOTE PRESENTATION End to End labelling with Automated Artwork and Regulatory Structured Content	ESKO BRAND SOLUTIONS
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	Leveraging End to End RIM Visibility Across Cross-functional Teams to Expand Regulatory Capabilities and Streamline Regulatory Processes Throughout the Product Life Cycle	Sharing Good Practices: Streamlining Global Submission Processes At A Global Company	Sharing experiences with the EU Clinical Trial Regulation and the use of CTIS
15:30 - 16:30	DRINKS & CANAPES RECEPTION		

See next page for Tracks 4-6

How it Works?

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Regulatory Affairs & CMC Strategy Overview 12th of October, 2022 – Radisson Blu Hotel Zurich Airport

	TRACK 4	TRACK 5	TRACK 6
TIME CEST	INTERMEDIATES & API	INTEGRATED DRUG DEVELOPMENT / OUTSOURCING	PROCESS RESEARCH & SCALE-UP
ROOM ►	Jura 1	Jura 2	Schwyz
08:00 - 08:30	REGISTRATION AND WELCOME		
08:30 - 09:00	OPENING KEYNOTE PRESENTATION A Comprehensive View and Vision of the Future: Exploring the Current Regulatory Landscape and Learning Outcomes from the COVID-19 Pandemic		
09:00 - 10:00		How Do You Create This Partnership for "One-Stop-Shop" with the CDMO in the Current Landscape (considering post-COVID etc.)? Which Factors Are Key?	Effective Scale-Up Strategies for Transition from Development to Manufacturing Scale
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 SOLUTION	How to Manage the Natural Uncertainties of Early Development HPAPI Compounds SK PHARMTECO		Building Safe and Scalable Processes: Strategies for and Advantages to Putting Process Safety Front and Center RAFFLES PHARMA
12:00 - 13:00	NETWORKING LUNCH		
13:00 - 13:30	ESKO BRAND SOLUTIONS	KEYNOTE PRESENTATION End to End labelling with Automated Artwork and Regulatory Structured Content	ESKO BRAND SOLUTIONS
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		CMC Complexities & Challenges in Drug Development	Product Process Research, Scale-up & Technology Transfer
15:30 - 16:30	DRINKS & CANAPES RECEPTION		

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, *VP, Business Development*, 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. Gopal Sirasani, Ph.D, *AVP, Business Development*, 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 - *VP, Business Development*, 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.

Gopal Sirasani, Ph.D - *AVP, Business Development*, TCG GreenChem

Dr. Gopal Sirasani is the Associate Vice President, CDMO Business Development & Technical Operations 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

A Comprehensive View and Vision of the Future: Exploring the Current Regulatory Landscape and Learning Outcomes from the COVID-19 Pandemic

- Discussing the effective outcomes we can use from the global regulatory success of COVID-19 vaccine development as a blueprint to plan, design and streamline future regulatory processes
- Accelerating the continuous collaboration among health authorities, regulatory teams, governments and pharma companies in order to foster life-changing therapies and reduce time to market time

Urszula Ścieszko-Fic
Regulatory Intelligence Head
Gedeon Richter

ABOUT THE SPEAKER

Urszula Ścieszko-Fic is a senior manager with over 20 years of experience in the area of regulatory affairs. She is a qualified pharmacist by education, finished postgraduate studies in clinical trials, pharmaceutical law, marketing and EMBA in Healthcare, gained professional experience in the Polish Agency on different positions, being the Polish CMDh member and managing Regulatory teams in pharmaceutical companies. Urszula is the Head of Regulatory Intelligence at Gedeon Richter Plc.

END OF OPENING KEYNOTE

KEYNOTE PRESENTATION

13:00 - 13:30 CEST

End to End labelling with Automated Artwork and Regulatory Structured Content

As regulatory scrutiny continues to propagate life sciences, it is vital for pharma companies to implement good practice guidelines into their labeling and artwork operations to prevent error deviations and decrease product recalls.

The presentation will introduce artwork and labelling best practices and solution that exist to help Pharmaceutical and medical devices companies of all sizes:

- Eliminate manual copy paste, with fewer handovers;
- Reduce the risk of mistakes;
- Get Better systematic traceability, transparency & predictability;
- Automate Artwork Creation and automatic output of all Documents and Variants;
- Create Right first time assets with increased efficiency.

All from a single end-to-end process for Regulatory, Labelling and Packaging content

Simon Cavanagh
Business Development Executive
ESKO

ESKO

ABOUT THE SPEAKER

Simon Cavanagh has 25 years of experience providing software solutions to global companies covering SAP, PLM and now Packaging Management systems. At Esko he is responsible for Strategic Pharmaceutical Accounts and looks after Esko's Pharmaceutical business across EMEA.

END OF KEYNOTE

Event Day

TRACK 1:
RIM AND DATA MANAGEMENT

The complexity in harmonizing processes, data, systems and workflows within a product life cycle is still one of the key challenges of regulatory teams. Unlocking the potential of disconnected data stored in disparate systems and technologies can help regulatory teams effectively navigate the complexity and expand capabilities. Pharma and medical device companies are constantly seeking innovative ways to align cross-functional teams, streamline regulatory activities, unifying systems through holistic view of regulatory information and process continuity. This track explores robust strategies in leveraging RIM by interconnecting quality datasets, regulatory processes, technology and people to enhance operational excellence and decision-making throughout the entire product life cycle.

9:00 – 10:00 CEST

ROUNDTABLE 1:
Best Practices to Create and Maintain a Global Dossier to Support Global Submissions While Handling Effectively the Local Regulatory Requirements and Diverse Authority Questions

- **How to manage the content of dossiers across various regions and through a full product lifecycle?**
- **Is having a global dossier a viable option?**
- **What can be considered as a core dossier?**
- **How to manage the various authority requests?**

Krisztian Fodor
Head of Global Regulatory Leads
Gedeon Richter

ABOUT THE SPEAKER

Dr. Krisztián Fodor is a regulatory science executive at Gedeon Richter Plc, a global specialty pharma company based in Budapest, Hungary. Currently he is managing the Global Regulatory Lead Unit, where he has broad oversight on the company's regulatory activities, both new developments and maintenance. He also gained experience at the Hungarian national competent authority, where he acted as a delegate to various EMA committees and working groups. He is committed to ensure fast and efficient regulatory procedures and excellent content management and interested to find innovative ways to fulfill the ever-changing regulatory requirements on a global scale.

11:00 – 12:00 CEST

SOLUTION FOCUS ROUNDTABLE 2:
How to overcome RIM challenges from a regulatory perspective

- **RIMS as trigger of digitalization in Regulatory Affairs**
- **Implementation of RIMS: who is the owner?**
- **An inter-teams approach for a successful implementation**

Beatriz Goñi
Regulatory Affairs Manager
Asphalion

ASPHALION

ABOUT THE SPEAKER

Beatriz Goñi
Expert degree in Quality for the Pharma Industry. PhD in Pharmacology. Pharmacy Degree by the University of Navarra.

- 10+ years' experience in Regulatory Affairs in Pharma Industry
- Quality Assurance Specialist
- CMC Expert
- Experience as R+D Project Manager focused on the development of drug candidates
- Experience in leading registration procedures (EU and ROW), scientific writing of regulatory documents for new submissions and letter of deficiencies
- Strategic Regulatory Advice. Review global regulatory submissions

14:30 – 15:30 CEST

ROUNDTABLE 3:
Leveraging End to End RIM Visibility Across Cross-functional Teams to Expand Regulatory Capabilities and Streamline Regulatory Processes Throughout the Product Life Cycle

- **Addressing organizational, data and process challenges to streamline regulatory activities and fully benefit from a comprehensive RIM strategy**
- **Exploring the best practices to accelerate the true implementation and utilization of AI/ML to automate workflows and reduce the length of timelines for faster approval**
- **Innovative approaches to align internal and external regulatory processes and IT systems to improve the speed, compliance and the reliability of the processes**

Tamas Szolyak
Director Global Regulatory Science & Portfolio Management
Gedeon Richter

ABOUT THE SPEAKER

Tamas Szolyak spent more than 20 years in the field of S&M having different leadership positions. Tamas, left the industry and worked in different HealthCare projects then moved to the field of regulatory, joined the national competent authority. Currently he is responsible for regulatory, PV and portfolio management in Gedeon Richter Plc. The combination of these professional areas provides great alignment opportunities in cross-functional operations both in development and LCM. Tamas act as Director Global Regulatory Science & portfolio Management.

END OF TRACK 1

Event Day

TRACK 2:
REGULATORY OPERATIONS & REGULATORY STRATEGY

Despite the unprecedented collaboration and communication globally over the course of COVID-19 crisis, there are still challenges in accelerating the process of bringing compliant products to global markets while adhering to country-specific registration/submission requirements to enhance the approval of potential life-saving therapeutics for patients worldwide. On the other hand, emerging technologies such as gene editing CRISPR technologies still remain unfavorable from a regulatory standpoint, and are not yet fully developed toward delivering all of their promises due to the unclear legal regulations at the national and international levels. This track aims to address the challenges in development, registration, submission, and monitoring strategies of globally unified therapeutics as well as persistent operational barriers to formulate frameworks and define regulatory strategies for emerging gene editing CRISPR technologies.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Accelerating Development, Registration, Submission, and Market Tracking Of Globally Unified Products and Create Profound Synergy Among Global Regulatory Authorities And Pharmaceutical Industry

- Discussing the persistent barriers to facilitate centralized procedures and labels aiding the simultaneous launch of new products in multiple markets
- Exploring the complexities in accelerating the process of bringing compliant products to global markets while adhering to country-specific registration/ submission requirements to meet diverse patient needs worldwide
- Discussing the latest updates and ongoing ICH processes to accelerate global harmonization through less cumbersome approval processes across countries, reduce product development time
- Building a steady bridge between emerging and developed countries in order to fill the gap in regulatory capacity and expertise
- Discussing the international agreements on rapid data sharing and harmonized standards to enable all aspects of product life cycle benefiting from increasing globalization

Anna Löfgren
Vice President, Head of Global Quality
SOBI

ABOUT THE SPEAKER

Anna Löfgren

Engaged and optimistic result-driven senior leader with adaptive mindset, integrity and passion for the patient and business. Strong skills in pharmaceutical quality, manufacturing and supply chain through product life cycle from development to commercial product with more than <25 years experience from AstraZeneca, Fresenius Kabi and Recipharm. Currently Responsible for the Global Quality organization within Sobi- a biopharmaceutical company focused on rare diseases treatment in the areas of haematology and immunology. Hold a BSc in Analytical Chemistry, MSc. Quality in Pharmaceuticals and biotechnology. Live in Stockholm, Sweden with husband and dog. Have 2 daughters who are studying in New York and Sweden.

14:30 – 15:30 CEST

ROUNDTABLE 3:
Sharing Good Practices: Streamlining Global Submission Processes At A Global Company

- Developing a roadmap from the earliest stages of research and development, through a sequence of global submissions, to market authorization/product maturation
- Exploring innovative tools and technologies to automate workflows, transform the submission creation and speeding up review process
- Strategies on adapting to the unpredictable requirements and responses of different regulatory authorities and increasing the quality and efficiency of data-driven regulatory submissions
- Identifying and implementing best approaches to better support global teams and submissions

Elisa Gomez-Reino Garrido
Sr Director, International Expansion, Global Regulatory and Quality
Alexion Pharmaceutical

ABOUT THE SPEAKER

Elisa Gomez-Reino is a senior leader in Regulatory Affairs at Alexion (AstraZeneca Rare Disease) where she leads the Regulatory Strategy for International Expansion of the Orphan Disease Portfolio. Previously, Elisa worked in several positions in other organizations, including Roche, MHRA, Biogen Idec, EMA in different positions in product development safety and quality. She graduated from Universidad de Santiago de Compostela with a degree in Pharmacy and has a MSc in Public Health from London School of Hygiene and Tropical Medicine.

END OF TRACK 2

Event Day

TRACK 3:
LABELLING, ARTWORK, REGULATORY CONTENT MANAGEMENT & REGULATORY SUBMISSION

Regulatory teams are shifting towards adopting structured content management strategies to integrate, orchestrate and optimize content workflows. Accelerating the optimization of content, labeling and artwork processes, enabling crossfuntional teams to work together efficiently, reducing manual steps and reusing regulatory content will be the main focus of this track. Here, we will address the regulatory challenges in authoring, reviewing, submission and compiling troves of documents and exploring the best practices in adoption of structured content authoring and reuse strategy to minimize errors and repetitive cycles.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Structured content management as a strategically important tool to drive the transition from paper to electronic labelling information for patients and HCPs

- Key drivers to accelerate the shift towards adopting robust data-driven regulatory structured content management
- Exploring content reuse strategies to drive efficiency and foster the transition from paper to electronic labelling information for patients and HCPs
- Addressing Patient's and HCP's needs by effective dissemination and communication of electronic labeling information

Koen Nauwelaerts
Regulatory Policy and Innovation Lead
Bayer

ABOUT THE SPEAKER

Koen Nauwelaerts holds a Master's degree in Pharmacy from Leuven University, Belgium and a PhD in Drug Development from the same university. Further he obtained an MBA degree from Vlerick Business School and completed the technology immersion program at MIT. Koen is currently working at Bayer as RA Policy and Innovation Lead. He joined Bayer as head of regulatory affairs and quality for the Belgium/Luxemburg region and previously has been active within MSD and Medicines for Europe in different roles in Regulatory Affairs and Quality. Besides his current role as RA Policy and Innovation Lead, Koen leads the internal global e-labeling initives at Bayer.

14:30 – 15:30 CEST

ROUNDTABLE 3:
Sharing experiences with the EU Clinical Trial Regulation and the use of CTIS

- Challenges with the training and implementation of CTIS use within the sponsor organisations
- Important aspects of prioritization of Clinical Trials to comply with the Clinical Trial Regulation
- Working models between the Sponsors and CROs
- First experiences with the initial Clinical Trial Applications in CTIS
- Planning for transition of studies into the CTIS system

Klara Dalmay
Director, RA International
PTC Therapeutics

ABOUT THE SPEAKER

Klara Dalmay is a MSc in biology and a lawyer by training and has 27 years of regulatory affairs experience, predominantly in international regulatory, CMC and clinical development in the pharma, biotechnology and CRO landscape. She is the CTIS Master Trainer of PTC Therapeutics as Sponsor organization. She leads the task force for the CTIS implementation to design internal processes and tools, and provide guidance as well as technical support to the CTIS users.

END OF TRACK 3

TRACK 4:
INTERMEDIATES & API

Successful completion of product development for active pharmaceutical ingredients (APIs) is a tremendously challenging task. This track aimed to identify how to maintain the quality and safety of APIs throughout its entire life cycle, risk mitigation strategies for drug shortage and exploring CMC challenges and potential solutions for rare disease.

11:00 – 12:00 CEST

SOLUTION FOCUS ROUNDTABLE 2:
How to Manage the Natural Uncertainties of Early Development HPAPI Compounds

- Process and technical challenges-planning for the unexpected
- Partnering with the CDMO for maximum flexibility
- Addressing uncertainty around safety profile of HPAPI

Samuel Baron
Director of R&D
SK biotek Ireland an SK pharmteco

SK PHARMTECO

ABOUT THE SPEAKER

Sam Baron is a PhD Chemist with expertise in production and technology transfer of intermediates and APIs, including HPAPIs. He has over 10 years' experience in developing, transferring, improving and troubleshooting small molecule API processes. Sam has been working at SK biotek Ireland's Swords Campus for 14 years; he is currently leading the R&D group.

END OF TRACK 4

TRACK 5:
INTEGRATED DRUG DEVELOPMENT / OUTSOURCING

Developing and distributing a safe and effective vaccine and therapeutic since the Covid-19 outbreak has garnered immense global interest. Exploring common CMC issues posed by the development of these products, CMC perspectives and relevant case studies that provide solutions to enable regulatory compliance, shorter review timelines, and support post-approval maintenance will be discussed in this track.

09:00 – 10:00 CEST

ROUNDTABLE 1:
How Do You Create This Partnership for "One-Stop-Shop" with the CDMO in the Current Landscape (considering post-COVID etc.)? Which Factors Are Key?

- What have we learned from the recent challenges in the CDMO space?
- How can the partnership become even better between the customer and the supplier (CDMO)?
- How do we prepare ourselves for the next challenge coming around the corner?

Tarita Qveflander
Global Head, Strategic Sourcing
Sobi - Swedish Orphan Biovitrum AB

ABOUT THE SPEAKER

Tarita Qveflander is an influential, passionate, and accomplished leader with 18+ years of pharmaceutical operations, supply chain, and procurement experience. With an extensive knowledge of global API/drug substance, drug product, and finished goods supply chains, including hands-on technical expertise and a deep understanding of quality and GMP regulations. Her natural networking ability expanded through living (in Finland, Sweden, Denmark, and Switzerland) and working in multiple countries and cultures (Europe, Japan, South Korea, Switzerland, and the US). She is fluent in six languages (Native Finnish, Native Swedish, Full Professional English, German, and Danish, and Limited Working Italian).

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14:30 – 15:30 CEST

ROUNDTABLE 3:
CMC Complexities & Challenges in Drug Development

- CMC resource management: balancing speed and knowledge in early and late phase projects
- A CMC dilemma: innovative solutions for challenging entities or platform solutions influencing entity selection?
- When drug delivery requires a device: combining formulation and device expertise can be an interesting adventure
- Learning from patients: how the concept of human factor studies can be applied in shaping product development
- The "magic equilibrium" between CMC in R&D and CMC in manufacturing operations

Andrea Casazza
Global Head, Chemistry, Manufacturing & Controls
Chiesi Farmaceutici S.p.A

ABOUT THE SPEAKER

Andrea Casazza is the R&D Global Head of Technical Development for Chiesi Farmaceutici S.p.a. He has more than 25 years of industry experience in developing pharmaceutical products for different therapeutic areas and patient populations via oral, injectable and inhalation delivery. Andrea managed diverse teams of analysts, formulators, engineers, chemists and device experts in large, small and medium pharma companies he strongly believes in the value of integrating the different disciplines in developing new products. In his career Andrea contributed to the development and approval of oral, injectable and inhalation products for both EU and US markets.

END OF TRACK 5

Event Day

TRACK 6:
PROCESS RESEARCH & SCALE-UP

Scaling up production remains one of the biggest challenges in pharma manufacturing. Designing processes and scale-up those processes from a process research, ensuring those processes are scaled-up efficiently. As such, it is important to ensure that the necessary steps and evaluations are carried out in order to manage complexities and reduce timelines. This track will take a closer look at effective strategies you will have to consider for a successful scale-up of your product's manufacturing process.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Effective Scale-Up Strategies for Transition from Development to Manufacturing Scale

- General Strategies and approaches to scale up processes (DS and DP) during the various phases of Drug Development
- Process Development toward Fast to clinic and Fast to Market approaches
- Technology Selections
- Regulatory dossier writing strategies
- Use of External Partners
- Process Management: Deviations, Changes, IPCs, Controls,
- Product testing and Specifications

Tomaso Guidi
Head of Formulation and Process Development Unit – GTD Global Technical Development, Chiesi Farmaceutici S.p.A

ABOUT THE SPEAKER

Tomaso Guidi studied Pharmaceutical Chemistry and Technologies at the University of Bologna (Italy). After graduating he started working at GSK and then Aptuit before joining Chiesi Farmaceutici in 2014. Tomaso Guidi covered several roles in the Pharmaceutical Development area, and he is currently Head of Formulation and Process Development at Chiesi Farmaceutici SpA. During his career, Tomaso worked on several dosage forms ranging from Solid Oral Dosage Forms, Inhalation Products, Lung Surfactants and Sterile Liquids, including biologics. His expertise is in the early phase of development, taking NCEs from preclinical stages and bringing them quickly to clinics and designing the proper formulation and process all along the drug development stages, up to the market and Life Cycle Management of pharmaceutical products.

11:00 – 12:00 CEST

SOLUTION FOCUS ROUNDTABLE 2:
Building Safe and Scalable Processes: Strategies for and Advantages to Putting Process Safety Front and Center

- Standards across the industry
- Unique challenges in CDMO world
- The tools a good developer must have
- Prioritization of testing (Don't always have to run everything on everything)
- Advantages of Flow Chem from safety perspective

Andrew T. Phillis
Chief Business Officer
Raffles Pharmatech

RAFFLES PHARMA

Raffles PharmaTech 莱佛士

ABOUT THE SPEAKER

Andrew Phillis studied Chemistry in his home country of New Zealand before moving to the Australian National University in Canberra to complete PhD research in natural products synthesis and synthetic methods development. He then joined GSK in chemical development where he worked on process development for clinical stage assets, commercial products and cost of goods improvement for legacy products, before co-founded Raffles Pharmatech, together with other pharma scientists with a shared vision of growing a company with process development and manufacturing expertise at its core.

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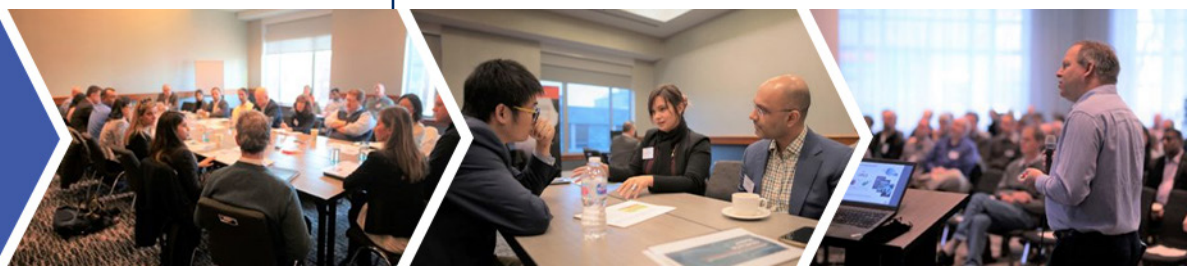

Event Day

14:30 – 15:30 CEST

ROUNDTABLE 3:
Product Process Research, Scale-up & Technology Transfer

- Formulation and Process Design, Process Characterization for establishing ranges, CQAs, KPPs, CPPs for the robust processes
- FMEA structure, Risk assessments, E&L expectations
- Combination Product challenges and troubleshooting, scale-up principles, facility compatibility, Managing equipment or facility changes

Dhananjay Jere
Director, Drug Product, Manufacturing and Supply
Fresenius Kabi

ABOUT THE SPEAKER

Dr. Dhananjay Jere has over 16 years of experience from early-stage to late-stage-commercial Biopharma drug product development, and is presently working with Fresenius-Kabi as a Director, Drug Product R & D, and Manufacturing for the Biosimilars. Prior to this, he has worked with Lonza as Scientific Ambassador, Senior Principal Scientist, Group Head. He has also worked with Hoffmann-La Roche on several positions in Switzerland and in the USA such as Principal Scientist, Strategic team leader, Group Leader. Dr. Jere has extensive experience in regulatory filings (IND/BLA/MMA) and regulatory interactions, and is a member of several consortiums. He has good experience in setting-up biopharma drug product development and manufacturing facilities. Dr. Jere has contributed to several (50+) conference talks, webinars, peer review publications, and patents on biological drug product development for intraocular, Cell therapy, and RNA-products. Dr. Jere has completed Executive MBA in International business from HSG, St. Gallen, Switzerland, and completed his PhD in Cell and Gene Therapy from Seoul National University, S. Korea. He has done his Bachelor's and Master's in Pharmacy from Mumbai, India.

END OF TRACK 6

END OF Regulatory Affairs & Chemistry, Manufacturing and Controls Strategy Meeting Europe 2022

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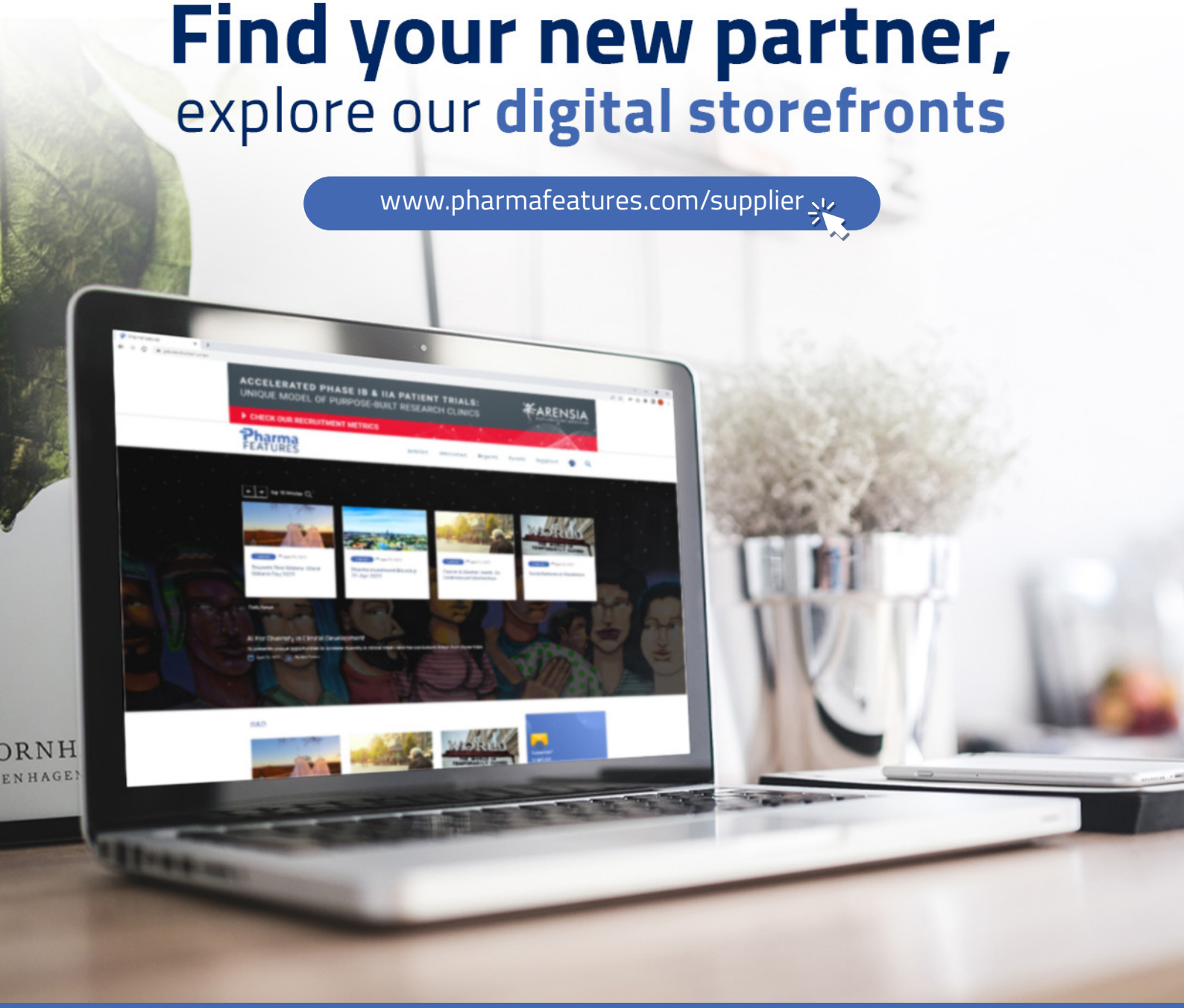

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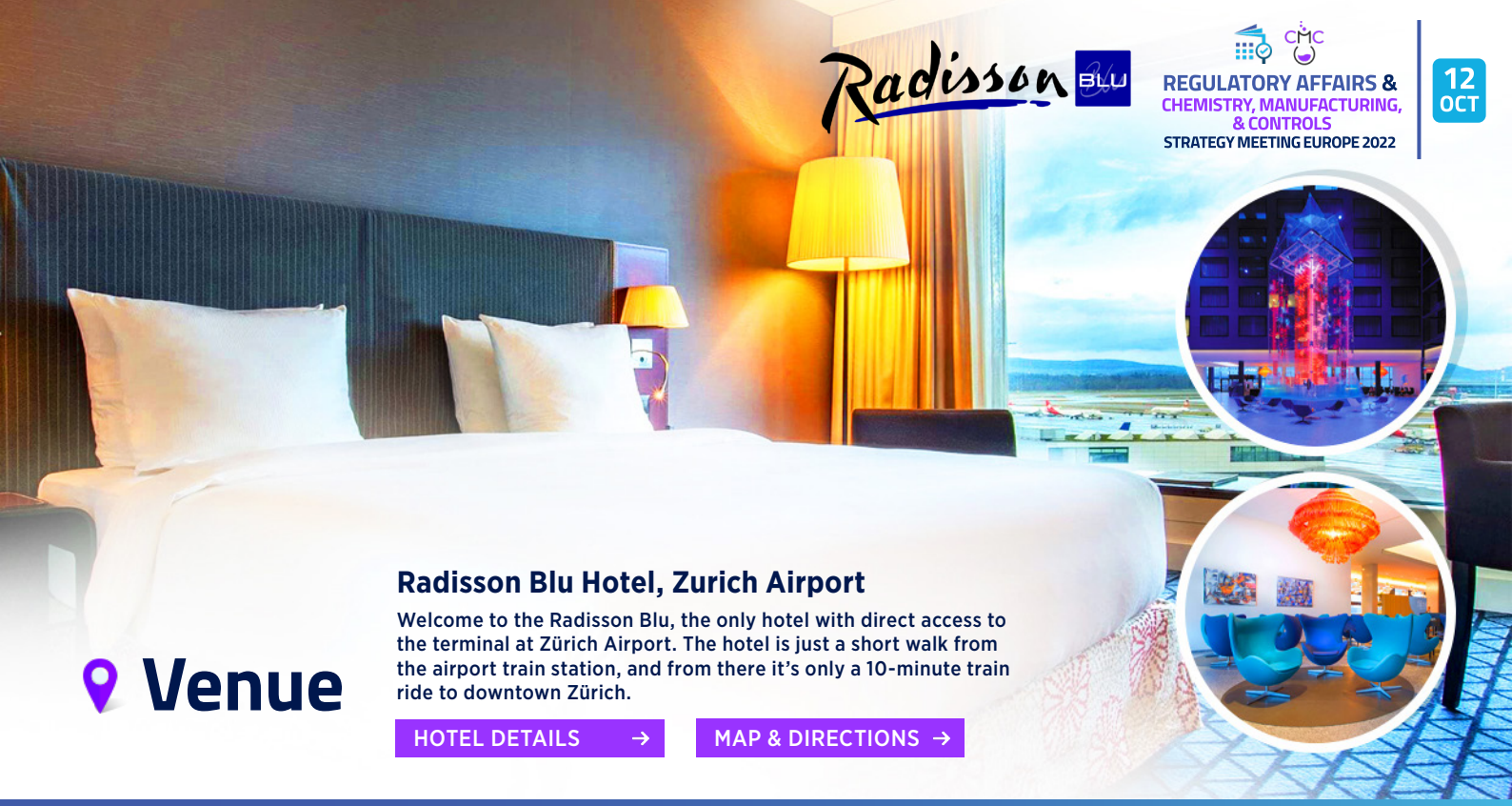

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OCT 11 TUE — BIOMANUFACTURING
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OCT 11 TUE — CELLANDGENETHERAPY
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OCT 12 WED — REGULATORYAFFAIRS
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NOV 08 TUE — ONCOLOGY
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NOV 09 WED — CLINICALOPERATIONS
Clinical Operations Strategy Meeting 2022
Le Meridien Cambridge

NOV 10 THUR — REGULATORYAFFAIRS
Regulatory Affairs Strategy Meeting 2022
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NOV 14 MON — DRUG DISCOVERY BIOLOGY
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NOV 15 TUE — MEDICINALCHEMISTRY
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