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**

CELL & GENE THERAPY

STRATEGY MEETING EUROPE 2022

Innovative Manufacturing, Clinical & Logistical Strategies to Boost Cell & Gene Therapy Efficacy and Accessibility to Patients

- Cell and Gene Therapy Vectors
- Emerging Biopharma
- Clinical Research
- Supply Chain
- Cell & Gene GMP Manufacturing
- CAR-T Cells
- TCR Immuno-therapies
- AAV Gene Therapy
- T Cell Immuno-therapies
- Process Research / Development

Featuring Industry Leaders and Decision Makers

Eric Halioua
Chief Executive Officer, President of the Board
PDC * Line Pharma

Steen Klysner
Chief Executive Officer
Amarna Therapeutics

Eduard Ayuso
Chief Technical Officer
Dinaquor

Dorothea Ledergerber
Chief Technical Officer
Tigen Pharma

Amir Goudarzi
Senior Director, Bioprocessing Technologies
Bayer

Peter Tiefenböck
Associate Director, Value Stream Leader PU Cell & Gene Therapy
Novartis

Michael Zaiac
Head of Medical Affairs Oncology Region Europe
Novartis

OUR SPONSORS

CRYOPDP a cryoport company · SanaClis · PELI BIOTHERMAL · aptamer GROUP · ROSA · CELLBOX THE LIVE CELL SHIPPER · 20 YEARS time:matters

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

Visit our website for future events →

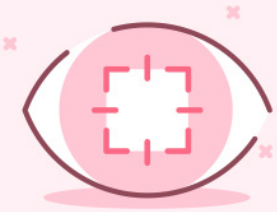
proventainternational.com
UK: +44 (0)20 3314 0100 | **US:** +1 (617) 614 0377
info@proventainternational.com
Proventa International
@proventaintl
@proventainternational
PROVENTA INTERNATIONAL

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

CELL & GENE THERAPY
STRATEGY MEETING
EUROPE 2022

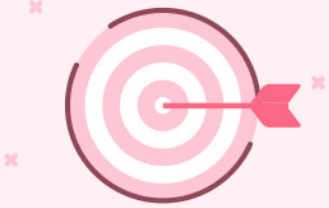
11 OCT

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

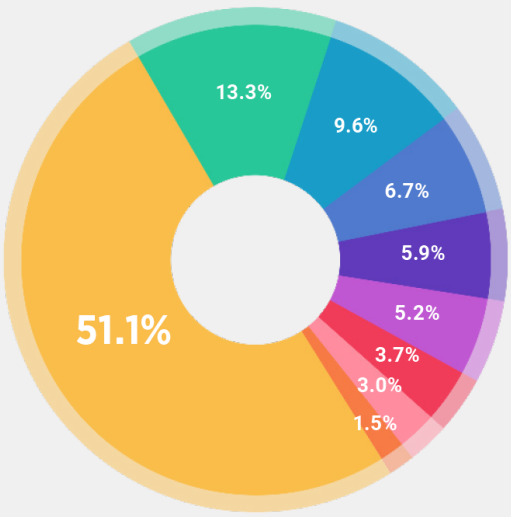
Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances to make lasting connections that benefit you.

CELL & GENE THERAPY It is undeniable that we are witnessing a revolution in therapeutics led by advances in regenerative medicine and, given their capacity to cure once considered incurable diseases, it is easy to understand how cell and gene therapies have contributed to this revolution. While this growth is exciting, the field has yet to overcome remaining challenges and keep up with continuous progress. The path to success is paved with technical and commercial hurdles that need to be overcome for them to achieve their full potential. An improved safety profile, development of allogeneic CAR-T therapies, reproducibility of high-quality batches are some of the factors amongst the others which will eventually determine their success. Our strategy meeting aims to address current challenges such as immunogenicity, scale-up, automation, and commercialization to create the infrastructure required for a widespread availability of cell therapy strategies

WHY should you attend THIS MEETING?

- Explore the future of cell-based immunotherapy: autologous vs allogeneic treatment
- Novel insights into the new class of CAR T-cells on the horizon that can target previously untargetable cancer drivers
- Investigate strategies on how to overcome AAV innate immunity barriers to further gene therapy development
- Discuss key considerations when designing clinical trials for rare diseases in gene therapy
- Establish robust and scalable manufacturing processes
- What are the specific features of cell therapy products that make their cold chains uniquely challenging?

SENIORITY OF ATTENDEES



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

Facilitator Faculty

Allan Van Konynenburg
Senior Director,
Global Depot Network
SanaClis

Feliks Kochan
Account Executive
Business Development
Manager
Peli Biothermal

Eduard Ayuso
Chief Technical Officer
Dinaquor

Giner Bjoern
MS&T Technical
Steward Cell and
Gene Therapy
Novartis

Ivan Gorbachov
Senior Director
Novartis Gene Therapies

Amir Goudarzi
Senior Director,
Bioprocessing
Technologies
Bayer

Eric Halioua
Chief Executive Officer
President of the Board
PDC * Line Pharma

Steen Klysner
CEO
Amarna Therapeutics

Dorothea Ledergerber
Chief Technical Officer
Tigen Pharma

Peter Tiefenböck
Associate Director,
Value Stream Leader PU
Cell & Gene Therapy
Novartis

I-Mei Yu
Principle Scientist,
RNA & Gene Therapy |
Drug Discovery |
Precision Therapy
Novo Nordisk

Michael Zaiac
Head of Medical
Affairs Oncology
Region Europe
Novartis

HOW HAS OUR Strategy Meetings Benefit The Life Science Industry

> *One-to-one meeting was useful that I could throw-in a lot of detailed questions and have clearer insights about offerings. I totally appreciate that."*
>
> **Sakthivel Sekar -**
> *Chief Executive Officer*, Sinopsee Therapeutics

> *I think in the small group setting where we were located a roundtable, it was really interesting to hear the perspective from the rest of industry."*
>
> **Serene Ong -**
> *Vice President, Commercial operations,Asia Pacific*, Marken

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

Intimate format events where senior leadership discuss the biggest challenges facing the industry.

Our Sponsors

Co-host Sponsors

CRYOPDP is the first choice courier for Life Sciences and Healthcare industries with more than 25 years of experience. Which has as its mission to improve the health of people around the world by providing global innovative temperature-controlled logistics solutions to the Clinical Research Community and Cell & Gene Therapy communities. CRYOPDP designs tailor-made solutions to secure the logistics of clinical trials and R&D samples, thanks to a team of temperature-controlled logistics experts and all the entities strategically located around the world. As the key reference partner in terms of customized, flexible and reliable logistic solutions, CRYOPDP services can meet all of your needs:

→ Comprehensive Life Sciences and Healthcare Logistics Solutions
→ Expertise in quality, cold chain and regulatory compliance
→ Dedicated account management and customer service
→ Innovative and flexible IT solutions

#DiscoverCRYOPDP at www.cryopdp.com

VISIT WEBSITE

SanaClis was founded in 2000 by seasoned industry experts, all of whom have had executive level positions in leading pharma companies and large global CROs. SanaClis is a full-service Global CRO with a fully integrated clinical supply chain, thereby offering a comprehensive range of end-to-end services for clinical trials. SanaClis has vast experience of successfully running studies for various sized sponsors, ranging from virtual biotechs through to top ten pharma companies, both in terms of its CRO services and Clinical supply services. In addition to being a full service CRO, SanaClis is one of the very few service providers with an extensive range of in-house logistics and clinical supply capabilities. SanaClis has a portfolio of privately owned GMP and GDP certified storage and distribution depots, strategically located across the EU and Eur-Asia.

VISIT WEBSITE

Peli BioThermal offers the widest range of temperature-controlled, thermally-protected packaging and service solutions to the global life sciences industry. The company's products are designed for use in Clinical Pharmaceutical, Cell & Gene, Clinical Trials and Commercial Pharmaceutical applications, as well as Air Ambulance and Military Medicine. We are dedicated to developing innovative products designed to fulfil the complex needs of the global life sciences industry. The company's customers benefit from its extensive expertise in ensuring that temperature stability is maintained throughout the distribution chain. The company also offers a complete portfolio of services, including Rental & Lease option, plus software to support end-to-end temperature-controlled packaging asset management.

VISIT WEBSITE

Aptamer Group develops custom affinity binders for use across the life sciences, using its proprietary Optimer® platform. Optimer binders can be used as antibody alternatives to offer novel or improved solutions for therapeutics, diagnostics, bioprocessing and analytical applications. Offering full platform compatibility, tuneable binding kinetics and high stability, Optimer binders are removing the barriers to innovation in the life sciences.

VISIT WEBSITE

Rosa & Co. was established in 2002 and is known worldwide for the creation of PhysioPD™ Research Platforms and Rosa Market Modeling. PhysioPD Research is a powerful component of modern drug development. It is a proven quantitative systems pharmacology (QSP) approach that complements the expertise and experience of clinicians, guides more effective experimental and trial design, and enables deeper understanding of empirical data. PhysioPD Research enables dramatically more effective learning about the connection of drug and disease mechanisms to relevant preclinical and clinical outcomes and supports more confident decisions at all stages in research and development.

VISIT WEBSITE

CELLBOX - THE NEW GENERATION FOR LIVE CELL SHIPMENTS
Cellbox Solutions is a young technology company developing and marketing innovative full service logistics solutions for the BioMedTech, Pharmaceutical and Academic sectors. Our flagship product, the Cellbox 2.0, offers the unique opportunity to incubate and cultivate cells and tissue during transport - saving time & effort - while maintaining the cell viability and improving the outcome of downstream applications and assays. As the market leader in normothermic atmospherically controlled shipping incubators, Cellbox is well positioned to meet the high quality demands that are associated with the logistics of ATMPs and other complex cell-based products.

VISIT WEBSITE

Exhibitor

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?

CELL & GENE THERAPY
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 5 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

Cell & Gene Therapy Strategy Overview 11th of October, 2022 – Radisson Blu Hotel Zurich Airport

TIME CEST	TRACK 1 CELL AND GENE THERAPY VECTORS	TRACK 2 CELL / GENE BASED THERAPIES	TRACK 3 CELL & GENE CGMP MANUFACTURING	TRACK 4 CLINICAL RESEARCH	TRACK 5 GLOBAL LOGISTICS & SUPPLY CHAIN
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	Addressing Challenges Posed in vivo by AAV Vectors: The Quest for the 'Perfect' Toolkit	iPSC-Derived Allogeneic Cell Therapies to address disease-specific challenges	Discussing Strategies to Increase Manufacturability of Allogeneic Cell Therapies	Enabling cell and gene therapy clinical development by addressing evidence generation and research reproducibility	Reworking logistics for cell and gene therapy
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	Addressing challenges in Vivo by AAV Vectors- Searching for the 'Perfect' toolkit	Autologous vs. Allogeneic Cells: Optimizing 'Off-The- Shelf' Therapeutics	Meeting the Manufacturing Challenges of Cell & Gene Therapies – To Buy Or Build?	Practical Consideration for Adoption, Accelerating and the Future of Cell and Gene Therapy SANACLIS	The importance of High Quality Temperature Controlled Packaging When Shipping Cell & Gene Therapies PELI BIOTHERMAL
12:00 - 13:00	NETWORKING LUNCH				
13:00 - 13:30	AFTERNOON KEYNOTE PRESENTATION We are in the middle of a cell & gene revolution				
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	Evading the immune response upon in vivo gene therapy with viral vectors	The Future of AAV-Delivered Gene Therapy - Throwing Out the Rule Book	A call to action in cell & gene: Improving Processes and Pioneering Innovation	Translational Safety: from pre-clinical/construct design to dose selection and First-in-Human Clinical Trials of Novel Gene Therapies [in Rare Diseases]	Building Your Cryogenic Supply Chain
15:30 - 16:30	DRINKS & CANAPES RECEPTION				

ADAPT IDEATIONS

IN PARTNERSHIP WITH:

PROVENTA INTERNATIONAL

DATE

Monday, 10th October 2022

VENUE

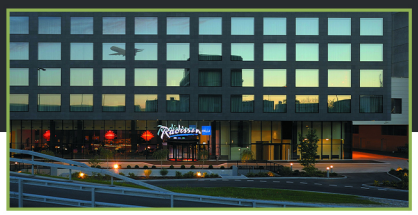
Radisson BLU

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

PROVENTA INTERNATIONAL

IN PARTNERSHIP WITH:

HAMILTON
THE MEASURE OF EXCELLENCE®

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:
KATH DE VELA
kv@proventainternational.com
+1 (617) 4534896 ext 325
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.

At TCG, we address these needs with a proven strategy utilizing the following inherent strengths:

- Top tier and experienced people from big-Pharma
- Large PRD group working across the globe
- Trust-based client relations and depth of engagement spanning two decades
- High end technology platforms and science, like continuous chemistry, catalysis
- Operational synergies amongst group companies
- World class facilities and infrastructure

We deliver integrated end-to-end solutions to the global life sciences' industries.

PROVENTA INTERNATIONAL

IN PARTNERSHIP WITH:

TCG Lifesciences | CHEMBIOTEK

TCG GreenChem

Why Book Your V.I.P Seat Now?

- Be amongst 10-15 Industry thought leaders from a mix of large Pharmaceutical Institutions ensuring you are given ample opportunity to raise questions and contribute from a strategic perspective.
- Wine, dine and network with industry leaders who face common challenges in 60-minute roundtable discussions that enable you to share ideas and lessons learned.
- Facilitated by expert moderators, these sessions provide a valuable dialogue with peers on current challenges and topical issues.
- No media, marketing or press, just pure and honest discussion to help solve your key strategic challenges for the next 3-9 months.

Contact Details:
GEN AMORILLO
ga@proventainternational.com
+1 (617) 4315492 ext 327
www.proventainternational.com

Event Day

AFTERNOON KEYNOTE PRESENTATION

13:00 – 13:30 CEST

We are in the middle of a cell & gene revolution

Dorothea Ledergerber
Chief Technical Officer
Tigen Pharma

ABOUT THE SPEAKER

Dorothea Ledergerber is a pharmacist with more than 20 years of experience in research, development, manufacturing and supply of pharmaceutical products. She received her PhD from the University of the Saarland, Saarbrücken, Germany. While with Novartis, she was leading manufacturing sites in Switzerland, Germany and Ireland. A highlight in her career was the build-up and operational launch of the first commercial Cell & Gene manufacturing facility for Novartis in Europe. In 2020, Dorothea moved on to Tigen Pharma, a Swiss biotech company in the field of cell therapies to cure cancer. Tigen is a disruptive catalyst, combining a unique culture with a multidisciplinary set of clinical and technical capabilities and a long-term perspective to the benefit of patients and society. Dorothea is a firm believer in cross-cultural and -functional teams to go beyond the beaten industry track.

END OF AFTERNOON KEYNOTE

Event Day

TRACK 1:
CELL & GENE THERAPY VECTORS

Viral vectors are the most commonly utilized agents for gene therapy within which Adeno-associated vectors (AAV) are the most promising. Nevertheless they are not without their set of challenges which is what this track will aim to address and explore the potential of non-viral vectors against the viral vectors.

11:00 – 12:00 CEST

ROUNDTABLE 2:
Addressing Challenges Posed in vivo by AAV Vectors: The Quest for the 'Perfect' Toolkit

- How to best address host immune responses limiting durable therapeutic gene expression
- Discuss a strategy that combines immune-modulation with better design of vectors: reducing the potential to trigger efficacy-limiting immune responses
- Improved criteria towards optimizing capsid engineering - effectiveness and scalable manufacturing
- Will there ever be a 'one size fits all' capsid? Highlight the progress in preclinical and clinical trials with optimized AAV capsids
- How to improve industrial manufacturing of AAV
- Discussing the route of administration

Eduard Ayuso
CTO
Dinaquor

ABOUT THE SPEAKER

Dr. Eduard Ayuso is an expert in the field of gene therapy using viral vector platforms and serves as Chief Technology Officer at DiNAQOR. With more than 50 scientific publications and more than two decades of academic and industry consulting experience, Dr. Ayuso has made significant contributions to the field of in vivo gene transfer in small and large animal models of diseases, as well as AAV vector development and analytics. He has served as Head of Innovative Vectorology at the French National Institute of Health and Medical Research (INSERM), and as the Scientific Director of the Translational Vector Core unit at University of Nantes. He currently serves as Vice President of the French Society for Gene and Cell Therapy. Dr. Ayuso earned his PhD in Biochemistry and Molecular Biology and his DVM from Autonomous University of Barcelona.

14:30 – 15:30 CEST

ROUNDTABLE 3:
Evading the immune response upon *in vivo* gene therapy with viral vectors

- Highlight the immune responses to some of the most common vectors used in gene transfer protocols
- How to circumvent or block these responses upon in vivo gene transfer
  - — Hiding the vector and its transgene product from the immune system
    - * Decrease vector dose, delivery to immune privileged site, preventing APC expression
  - — Hiding immune system from the vector
    - * Immune suppression, Immune modulation
- What are the current limitations of non-viral vectors, and how can they be overcome?
  - — Transduction, transgene expression and toxicity
  - — Can they also stimulate the innate and/or the adaptive arm of the immune system

Steen Klysner
CEO
Amarna Therapeutics

ABOUT THE SPEAKER

Steen Klysner is Chief Executive Officer at Amarna Therapeutics. Steen Klysner comes to Amarna with over 30 years of experience in the life sciences industry. Prior to joining Amarna, Dr. Klysner served as CEO of the Swedish ExpreS2ion Biotech Holding AB in parallel with the Danish ExpreS2ion Biotechnologies ApS. Earlier, he was Senior Vice President (SVP) of preclinical R&D and SVP of Quality of Allergopharma, the Allergy Business Unit of Merck KGaA. He also served as CEO of Nordic Vaccine in Copenhagen, focusing on the development of non-invasive vaccination based on an integrated nanoparticle adjuvant and delivery platform. Prior to that he has also held positions at Pharmexa, Novo Nordisk and ALK. Dr. Klysner holds a Ph.D. from Technical University of Denmark combined with an Industrial Scientist Research Degree from the Danish "Academy of Technical Sciences", a M.Sc. degree in Biochemistry from the University of Copenhagen and a B.Sc. in sports from the University of Copenhagen. Finally, Dr. Klysner is author/co-author of numerous patents and scientific publications in (inter)-national peer-reviewed medical journals.

END OF TRACK 1

Event Day

TRACK 2:
CELL/GENE BASED THERAPIES

Gene therapy involves the transfer of genetic material, usually via carrier or vector, and the uptake of that gene into the appropriate cells of the body while cell therapies involve the transfer of cells with the relevant function into the patient. Both approaches have the potential to treat the underlying cause of genetic and acquired diseases by replacing the missing proteins or cells. Chimeric antigen receptor (CAR) T cell therapy has emerged as one of the major breakthroughs in cancer immunotherapy and we investigate its potential in solid tumors in this track.

11:00 – 12:00 CEST

ROUNDTABLE 2:
Autologous vs. Allogeneic Cells: Optimizing 'Off- The- Shelf' Therapeutics

- **Approaches to determine which factors need consideration when selecting either therapy**
- **Reviewing between allogeneic therapeutic options: patient eligibility, previous encounter with CAR T-cell therapy, severity of patient condition**
- **What are some of the challenges associated with allogeneic therapies?**
  - **— Circumventing rejection of cell administration**
  - **— Need for gene-editing and procurement of a large enough quantity of certain cell types**
  - **— Manipulating the host and cell interaction to influence the rejection direction and graft-versus-host disease direction**
- **Can allogeneic T cells be used as a personalized therapy generating several CAR T-cell products with different antigen specificities?**
- **Higher possibility to leverage automation and scale up the manufacturing process**

Eric Halioua
Chief Executive Officer President of the Board
PDC * Line Pharma

ABOUT THE SPEAKER

Eric Halioua

Serial entrepreneur that combines strong strategic, technological and managerial experience with proven track record of deal-making and fund-raising. During his career he achieved together with its different teams to bring four drug candidates from research to the clinics (up to phase IIb). Overall, he has raised as of now a total of more than €160 million from VCs and strategic partners in Europe, USA, Japan and Korea and have had numerous successes in the sale and initial public offering of biotechnology companies. He is President and CEO of the biotechnology company PDC-Line Pharma and board member of Cell Matters. He was also a Board Member of the French biotechnology company Vivalis/Valneva and the Belgian company Bioxodes, the Health Cluster of Wallonia BIOWIN and the industrial association European Biotechnology Entreprises (EBE). Eric have been as well co-Inventor of the first worldwide GMP approved mobile manufacturing unit for cell therapy (WO 2014049151 A). He worked for 12 years as a Principal in the Healthcare and Life Sciences Practice of Arthur D. Little where he led work in the areas of strategy, M&A and technology & innovation management. He is co-founder of 4 biotechnology companies called Myosix, Murigenetics, Digital-Orthopaedics and HairClone.

- Myosix is a tissue engineering company specialising in musculoskeletal cells culture used in the regeneration of the heart muscle. The company has been bought by Genzyme mid-2002.
- Murigenetics is a Biotechnology company developing therapies for genetic disorders.
- Digital Orthopaedics is a Digital Health company providing access to a comprehensive Clinical Decision Support System for musculoskeletal pathologies.
- HairClone is a Biotechnology company developing cell-based hair treatments and Follicle Banking Service.

14:30 – 15:30 CEST

ROUNDTABLE 3:
The Future of AAV-Delivered Gene Therapy - Throwing Out the Rule Book

- **Approaches to increasing the potency and stability of AAVs**
  - **— Altering aspects of the manufacturing and purification process, for example improving full/empty ratio**
  - **— Improving the reagents the vector is stored in**
- **Engineering new capsid serotypes that are more tissue-specific and/or more immune-evasive**
- **Beyond episomal expression - new cargo?**
- **Novel viral vectors - what is the next blockbuster viral vector?**

I-Mei Yu
Principle Scientist, RNA & Gene Therapy | Drug Discovery | Precision Therapy
Novo Nordisk

ABOUT THE SPEAKER

I-Mei Yu joined Novo Nordisk in 2022 as a principal scientist and is responsible for viral delivery strategy within the RNA & Gene Therapy area. She is trained in structural virology and protein biochemistry, and received her PhD from Purdue University followed by postdoc training at Princeton University. I-Mei has extensive experience within AAV gene therapy pipeline development, leading projects from discovery through preclinical study. Since joining Novo, I-Mei helped build the team and set the framework for the viral delivery department to support all therapy areas, as well as contributing to research project portfolios and managing external partnerships.

END OF TRACK 2

Event Day

TRACK 3:
CELL AND GENE THERAPY MANUFACTURING

The early promise offered by cell and gene therapies is tempered by the challenges associated with developing, manufacturing, and delivering these therapeutics. To consistently produce high-quality batches, companies will need to establish practices—from starting materials, to process development, to current good manufacturing practice (CGMP) compliance. Many also face the decision to either build their own manufacturing facility or utilize a centralized approach. All this and more will be addressed in this track.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Discussing Strategies to Increase Manufacturability of Allogeneic Cell Therapies

- Innovative manufacturing processes to achieve scalability and robustness to boost therapeutic potential of allogeneic cell therapies
- Understand the importance of establishing collaborations with external service providers to develop and integrate advanced technology
- Exploring the role of automation in commercialization and mass production: End-to-end, closed or modular?
- How to minimizing tech transfer costs through using combination of off-the shelf manufacturing modules and configurable platforms
- What does an optimal manufacturing roadmap look like? How do you balance manufacturing flexibility with robustness and cost-effectiveness?
- Need to carefully evaluate and select-off-the shelf technology that can be incorporated into future robust, configurable systems when your demand increases

Amir Goudarzi
Senior Director Bioprocessing Technologies
Bayer

ABOUT THE SPEAKER

Amir Goudarzi has more than 15 years of experience in the bioprocess industry. In his latest role at UCB Pharma in Belgium, Amir lead global tech transfer of (early to late stage) biologics from development labs to pilot to full commercial scale. Amir & his team look after addressing industrialization of these processes by tackling manufacturing challenges, scale up/scale down rationals, automation integrations and plant engineering aspects at UCB's internal & external BioDS manufacturing sites. With broader UCB development teams, Amir devised the long range development & investment plans for UCB to enable implementation of state of the art bioprocesses in state of the art facilities at UCB. As of May-2022, as Sr Director BioProcess Technologies, Amir will join Bayer's global advanced manufacturing teams with focus on CGT/mAbs DS & DP processes.

11:00 – 12:00 CEST

ROUNDTABLE 2:
Meeting the Manufacturing Challenges of Cell & Gene Therapies – To Buy Or Build?

- Why is the current approach to cell & gene manufacturing not fit for the future? (Tsunami of therapies, speed, cost, sustainability)
- What parts of the current approach have the biggest potential for improvement? (Coming out of infancy, Holistic approach to data, smart process and equipment engineering, collaboration across functions)
- Why do we need a scalable and commercially viable platform process early in the product's life cycle? (Infrastructure, talent/people, seamless transfer to later stage developments)
- In- house, outsource or other models? How will the supply landscape shape in the future and where are the major opportunities and roadblocks?

Dorothea Ledergerber
Chief Technical Officer
Tigen Pharma

ABOUT THE SPEAKER

Dorothea Ledergerber is a pharmacist with more than 20 years of experience in research, development, manufacturing and supply of pharmaceutical products. She received her PhD from the University of the Saarland, Saarbrücken, Germany. While with Novartis, she was leading manufacturing sites in Switzerland, Germany and Ireland. A highlight in her career was the build-up and operational launch of the first commercial Cell & Gene manufacturing facility for Novartis in Europe. In 2020, Dorothea moved on to Tigen Pharma, a Swiss biotech company in the field of cell therapies to cure cancer. Tigen is a disruptive catalyst, combining a unique culture with a multidisciplinary set of clinical and technical capabilities and a long-term perspective to the benefit of patients and society. Dorothea is a firm believer in cross-cultural and -functional teams to go beyond the beaten industry track.

14:30 – 15:30 CEST

ROUNDTABLE 3:
A call to action in cell & gene: Improving Processes and Pioneering Innovation

- Formulating and executing a development and manufacturing strategy
  - — Comprehensive evaluation of existing state-of-the-art technology for a given therapeutic modality
  - — Emerging trends that may impact a long-range scale-up plan
- Using Single-use technologies (SUTs), modular cleanrooms and rapid automation to push facilities towards commercial manufacturing
- Can Manufacturing Execution Systems (MES) help track and trace during a process?
- Establishing more scalable, reliable manufacturing paradigms: Take what works in the lab and make it work in a full-scale facility

Peter Tiefenböck
Associate Director, Value Stream Leader PU Cell & Gene Therapy
Novartis

Giner Bjoern
MS&T Technical Steward Cell and Gene Therapy
Novartis

ABOUT THE SPEAKERS

Peter Tiefenböck

- Facilitator/Associate Director PU Cell&Gene Therapy
- Licensed pharmacist
- PhD in Pharmaceutical Technology
- In-depth knowledge of the Cell and Aseptic processes
- High awareness of manufacturing quality and validation
- Experience in GxP and Quality Assurance
- Project Management and Implementation Strategies
- People Management (15 direct / 40+ indirect reports)
- Focused on patient – quality – efficiency

Giner Bjoern

13 years with Novartis Pharma AG. 9 years of does working in Cell and Gene Therapy in several functions in Development, Production Unit and Manufacturing Science & Technologies (MS&T) currently as Technical Steward. Started the CGT journey in Morris Plains US for Novartis by supporting the Tech Transfer from University of Pennsylvania to a GMP Facility of Novartis of the first CART therapy as well as launching it commercial in the US and abroad. Since 4 years in Switzerland Stein located for launching the therapy for EMA and support routine manufacturing as well as new technologies.

END OF TRACK 3

Event Day

TRACK 4:
CLINICAL RESEARCH

Cell and gene therapies are often aimed at addressing rare and orphan indications with low patient prevalence. Finding sufficient numbers of patients to conduct studies to establish safety profiles of novel therapeutic platforms is problematic with traditional study designs. Much in the same way, traditional randomized controls trials may not be suitable or ethically acceptable when working in life-threatening indications. For this reason, developers need to be innovative in increasing the efficiency of studies and accelerating their execution in patients with unmet needs. This track will delve further into these issues and attempt to find viable solutions.

09:00 – 10:00 CEST

ROUNDTABLE 1:
Enabling cell and gene therapy clinical development by addressing evidence generation and research reproducibility

- Previous lines of treatments and their potential influence on cell therapy
- (active) comparators, artificial control arms or single arm
- timing of measurements (cell retrieval) and definition of population for statistical analysis (everyone harvested, every recipient, every recipient with a selected dose)
- long-term cure endpoints and potential surrogates to facilitate patient access

Michael Zaiac
Head of Medical Affairs Oncology Region Europe
Novartis

ABOUT THE SPEAKER

Michael Zaiac pursued a postgraduate career in Surgery and Surgical Oncology in the UK and in Germany gaining an MD in myocardial preservation in 1989 and an FRCS in 1992. Since joining the pharmaceutical Industry in 1994 he covered roles of increasing responsibility in clinical research, medical affairs and strategic marketing and participated in new medicines launches, large development programmes for small molecules and monoclonal antibodies and the day-to-day management of medical affairs at country, regional and global level. He has published on surgery, breast cancer, sarcoma targeted small molecules, mToR and general aspects of pharmaceutical medicine.

11:00 – 12:00 CEST

SOLUTION FOCUS ROUNDTABLE 2:
Practical Consideration for Adoption, Accelerating and the Future of Cell and Gene Therapy

- Without a doubt, the cell and gene therapies (CGT), including personalized medicines have rapidly transformed the treatment landscape. Join our interactive discussion on:
  — Establishing robust routes and procedures
  — Differentiating logistical challenges for CGT trials

Allan Van Konynenburg
Senior Director, Global Depot Network
SanaClis

SANACLIS

ABOUT THE SPEAKER

Allan van Konynenburg has more than two decades of experience in Business Development and Operations in the pharmaceutical arena, specifically in specialty logistics and supply chain. He brings with him a wealth of knowledge and experience across the pharmaceutical ecosystem, extending to Warehousing, Fulfilment, Distribution, CTSM, Logistics, Direct-to-patient, and Cell & Gene therapy. Allan is responsible for SanaClis vendor relationships, identification of specialized Clinical Trial Depots, formalization of business relationship with current and new vendors and establishing and negotiation of unified pricing models. His knowledge and experience play a key role in managing innovative approaches to existing and new business challenges and work with teams across SanaClis to deliver customer-centric products and services that support SanaClis' mission statement.

14:30 – 15:30 CEST

ROUNDTABLE 3:
Translational Safety: from pre-clinical/construct design to dose selection and First-in-Human Clinical Trials of Novel Gene Therapies [in Rare Diseases]

- Leverage the learning phase (determining how best to use the therapy for a particular disease) to design and conduct rigorous clinical evaluations, particularly transition from pre-clinical model to studies in humans.
- Importance of demonstrating efficacy and safety in preclinical studies so as to understand the potential toxicities and risks and benefits of the proposed treatment before initiating early-phase clinical trials
- Why closer attention needs to be paid to the quality and design of clinical studies (e.g use of placebo blinding vs open label, dose selection and study design) in cell & gene therapies than in small molecule drugs
- Addressing challenges of early phase research such as:
  — defining the lowest effective dose and the optimal modality of delivery
  — avoid conducting an uninformative trial—that is, one that does not provide results that are of value to patients, researchers, clinicians, or policy makers
- Need for a greater deal of experience and safety data from rare disease indications before the field will start thinking about more common addressable diseases
- Is it possible to use the results from one trial in a rare disease to shorten the development time for a similar disease?

Ivan Gorbachov
Senior Director
Novartis Gene Therapies

ABOUT THE SPEAKER

Dr Ivan Gorbachov is an experienced pharmaceutical development and biotechnology leader with particular focus on advanced therapies. He is US-trained physician certified by ABIM, followed by a career in clinical drug development at Roche, Novartis, as well as in small biotech. His latest work was dedicated to challenges of translational safety in gene therapy first at AveXis and more lately at Novartis Gene Therapies.

END OF TRACK 4

TRACK 5:
GLOBAL LOGISTICS & SUPPLY CHAIN

Since patient cells are the foundation of these life saving therapies, CGT supply chains present unique challenges not faced in the development, manufacturing, and transport of biologics. Cells require special care and consideration, such as strict temperature controls and the ability to track and verify chain of custody from collection to final formulation. To ensure the industry can realize the potential of CGTs, we discuss improved solutions that reliably support the control and transport of critical CGT raw materials and products.

11:00 – 12:00 CEST

SOLUTION FOCUS ROUNDTABLE 2:
The importance of High Quality Temperature Controlled Packaging When Shipping Cell & Gene Therapies

- Cryo or dry ice? Which is the most appropriate coolant for your application, what are the pro's and con's when using these types of coolant?
- What products are best suited for Direct to Patient and / or Direct from Patient to ensure therapies and samples are delivered at the correct temperature?
- With the growing need for offering sustainable packaging for pharma deliveries, how much importance do you and your suppliers place on this?

Feliks Kochan
Account Executive Business Development Manager
Peli Biothermal

PELI BIOTHERMAL

ABOUT THE SPEAKER

Feliks Kochan joined Peli BioThermal in 2021 and is responsible for selling and developing the company's range of NanoCool products to the Pharmaceutical market within EMEA. He has extensive experience within the Biotech and novel medicines sector gained over a number of years in the field, modification of viral vectors for gene therapy applications in particular.

END OF TRACK 5

END OF Cell & Gene Therapy Strategy Meeting Europe 2022
SEE YOU ON OUR NEXT EVENT!

PROVENTA TALENT
A PROVENTA INTERNATIONAL BRAND

Your Partner for Recruitment Solutions

We have the expertise to recruit across all markets within the life science industry and at global level.

VISIT OUR WEBSITE →

CONTACT US FOR MORE DETAILS

Michèle Bartouilh-Neugebauer
(Head of Talent Acquisition Division)

mbn@proventainternational.com

+44 (0)20 3314 0100 (UK)
+1 (617) 614 0377 (US)

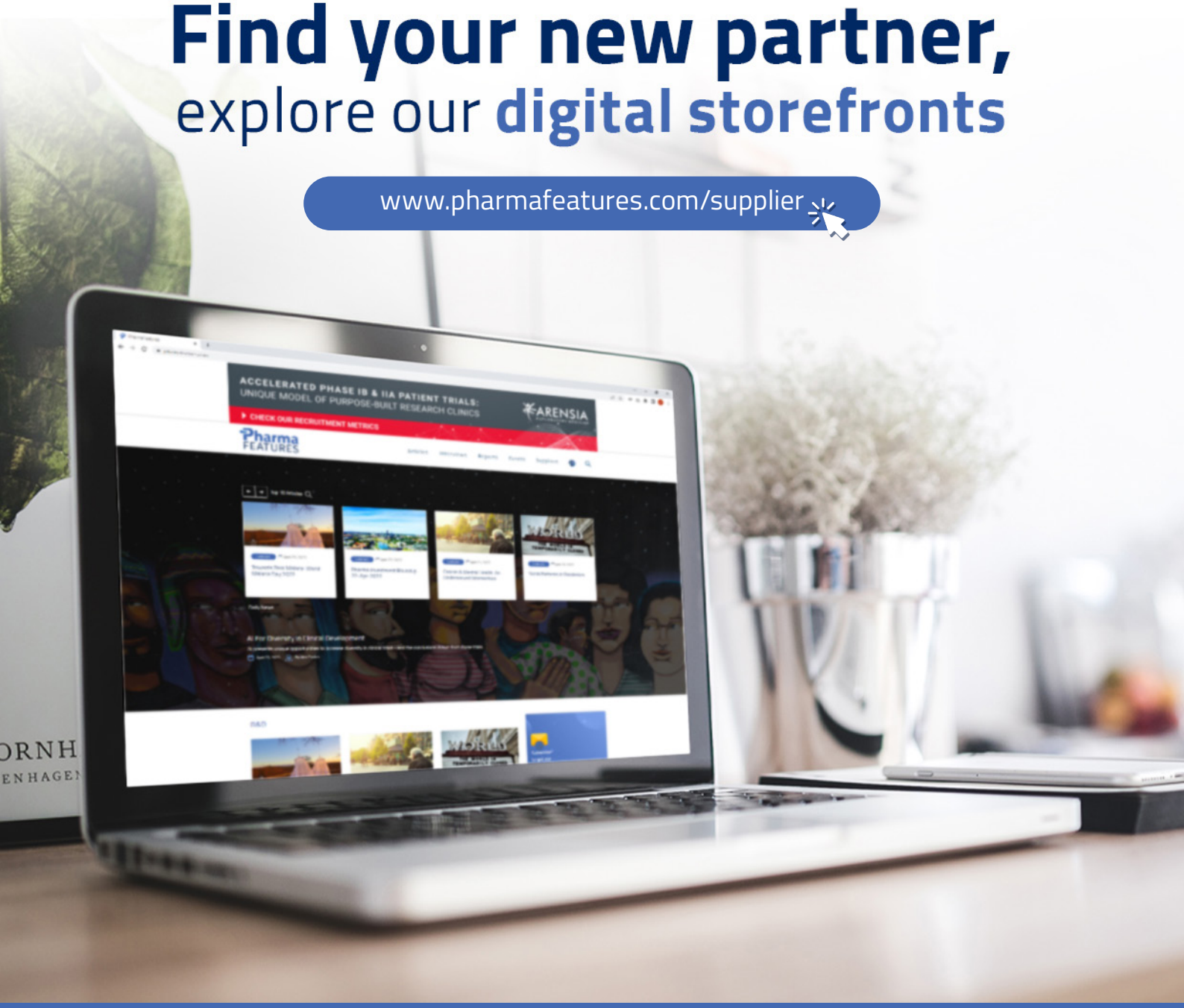
www.proventaTALENT.com

Pharma FEATURES

Find your new partner,

explore our digital storefronts

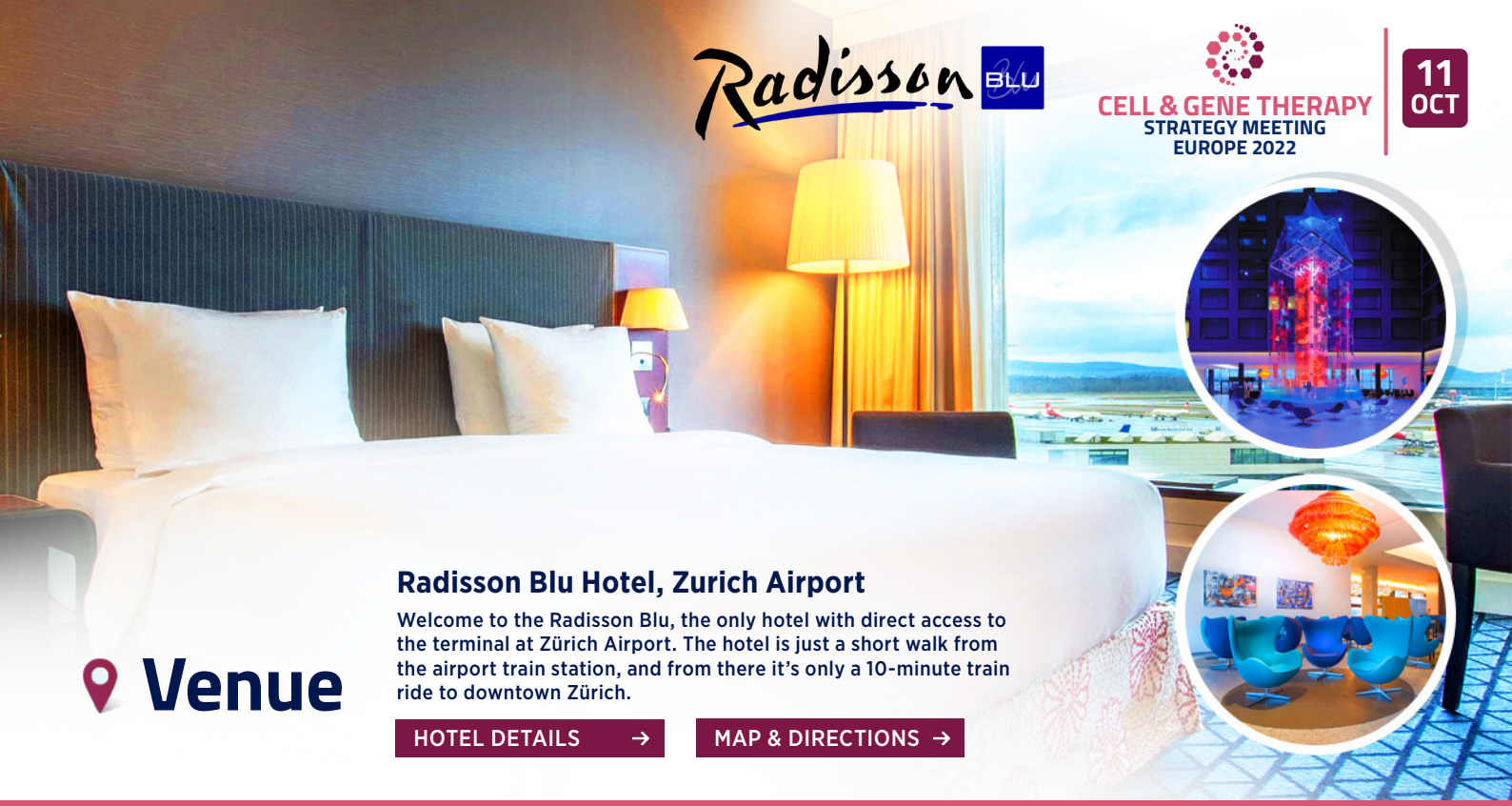
www.pharmafeatures.com/supplier



Contact us to discuss how we can help generate growth for your business.

Jamie McBarek - Commercial Director
jmcbarek@proventainternational.com

+44 (0)20 3314 0100 (UK) | +1 (617) 614 0377 (US)
web@pharmafeatures.com



CELL & GENE THERAPY
STRATEGY MEETING
EUROPE 2022

11 OCT

Venue

Radisson Blu Hotel, Zurich Airport

Welcome to the Radisson Blu, the only hotel with direct access to the terminal at Zürich Airport. The hotel is just a short walk from the airport train station, and from there it's only a 10-minute train ride to downtown Zürich.

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
Radisson Blu Hotel Zurich Airport

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

Innovative Manufacturing, Clinical & Logistical Strategies to Boost Cell & Gene Therapy Efficacy and Accessibility to Patients

Visit our website for future events →