WELCOME!

ZETA
SYMPOSIUM
March 6-8, 2023 // AUSTRIA

INFORMATION & PROGRAM

THE ZETA SYMPOSIUM IS SUPPORTED BY
BOEHRINGER INGELHEIM, LOBA, OCTAPHARMA AND UCB

AGENDA

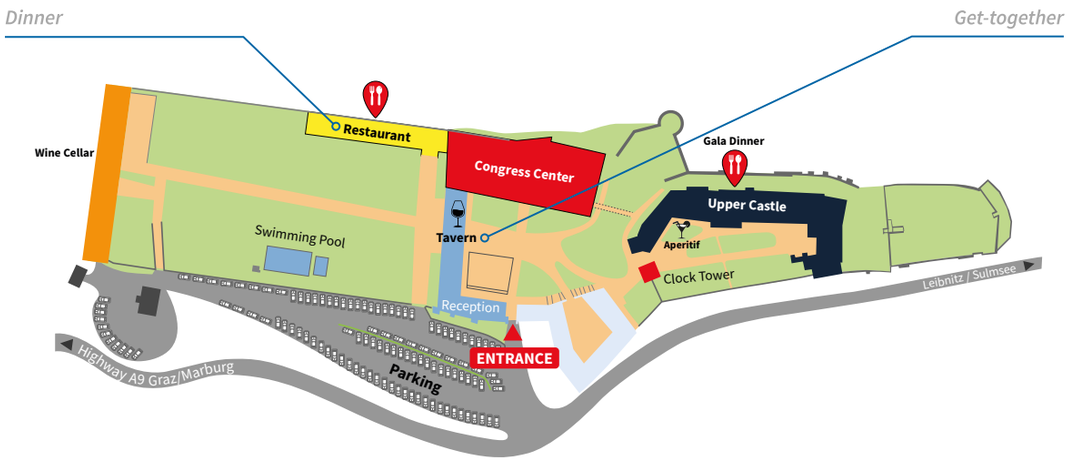
Monday, March 6, 2023

Mon 6 Tue 7 Wed 8

03.00 – 06.00 pm **Check-in at Schloss Seggau**

06.00 – 07.00 pm **Get-together**

07.00 – 10.00 pm **Dinner at Schloss Seggau**



AGENDA

Tuesday, March 7, 2023

Mon 6 Tue 7 Wed 8

SESSION I

08.00 am **Good Morning Coffee**

09.00 – 09.15 am **Welcome and Opening** of the ZETA Symposium
Dr. Andreas Marchler, Managing Director, ZETA Holding

09.15 – 10.00 am **Medical Genetics – Quo Vadis?**
Keynote speaker: Univ.-Prof. Dr. Markus Hengstschläger, Medical University of Vienna // Discussion

10.10 – 10.40 am **Digitalization in Biopharma – Trends and Use Cases**
Key speaker: Dr. Christian Eckermann, Managing Director, Boehringer Ingelheim Biopharmaceuticals GmbH // Discussion

10.50 – 11.35 am **Break & Discussion at the Sponsor Forum**
Technological Innovations to be Expected Within the Next Few Years

SESSION II

11.35 – 12.10 am **Biopharma & Data – Learning from Today to Anticipate the Future**
Key speakers: Pierre-Olivier Estève, Partner, McKinsey & Company; Clément Neri, Associate Partner, McKinsey & Company // Discussion

12.10 – 13.00 pm **The Future of Industrial Operations – Siemens Xcelerator – What Can We Expect and What Needs to be Changed?**
Key speaker: Frank Paetow, Director Customer Driven Innovation, Siemens AG Digital Factory // Discussion

01.00 – 02.30 pm **Lunch at Schloss Seggau**

AGENDA

Tuesday, March 7, 2023

Mon Tue Wed

6 **7** 8

SESSION III

02.30 – 03.00 pm **Bioprocessing Innovations in the Era of Digitalization, Clinical Acceleration & Process Intensification**
Key speaker: Stefanos Grammatikos, Vice President Biotech Sciences, UCB S.A. // Discussion

03.10 – 03.40 pm **Case Study: Design, Build and Qualify Evolving Cell and Gene Therapy Facilities**
Key speaker: Phani Sukhavasi, Head of Global Engineering, Vertex Pharmaceuticals Inc. // Discussion

03.45 – 04.30 pm **Break & Discussion at the Sponsor Forum**
Flexibility and Agility – Strategies to Meet Supply Chain Challenges

SESSION IV

04.30 – 05.00 pm **Collaboration – Digitalization and Sustainability**
New Challenges for Design and Construction of Production Buildings of the Future
Key speaker: Univ.-Prof. Christoph M. Achammer, CEO, ATP architects engineers // Discussion

05.10 – 06.00 pm **Panel Discussion:**
Biopharma Industry in Transition – Next Generation Manufacturing Strategies to Meet Patient Needs Faster // plus other hot topics from Sponsor Forum discussions
Moderator: Gert Moelgaard

07.00 – 10.00 pm **Gala Dinner at Schloss Seggau**

AGENDA

Wednesday, March 8, 2023

Mon Tue Wed

6 7 **8**

SESSION I

08.00 am **Good Morning Coffee**

08.30 – 09.00 am **Modular Plant Engineering for Resilient Growth**
Key speaker: Dr. Andreas Bamberg, Executive Director, Merck Group // Discussion

09.10 – 09.40 am **Protect Everything You Operate – Securing the Digitalization Journey**
Key speaker: Daniel Bren, CEO & Co-Founder, OTORIO // Discussion

09.45 – 10.30 am **Break & Discussion at the Sponsor Forum**
US - Europe - Asia: Different Markets, Different Requirements: Just Challenges or Opportunities?

SESSION II

10.30 – 11.00 am **A Peak into the Future: Quantum Computing Meets Pharma & Chemicals – A Perfect Match?!**
Key speaker: Clemens Utschig-Utschig, Head of IT Technology Strategy, CTO, Boehringer Ingelheim RCV // Discussion

11.10 – 11.30 am **Next Generation Pharmaceutical Manufacturing**
Key speaker: Dr. Thilo Kaltenbach, Senior Partner, Roland Berger // Discussion

11.35 – 11.45 am **Break**

SESSION III

11.45 – 12.15 pm **FDA Efforts During COVID and Beyond: Facilitating Innovation to Address Public Health Needs**
Key speaker: Ritu Nalubola, Ph.D. , Director, Europe Office, U.S. Food and Drug Administration // Discussion

AGENDA

Wednesday, March 8, 2023

Mon 6 | Tue 7 | Wed **8**

12.30 – 01.45 pm **Lunch at Schloss Seggau**

02.00 – 03.00 pm **Transfer** to ZETA headquarters in Lieboch

03.00 – 04.30 pm **Workshops**

Workshop I: From Integrated Engineering to Integrated Operations
Best practice LOBA high-end biotechnology production facility
(ZETA Moderators: Martin Mayer, Armin Erlacher, Clemens Borkenstein)

Workshop II: Innovations in Industrial Applications
Best practice in magnetic mixing technology, sterile connectors and equipment characterization
(ZETA Moderators: Nicole Zangl, Florian Krainer, Georg Pöschl)

05.00 pm End of the ZETA Symposium 2023

On Wednesday, the **participants who visit the Innovation Zentrum ZETA (IZZ)** can leave their luggage with ZETA employees for safekeeping at the reception desk of Hotel Schloss Seggau **between 7.30 and 8 am.** The luggage will then be transferred to ZETA headquarters (IZZ) by bus where it can be picked up before leaving for the airport or train station.

COVID testing is available at the reception of Hotel Schloss Seggau.

Please note that photos will be taken during the event. ZETA will use these photos to promote the event series "ZETA Symposium".

SHUTTLE SERVICE

to / from hotels *Staribacher* or *Am Seggauberg*

Monday **6**	*Tuesday* **7**	*Wednesday* **8**
	07.30 | 07.45 | 08.00 **08.15 | 08.30**	**07.30 | 07.45** **08.00 | 08.15**
17.00 | 17.15 **17.30 | 17.45**	**18.00 | 18.15** **18.50 | 19.05**	
21.30 | 22.00 | 22.30 **23.00 | 23.30 | 24.00**	**21.30 | 22.00 | 22.30** **23.00 | 23.30 | 24.00**	

If you require the shuttle service at any other time than indicated, please contact the May-Taxi **+43 3452 20280**

*shuttle to **hotels** Staribacher or Am Seggauberg*

*shuttle to **Schloss Seggau***

Tuesday, March 7, 2023
SESSION I, 09.15 – 10.00 am
Keynote speaker

Medical Genetics – Quo Vadis?

Univ.-Prof. Dr. Markus Hengstschläger
Institute of Medical Genetics, Medical University of Vienna

Predictive analytics and artificial intelligence applied for the interpretation of whole human genome data obtained by next-generation sequencing offer an enormous opportunity for the development of new therapeutic strategies. However, this current merger of biotechnology and information technology also calls for a biological and ethical discussion about the definition of health and disease. We all are genetic individuals and the vast majority of what defines an individual human being is the result of nature and nurture. Humans cannot be reduced to their genes. In November 2018, in China the claim was made that the first humans modified by germline gene therapy had been born on planet Earth. While there seems to be broad international consensus that genome editing is not yet mature enough to be used to modify the human germline, even in the context of monogenetic diseases, this "(un)scientific" attempt once again stimulated the discussion on human enhancement and transhumanism. Medical genetics – what can be done, what should be done?

Biography

Univ.Prof. Dr. Markus Hengstschläger studied genetics at the University of Vienna, did research at Yale University in the USA and was finally appointed university professor at the Medical University of Vienna, where he now heads the Institute of Medical Genetics. The award-winning and internationally recognized scientist teaches students and is active in the fields of genetic diagnostics, basic research and innovation consulting.
He has received the order of merit for services rendered to the Republic of Austria and among other activities he is Deputy Chairman of the Austrian Bioethics Commission, was Deputy Chairman of the Austrian Council for Research and Technology Development, is a member of the University Council of the University of Linz and head of the think tank Academia Superior. Hengstschläger is also a science presenter on Austrian radio and the author of four bestselling books.

Presenting author details
Univ.-Prof. Dr. Markus Hengstschläger

Tuesday, March 7, 2023
SESSION I, 10.10 – 10.40 am

Digitalization in Biopharma – Trends and Use Cases

Dr. Christian Eckermann
Managing Director, Boehringer Ingelheim Biopharmaceuticals GmbH

This lecture provides an overview of the current trends in digitalization in the biopharmaceutical industry. This includes examples from Boehringer Ingelheim: the virtual factory (which uses virtual and augmented reality as well as smart glasses for customer experience, audits, trainings, etc.); automatic customer data share platforms; the application of IoT with networked machines and robotics; usage of artificial intelligence for deviation root cause advice or deviation management via natural language processing; paper-free factory operations. Additionally, an in-house developed platform for in silico production process optimization based on machine learning and mechanistic process models will be presented. The most recent achievement of this technology is a 15% yield improvement for a well-established commercial biopharmaceutical product to the benefit of the patients.

Biography

Dr. Christian Eckermann is Managing Director of the Boehringer Ingelheim Biopharmaceuticals GmbH and oversees the Biopharma Contract Development and Manufacturing Business (BioXcellenceTM). Christian has more than 20 years of experience in biopharmaceutical research, development, manufacturing and quality management. In previous roles he was head of a biopharma site in Vienna, Austria, with accountability for all microbial CMC development and large-scale production activities of Boehringer Ingelheim. He was also responsible for several site expansion projects, including a >140000 L cell culture facility. Before 2013, Christian worked for 10 years in various functions in Process Science and Operations, where he was in charge of the successful product transfers, scale up, clinical and market supply of biopharmaceutical medicines at Biberach, Germany.
Christian is the author of several publications, holds various patents, and developed the trademark protected RAPPtor® technology platform.

Presenting author details
Dr. Christian Eckermann
linkedin.com/in/christian-eckermann-17ab2869

Biography

Pierre-Olivier is a partner at the McKinsey & Company's Frankfurt office. He co-leads the biopharma service line and leads the Operations Excellence Program. He has been serving (bio)pharmaceutical clients to unleash their full operations potential in larger transformations and turnarounds.
Most recently, he has helped clients on a range of engagements, including a three-year end to end throughput transformation for a biopharmaceutical client, a network optimization exercise at a pharmaceutical company and developing the cultural and managerial change approach for a biopharmaceutical client to implement concurrent manufacturing on fermentation lines.
Pierre-Olivier holds a Mechanical Engineering degree from École Centrale de Lyon, and a degree in Industrial Engineering from the Technical University of Darmstadt. He also holds an MBA from Collège des Ingénieurs in Paris.

Presenting author details
Pierre-Olivier Esteve
linkedin.com/in/pierre-olivier-estève

Tuesday, March 7, 2023
SESSION II, 11.35 – 12.10 am

Biopharma & Data – Learning from Today to Anticipate the Future

Pierre-Olivier Estève, Partner;
Clément Neri, Associate Partner,
McKinsey & Company

The biopharma industry is facing significant external forces impacting operations strategy and execution. Understanding key trends in biopharma operations and linking these to the acute headwinds in the industry will inform players where to act. Embracing the opportunity offered by the digital disruption will lead to a new vision of biopharma operations of the future. As a consequence, a new way of working will be required, which will have an impact on the majority of the workforce in manufacturing sites.

In this session, insights from McKinsey's global pharma benchmark POBOS on recent trends regarding key performance indicators in biopharma operations will be shared and linked to recent head- and tailwinds in the industry. The vision of future biopharma manufacturing which derives from these trends will be discussed and impact opportunities across the value chain will be presented, which have already been demonstrated by first-movers. The session will close off by illustrating the effects on the day-to-day operations of the workforce, and by discussing the shift in capabilities that will be required and where players typically source these profiles from.

Biography

Clément Neri is an associate partner at the McKinsey & Company's Lyon office. He is a Lean Six Sigma Black Belt and an expert across operations, focusing particularly on manufacturing transformations in the (bio)pharmaceutical industries.
He previously worked at General Electric Healthcare in France and Finland, Alstom and Linovati Inc. in Canada. Most recently, he has helped clients on various engagements, such as supporting a biopharma player in its strategic transition towards digital and analytics manufacturing operations, various manufacturing transformations and network optimization for a global biopharma company and an operations organization effort at a biopharmaceutical client.
Clément holds a degree in Engineering from École Centrale de Lyon, a Master's degree in Biomechanics from Lyon University, a Lean Six Sigma Green Belt certification from General Electric and a Black Belt certification from Linovati inc.

Presenting author details
Clement Neri
linkedin.com/in/clementneri

Tuesday, March 7, 2023
SESSION II, 12.10 – 13.00 pm

The Future of Industrial Operations – Siemens Xcelerator – What Can We Expect and What Needs to be Changed?

Frank Paetow
Director Customer Driven Innovation, Siemens AG Digital Factory

Industry is facing tremendous challenges. Challenges which no one will be able to solve on their own. Just think about climate change and the need for more sustainability. It requires intensified efforts towards a digital transformation of industry to master these challenges. Thus, the future of industrial operations will be different. We will share aggregated insights from in-depth future visioning workshops from over 80 industrial leading companies and how they envisage their future operations. Furthermore, we will look at the status-quo and into strategies and options to make these future operations scenarios become a reality.

We are certain that we can master the transformation of industry. Together. Now.

Biography

Frank Paetow has been with Siemens in Erlangen, Germany, for over 16 years. As Director of Customer Driven Innovation, he currently works with decision-makers in industrial enterprises to shape the future of industrial production. His goal is to develop applications of digital technology, with a focus on automation to yield growth, stability, and a better work environment for people. Frank is also a co-founder of 5thIndustry in Berlin, a company dedicated to developing apps tailored to the needs of production. His academic background is in industrial engineering, computer sciences and economics, with degrees from the University of Applied Sciences Stralsund and Fern-Universität Hagen.

Presenting author details
Frank Paetow
linkedin.com/in/frankpaetow/

Tuesday, March 7, 2023
SESSION III, 02.30 – 03.00 pm

Bioprocessing Innovations in the Era of Digitalization, Clinical Acceleration and Process Intensification

Stefanos Grammatikos, Ph.D.
Vice President Biotech Sciences, UCB S.A.

Current trends in clinical development acceleration and bioprocess intensification impose an unprecedented compression of CMC development timelines and new bioprocessing challenges downstream of the cell culture bioreactor. In this talk I will present our digitalization concept together with a series of innovations we have introduced in the UCB antibody manufacturing platform – some incremental and some potentially disruptive – in an effort to be fast, efficient, high performing and environmentally friendly and to avoid complications while rising to the latest challenges of bio-CMC development and bioprocessing.

Biography
Stefanos Grammatikos is head of Biotech Sciences, the Bio CMC organization of UCB. He oversees drug substance, formulation, drug product and analytical method development and clinical supply for all of UCB's pipeline biologics and gene therapy products. The first asset fully CMC-developed under his leadership was Bimekizumab/Bimzelx® (anti-IL17AF), closely followed by Rozanolixizumab (anti-FcRn).
From 1996 to 2008, Stefanos held several technical management positions in bioprocess development and manufacturing at Boehringer Ingelheim Pharma. As early as 1998 he realized the importance of cell line development to biopharmaceutical manufacturing and initiated a pioneering concept for clone selection based on FACS and early high-throughput automation. His post-doctoral research work (1995-1996) has contributed to the understanding of the impact of cell culture process on product quality.
Stefanos holds a BSc degree in Chemical Engineering from UC Berkeley and MSc and PhD degrees in Biochemical Engineering from Northwestern University. He was awarded the Medal of the European Society for Advanced Cell Technologies (ESACT) in 2015. He is an elected member of the Executive Committee of ESACT and has been Vice Chairman of the society since 2022.

Presenting author details
Stefanos Grammatikos
linkedin.com/in/stefanos-grammatikos-9619116

Tuesday, March 7, 2023
SESSION III, 03.10 – 03.40 am

Case Study: Design, Build and Qualify Evolving Cell and Gene Therapy Facilities

Phani Sukhavasi
Head of Global Engineering, Vertex Pharmaceuticals Inc.

The drug-development landscape for cell and gene therapies is evolving rapidly and the user requirements are often outdated before the facility is constructed and released for GMP use. Fungibility-by-design adds reasonable flexibility and adaptability with a perfect balance between cost, schedule, efficiency, and sustainability, without compromising quality and compliance.
This case study covers the unique challenges, non-traditional strategies, challenging schedules, COVID impact on the entire life cycle from concept, design, build, and commissioning right through to qualification of Vertex's new Cell and Gene Therapies facility in Boston, USA.
In June 2019, Vertex announced the establishment of a new research site in the Boston area where research, development and clinical manufacturing for cell and genetic therapies will be primarily based. Cell and genetic therapies represent two rapidly emerging therapeutic modalities with the potential to treat — and even cure — several of the diseases Vertex is focused on, including cystic fibrosis, sickle cell disease, Duchenne muscular dystrophy and Type 1 diabetes. Further investment in a research site specifically designed to advance these programs will be key to Vertex's continued and sustained leadership. At Vertex Cell and Genetic Therapies (VCGT), research teams will bring together the best biological, technological, and enhanced manufacturing capabilities to ensure Vertex can bring these cutting-edge transformative therapies to patients as quickly as possible.

Biography
Fifteen years of CAPEX and start-up experience in pharmaceuticals and biotech industry, and an in-depth knowledge of drug development and commercialization life cycle from Process Engineering to Inspection Support.
Currently, Phani works at Vertex Pharmaceuticals Inc. as head of Global Engineering managing the Automation, Capital Projects Engineering, Site Engineering, Engineering Documentation, Sustainability and C&Q departments. His team supports R&D and the manufacturing of small molecules, aseptic processing, cell and gene therapies. To date, Phani managed over 14 start-ups with various project sizes.
Phani has a Master's degree in Management from Harvard University Extension School, a Master's degree in Chemical Engineering from University of South Alabama and a Bachelor's degree in Chemical Engineering from JNT University.

Presenting author details
Phani Sukhavasi
linkedin.com/in/phani-sukhavasi-2674b115/

Tuesday, March 7, 2023
SESSION IV, 04.30 – 05.00 pm

Collaboration – Digitalization and Sustainability New Challenges for Design and Construction of Future Production Buildings

Univ.-Prof. Christoph M. Achammer
CEO, ATP architects engineers

The lecture describes the general situation and organization of the design and construction industry and compares it to the wider economy. The importance of this industry, both financially and especially as a major consumer of energy and other resources, calls for a new culture of collaboration and thus also for new organizational concepts and processes. The virtual description of future buildings using Building Information Modeling offers huge potential for change in this context.
Given that buildings for research & production have always acted as incubators for innovation in the construction industry – in terms of design solutions, materials, and processes – the lecture will highlight potential approaches for the next generation. Current projects will be used to illustrate the need to continuously evaluate the procurement and use of materials, costs, and carbon footprints throughout the design and construction process. This combination of academic and practical experience will create value by outlining perfect structures to support the individual core processes of research & production.

Biography
Architect Christoph M. Achammer is Chairman of the Executive Board and Architecture Partner of ATP architects engineers. ATP with its team of around 1,000+ employees is Europe's leading integrated design company. With headquarters in Innsbruck (AT) and the support of its own research and consulting subsidiaries, ATP carries out design work at eleven European offices located across the DACH and CEE regions. With 40 years experience in interdisciplinary planning, ATP is the market leader in the integrated design of lifecycle-oriented buildings.
As a Professor for Integrated Construction Planning and Industrial Building at Vienna University of Technology, Christoph M. Achammer encouraged research at the Institute for Interdisciplinary Building Process Management in the fields of integrated design, sustainability, BIM and digitalization.

Presenting author details
Univ.-Prof. Christoph M. Achammer
linkedin.com/company/atp-architekten-ingenieure

Wednesday, March 8, 2023
SESSION I, 08.30 – 09.00 pm

Modular Plant Engineering for Resilient Growth

Dr. Andreas Bamberg
Executive Director, Merck Group

"Be fast, the market won't wait!" was the first hypothesis from the 48th Tutzing Symposium in 2009. The "50%" concept was born: from new product to new plant in half the time. As a result, numerous initiatives emerged, mainly to further develop ways to minimize market risk by accelerating the introduction of new products, while increasing quality requirements at the same time. The focus was always on modular systems. A much-cited benchmark was developed in the f3 Factory Initiative and published in the Dechema white paper "Modular Plants", among others.
Given the volatile market environment, less robust supply chains, and high efficiency and sustainability demands, we must use technology to ensure resilient growth. Modular plants can be instrumental in dealing with diversified supply chains, introducing new products with moderate investment, and increasing the efficiency of our production – if they are orchestrated by modular automation. This last part in particular is an achievement of the past few years and goes far beyond the 50% idea of Tutzing 2009.
This lecture will show that the economic and ecological potentials of modular plants can only be realized in full if all parties involved are interlinked early on in the product life cycle. If distributed knowledge and skills are to work together efficiently in this environment, established roles, procedures, and systems have to be rethought.

Biography
Andreas Bamberg studied Information Technology at Berlin University of Technology and graduated with a doctorate in Process Systems Engineering in 1994. In 1998, he joined Merck KGaA in Darmstadt, Germany. Through various international positions in process development and plant engineering, including assignments to Vevey, Switzerland, and Shanghai, PR China, he reached his current position as Head of Process Development Engineering at Merck Electronics KGaA.
As founding chair of the NAMUR working group "AK 1.12 Module/Plug and Produce" he has been accompanying and influencing research and development of modular plant technology in conjunction with modular automation since 2010. His recent efforts focus on combining modular automation with digital twin and seamless engineering technologies.

Presenting author details
Dr. Andreas Bamberg

Wednesday, March 8, 2023
SESSION I, 09.10 – 09.40 pm

Protect Everything You Operate – Securing the Digitalization Journey

Daniel Bren
CEO & Co-Founder, OTORIO

In the post-pandemic world, businesses will have to find innovative ways of staying competitive. Companies that embrace this challenge and make use of new technologies are likely to be winners in an ever-changing economic landscape. Staying ahead of the curve means continuously innovating – and that's exactly what digital transformation does.
Harnessing cutting-edge solutions to enhance business operations has never been more important for long-term success; moreover, autonomous operation is the future of efficiency, giving machines the freedom to take on tasks without requiring constant human supervision. With automated solutions taking care of mundane processes, businesses and individuals can devote more energy towards ambitious projects that will push our world forward.
To make advancements, you must be willing to take a leap of faith – risks come hand in hand with progress. As digital technology expands, so too do its complexities. Companies must grapple with increasingly complex challenges around scalability and security while attending to the needs of their customers in an ever-changing landscape. With digital resiliency as its foundation, organizations need now to maintain critical operations with maximum security and reliability.
In the talk, OTORIO will present the strategy and its successful implementation.

Biography
Daniel Bren has 25 years of experience in cyber research, development, systems engineering, cryptography and threat analysis. A former brigadier general in the Israel Defense Forces, Bren dedicated his military career to developing and adapting proactive cyber defense systems. He formed Israel's Military Joint Chief Cyber Defense Unit, served as its first commander, and additionally served as head of the C4I (J6) Force Buildup & Mission Support Division and head of the IDF's CIO division (aka "Lotem"). In 2018, Bren co-founded OTORIO, a provider of industry-native cyber security solutions. He holds an Electrical Engineering B.Sc. EE from Tel Aviv University (laude) and an Electrical Engineering M.Sc. EE from the Technion (laude).

Presenting author details
Daniel Bren
twitter.com/OTORIO_Cyber?s=20&t=e-7TaNKY-awpFYxKhUYrvgA
linkedin.com/in/daniel-bren-8873472a

Wednesday, March 8, 2023
SESSION II, 10.30 – 11.00 am

A Peek into the Future: Quantum Computing Meets Pharma & Chemicals – A Perfect Match?!

Clemens Utschig-Utschig
Head of IT Technology Strategy, CTO, Boehringer Ingelheim RCV

Quantum computing can potentially revolutionize the way we look at molecules and help us uncover previously unknown system properties. Leveraging these new insights may help us to design better drugs in the future. Currently we see a lot of hype being generated through at times questionable marketing messages. This session gives a realistic view into the current state of quantum computing with a focus on pharmaceutical use cases, and highlights what needs to happen to make this technology ready for prime time.

Biography
Clemens is the Head of IT Technology Strategy / CTO at Boehringer Ingelheim, a leading global pharmaceutical research company.
Earlier in his career, he focused on building and running software engineering at Boehringer Ingelheim's Digital Lab, BIX, as well as work at Oracle in the Silicon Valley.

Presenting author details
Clemens Utschig-Utschig
linkedin.com/in/clemensutschig/

Wednesday, March 8, 2023
SESSION II, 11.10 – 11.30 am

Next Generation Pharmaceutical Manufacturing

Dr. Thilo Kaltenbach
Senior Partner, Roland Berger

Over the past few years, we have been witnessing a number of key trends and disrupting events that have a significant impact on the requirements placed on pharmaceutical supply chains. Advancements in biotechnology and diagnostics produced a number of individualized therapies and new modalities such as CGT therapeutics which increasingly require high proximity to patients, and modular manufacturing. In some instances, delivery times and supply chain configurations have become more important clinical decision drivers for therapies than clinical data. At the same time, enabling digital technologies and capacities have developed and are increasingly used to accelerate development and manufacturing. Geopolitical tensions as well as the pandemic lockdowns have led to supply chain shocks and are currently changing the criteria on which investment decisions will be made. The supply chain will look completely different by 2030; it will be much more modular, delocalized, and individualized than today. Chief Operating Officers will become technology leaders and will have to make a number of highly strategic decisions. This opens up a whole new set of challenges to the decision makers. The presentation will cover the toughest challenges and suggest ways of turning them into opportunities.

Biography

Dr. Thilo Kaltenbach is a senior partner and member of the management team of the global Life Science Practice of Roland Berger. As an approbated pharmacist he holds a PhD in pharmaceutical chemistry from the University of Münster. He conducted his thesis research on the introduction of capillary electrophoresis into quality control in collaboration with an international working group of US FDA, EDQM and a number of OMCL laboratories.
In parallel, he studied Business Administration at the University of Hagen. For more than 20 years he has been engaged as a management consultant on global assignments in translational medicine, supply chain configuration, as well as commercial strategies primarily for pharmaceutical and medtech companies, and for financial investors. He has also helped to shape the regulatory environment in several projects for the government. Dr. Thilo Kaltenbach is the author of a number of publications, including the Roland Berger Future of Health series, as well as on new modalities, innovation and translation, supply chain strategy, and performance improvement.

Presenting author details
Dr. Thilo Kaltenbach

linkedin.com/in/thilo-kaltenbach-420ba74

Wednesday, March 8, 2023
SESSION III, 11.45 – 12.15 pm

FDA Efforts During COVID and Beyond: Facilitating Innovation to Address Public Health Needs

Ritu Nalubola, Ph.D.
Director, Europe Office, U.S. Food and Drug Administration

Scientific and technological innovation addressing public health needs are important drivers for FDA's regulatory portfolio. An essential role that FDA plays is to help accelerate patient and consumer access to safe, effective, and innovative medicinal and food products. FDA actively promotes scientific and technological innovations by using novel research tools and providing regulatory predictability and assistance to developers. This presentation highlights three examples of such pioneering efforts by FDA that enabled availability of safe and effective groundbreaking products. Throughout the COVID pandemic, FDA used its expertise and regulatory authorities to respond and adapt quickly, authorizing vaccines and treatments, without compromising our standards. In the area of digital health, FDA is working to reimagine its regulatory approach to leverage the unique benefits of these new technologies, including artificial intelligence and machine learning-based software. As the world experiences a food revolution, FDA is also supporting innovation in food technologies while always prioritizing the safety of foods available to U.S. consumers, having completed first pre-market consultations of novel products enabled by genome editing, and by cultured animal cells.

Biography

Scientific and technological innovation addressing public health needs are important drivers for FDA's regulatory portfolio. An essential role that FDA plays is to help accelerate patient and consumer access to safe, effective, and innovative medicinal and food products. FDA actively promotes scientific and technological innovations by using novel research tools and providing regulatory predictability and assistance to developers. This presentation highlights three examples of such pioneering efforts by FDA that enabled availability of safe and effective groundbreaking products. Throughout the COVID pandemic, FDA used its expertise and regulatory authorities to respond and adapt quickly, authorizing vaccines and treatments, without compromising our standards. In the area of digital health, FDA is working to reimagine its regulatory approach to leverage the unique benefits of these new technologies, including artificial intelligence and machine learning-based software. As the world experiences a food revolution, FDA is also supporting innovation in food technologies while always prioritizing the safety of foods available to U.S. consumers, having completed first pre-market consultations of novel products enabled by genome editing, and by cultured animal cells.

Presenting author details
Ritu Nalubola, Ph.D.

NEW AT ZETA SYMPOSIUM 2023:
THE SPONSOR FORUM

Visit our sponsors' tables during conference breaks and participate in the round table discussions at our Sponsor Forum!
Special insights will be provided by our hand-selected business partners:

SIEMENS, CYTIVA, GEMÜ, ENDRESS+HAUSER & TURCK

ROUND TABLE DISCUSSION
BREAK 1
10.50 – 11.35 am

Technological innovations to be expected within the next few years

// March 7, 2023

ROUND TABLE DISCUSSION
BREAK 2
03.45 – 04.30 pm

New project delivery concepts to reduce project execution time by half

// March 7, 2023

ROUND TABLE DISCUSSION
BREAK 3
09.45 – 10.30 am

US - Europe - Asia: Different Markets, Different Requirements: Just Challenges or Opportunities?

// March 8, 2023

MEET
SIEMENS

Michael FREYNY
Head of Digital Industries

PARTICIPATE IN THE **ROUND TABLE DISCUSSIONS** AT OUR **SPONSOR FORUM!**

Gino DE KONINCK
Regional Sales Director
Western Europe

Olaf OPHOFF
Vice President Business Unit
Automation Systems

MEET
TURCK
Your Global Automation Partner

MEET

Endress+Hauser

Klaus KÖHLER
Global Industry Manager
Life Sciences

Dr. Markus HEINY
Industry Manager
Life Sciences

PARTICIPATE IN THE **ROUND TABLE DISCUSSIONS** AT OUR **SPONSOR FORUM!**

Christopher SANDUSKY
Director, Automation Solutions

Kenneth CLAPP
Senior Manager

MEET

cytiva

MEET

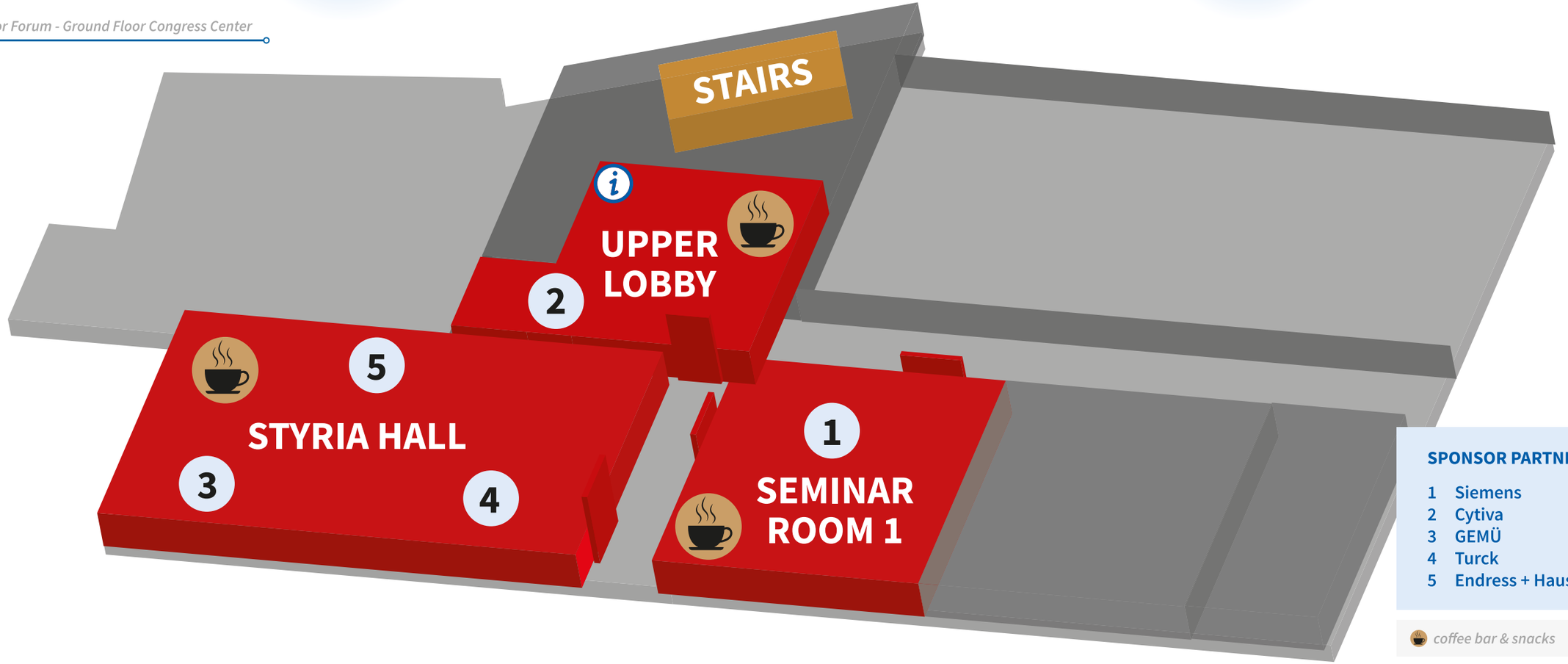
GEMÜ

Stephan MÜLLER
Managing Director

PARTICIPATE IN THE **ROUND TABLE DISCUSSIONS** AT OUR **SPONSOR FORUM!**

Use this opportunity to learn from the best, discover the perspectives of scientific partners, exchange experiences with experts from different disciplines, and get valuable insights into innovative process development and production technology!

Sponsor Forum - Ground Floor Congress Center

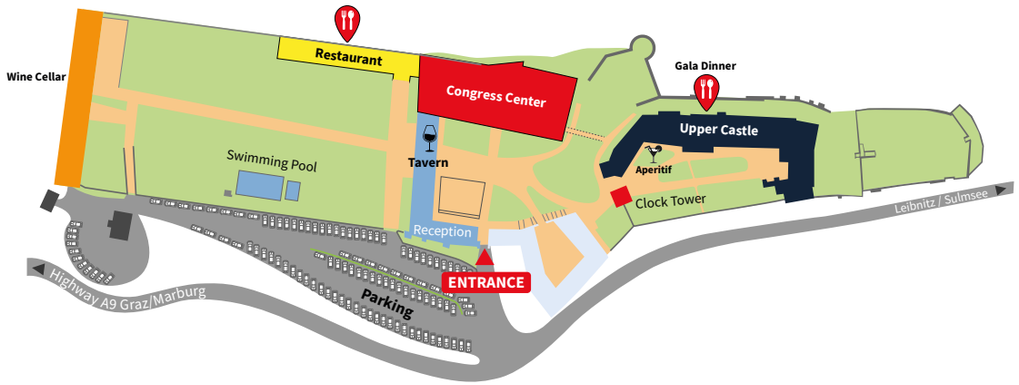


SPONSOR PARTNER

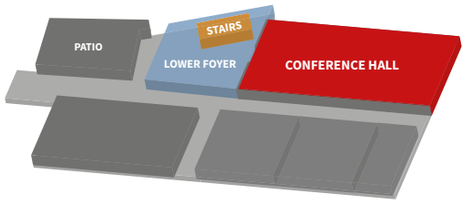
1 Siemens
2 Cytiva
3 GEMÜ
4 Turck
5 Endress + Hauser

coffee bar & snacks *info point*

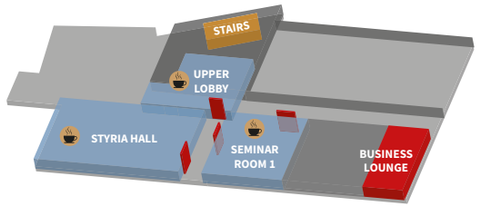
SCHLOSS SEGGAU



Conference Hall - Basement Congress Center



Business Lounge - Ground Floor Congress Center



CONTACT

CONTACT PERSON ON SITE	*MOBILE*	*EMAIL*
Daniela EUSTACCHIO	+43 664 808 52 1407	daniela.eustacchio@zeta.com
Anick LÖFFLER	+43 664 808 52 1522	Info Point
Petra ZEISBERGER	+43 664 808 52 1404	Shuttle Service

MANAGING DIRECTORS

Andreas MARCHLER	+43 664 808 52 1002	andreas.marchler@zeta.com
Alfred MARCHLER	+43 664 808 52 1006	alfred.marchler@zeta.com
Josef MAIER	+43 664 808 52 1390	josef.maier@zeta.com

SALES TEAM

Manfred SEIFERT	+49 172 73 509 48	manfred.seifert@zeta.com
Alexander LAUSECKER	+43 664 808 52 1400	alexander.lausecker@zeta.com
Sushaant BAKHRU	+43 664 808 52 1408	sushaant.bakhru@zeta.com
Lindsay SMART	+1 484 666 8007	lindsay.smart@zeta.com
Tobias HEIM	+49 151 550 510 66	tobias.heim@zeta.com
Maximilian VAN DE GRAAF	+49 151 550 510 20	maximilian.vandegraaf@zeta.com
Nicole ZANGL	+43 664 808 52 1401	nicole.zangl@zeta.com
Christine KOLLAND	+43 664 808 52 1554	christine.kolland@zeta.com
Martin MAYER	+43 664 808 52 1080	martin.mayer@zeta.com

The ZETA Symposium
is sponsored by:

www.zeta.com/**symposium**