2023

GENAP SUMMIT

ASEPTIC PROCESSING TECHNOLOGY | GENE & CELL THERAPY

Aseptic Processing Technology | Gene & Cell Therapy: CMC & Vector Development

Meliá Milano*****

Via Masaccio, 19 - Milano, Italy

23 - 24 February

SPONSORS

PLATINUM

PALL CORPORATION

GOLD

NOVATEK INTERNATIONAL

CATUG

PROTAK SCIENTIFIC
RAPID VALIDATION FOR BIO-DECONTAMINATION

BECKMAN COULTER Life Sciences

MEDIA PARTNERS

LAB WORLD

Gene Therapy Net
www.genetherapynet.com
- Breaking News
- Conferences
- Clinical Trials
- Viral Vectors
- Legislation
- Societies

KC World With Science www.kindcongress.com

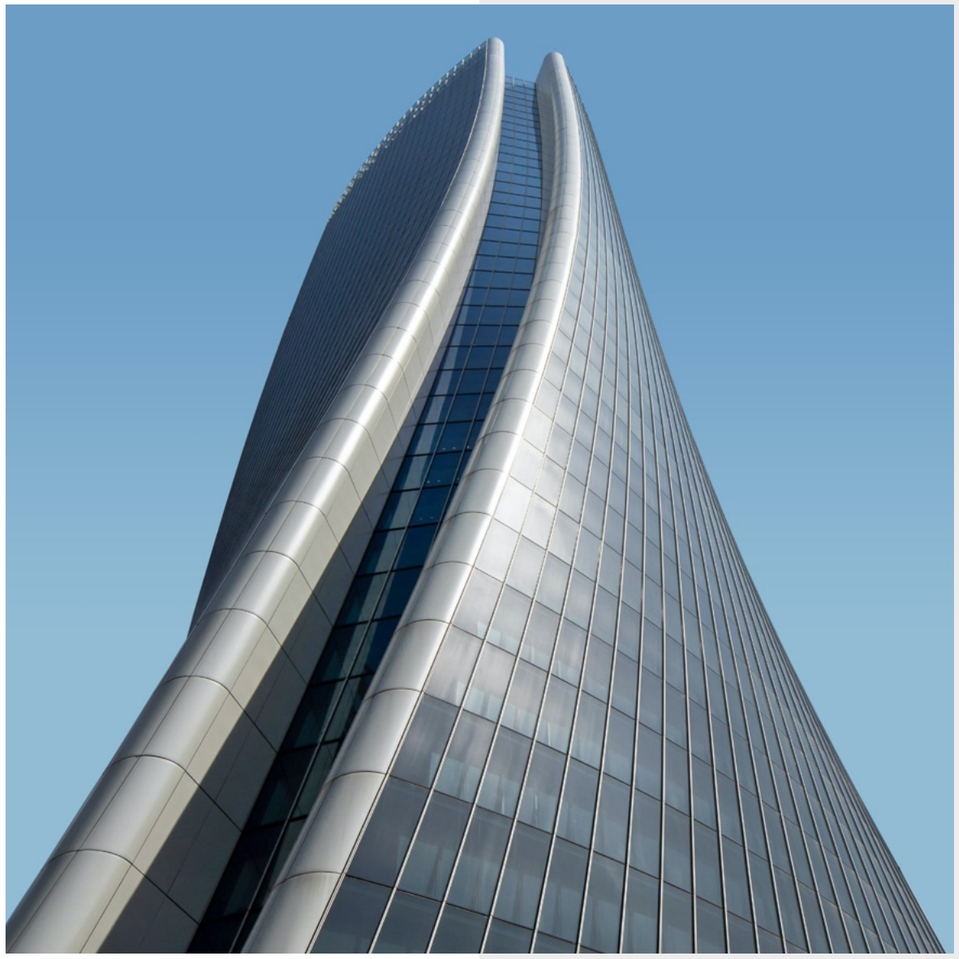
Bio-Equip www.bio-equip.cn

ManuscriptEdit by Researcher

LABePEDIA THE LAB EQUIPMENT ENCYCLOPEDIA www.labepedia.com Join Free. Sell & Source Globally.

HealthcareTech OUTLOOK

SPONSORED BY



GENNAP SUMMIT

On the APT track you will learn about environmental monitoring systems, facility cleaning and disinfectant qualification, aseptic cleanroom operations, filtration, sterilization, aseptic process simulation, and regulatory requirements. Further discussions at the GCT Track we will focussing on vector improvement for both ex vivo and in vivo approaches, dedicated sessions on CMC strategy, analytical development and qualification, product-related impurities and their link to quality, bioassays, comparability, stability, formulation, and the emergence of non-viral gene therapies.

KEY PRACTICAL POINTS

GCT TRACK

- Requirements in bringing drugs to market
- Vector serotypes to produce more durable gene expression
- Vector Design and Development for Gene and Cell Therapies
- Current challenges and future of gene therapy technical development
- Lessons learnt from commercial products/ late-stage products
- The complexity of vector development and production
- Investors perspective of gene therapy development
- Reducing timelines for cell and gene therapy drug development
- CMC strategies for rare diseases
- Qualifying starting materials/intermediary materials
- Developing novel vectors to reduce immunogenicity
- Successful strategies to accelerate CGT process development from preclinical to manufacturing and commercialisation
- Efficient enabling novel technologies and resources
- Defining optimal regulatory pathways
- Critical elements of establishing a robust CMC strategy
- Identifying and measuring of CQAs and determining CPPs
- Crucial factors in easing the complexity of vector development and production
- Achieving technical, regulatory, and cost efficiency for manufacturing safe gene and cell therapy products
- Critical aspects of establishing an efficient, consistent, and flexible CMC strategy
- Controlling a product's CQAs by controlling the process' CPPs
- Emerging technologies improving effectiveness and CGTPs manufacturing processes and production
- Crucial components of controlling and scaling manufacturing process and operations for CGTPs
- Development of Pediatric Gene Therapy Using Nuclease-Free Genomic Editing Technology

APT TRACK

- The Evolution of Aseptic Technologies
- Cleanrooms for the Annex 1 updates
- Implementation of quality risk management
- Regulatory framework
- Antibody Drug Conjugates / HPAPIs production
- Lyophilization of highly potent products and aseptic processing.
- Occupational safety requirements
- Aseptic process development, validation and evaluation.
- Highly potent facility design and engineering considerations
- Isolator Technology use in aseptic processing for loss minimization/elimination.
- Overcoming technical challenges in decontamination processes and material transfers.
- Cleaning and disinfection programs for aseptic facilities.
- Cross contamination prevention and control for highly potent products.
- Robotics in aseptic processing
- Gloveless Isolators and dose control
- ADC/HPAPI aseptic processing fill and finish
- Challenges for manufacturers in cell and gene therapy production systems
- Airflow visualization for contamination risks assessment.
- Implementing containment technologies in aseptic processing
- Boosting sterilization: successful strategies, advanced technologies implementation.
- Cleaning automation and technologies.
- Gowning: procedures, training, personnel qualification.
- Microbiology techniques use in aseptic processing.
- Integrating sanitization techniques to empower contamination control.
- Filtration: filter integrity testing in aseptic processing.
- Single-use systems implementation.
- Assess airflow visualization to limit risk for product contamination
- Describe the importance of filter integrity testing for aseptic operations

SPEAKERS

Alison Armstrong

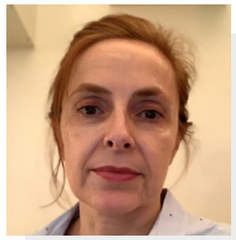
Senior Director, Global Head Technical and Scientific Solutions
at Merck KGaA

Chiara Pacini

Bioprocess Specialist at Pall Corporation

Chris Berridge

Global Technical Consultant, Bioquell Specialist
at Ecolab Life Sciences



Christiane Niederlaender

Vice President Technical CMC
at Parexel

Lutz Ehrhardt

Senior Marketing Manager Centrifugation at Beckman Coulter Life Sciences

Magnus Gustafsson

Chief Business Officer
at Biovian

Michele Simone

Corporate Quality Management Director
at Bracco

Richard Denk

Senior Consultant Aseptic Processing & Containment
at SKAN AG

David Estapé

Senior Process Specialist & Senior Fellow
at CRB

Donald Singer

Senior Microbiology Technical Consultant
at Ecolab Life Sciences

Edith Filaire

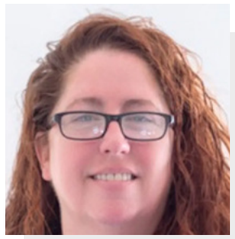
Professor and Scientific Director
at ICARE GROUP

Fabian Stutz

CEO
at Pharmabotix AG

Silvia Aldi

Product Manager for Cell & Gene Therapy
at SKAN AG



Susan Cleary

Director Product Development
at Novatek International

Zhihao Peter Qiu

External Advocacy Lead China
at Roche Genentech

Zsuzsanna Izsvák

Group leader
at Max Delbrück Center of Molecular Medicine, Berlin

Frank J.T. Staal

Professor
at Leiden University Medical School

James Drinkwater

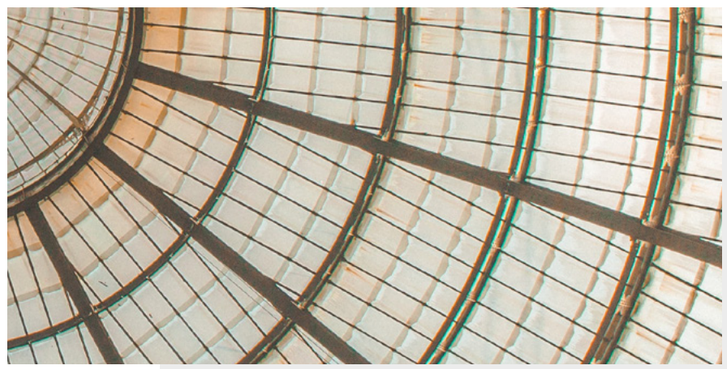
Head of GMP Compliance
at Franz Ziel

Juha Mattila

Director, Sterilization Technologies
at STERIS Life Sciences

Kate Marshall

Technical Director
at Protak Scientific



SCIENTIFIC AGENDA

DAY 0 FEBRUARY 22, 2023

18:30 - 20:00

Pre-Conference Cocktail Reception

*At **Mélia Milano Hotel***

DAY 1 FEBRUARY 23, 2023

APT TRACK

Morning Sessions Chairperson:
Richard Denk, SKAN AG

8:00 - 8:30

Registration and Welcome Coffee

8:30 - 9:00

Annex 1 - GMP Compliance when working with Robotics in Aseptic Processing

*By **Richard Denk**, Senior Consultant Aseptic Processing & Containment at SKAN AG*

9:00 - 9:30

Aseptic processing applied in Gene & Cell therapy following QRM principles

*By **James Drinkwater,** Head of GMP Compliance at Franz Ziel*

9:30 - 10:00

Speed Networking

10:00 - 10:30

Morning Coffee-Break

10:30 - 11:00

Modular and Flexible Robotics Systems for CGT

*By **Fabian Stutz**, CEO at Pharmabotix AG*

11:00 - 11:30

FDA's Regulatory Review and Inspection of Biological Products Manufactured Using Aseptic Processing

*By **Zhihao Peter Qiu**, External Advocacy Lead China at Roche Genentech*

11:30 - 12:20

Meeting the challenges of Annex 1 with innovation in rapid H2O2 validation.

*By **Kate Marshall**, Technical Director at Protak Scientific*

12:20 - 13:00

Overcome development and manufacturing challenges for viral vector sterilizing filtration

*By **Chiara Pacini**, Bioprocess Specialist at Pall Corporation*

13:00 - 14:00

Lunch & Networking Break

GCT TRACK

Afternoon Sessions Chairperson:
Alison Armstrong, Merck KGaA

14:00 - 14:30

Developing stem cell-based gene therapy for RAG1 and RAG2 deficient SCID

*By **Frank J.T. Staal**, Professor at Leiden University Medical School*

14:30 - 15:00

Sleeping Beauty Transposon Vectors for Therapeutic Applications

*By **Zsuzsanna Izsvák**, Group leader at Max Delbrück Center of Molecular Medicine, Berlin*

15:00 - 15:30

CMC considerations for Cell and Gene therapy products

*By **Alison Armstrong**, Senior Director, Global Head Technical and Scientific Solutions at Merck KGaA*

15:30 - 16:00

DGE-AUC: Adapting the Power of Density Gradient Separations for Gene Therapy Analytics

*By **Lutz Ehrhardt**, Senior Marketing Manager Centrifugation at Beckman Coulter Life Sciences*

16:00 - 16:30

Afternoon Coffee Break

16:30 - 17:30

Panel Discussion

• Ensuring clinical success: Clinical data generation
• The future and commercial sustainability of ATMPs
• ATMP – Regulatory, process and supply chain: Challenges & opportunities
• CGT Bioprocessing and digitalization
• Viral-Vector Therapies at scale: today's Challenges and future opportunities

*Panelists: **Alison Armstrong; Frank J.T. Staal; Zsuzsanna Izsvák; Christiane Niederlaender***

*Moderated by **Silvia Aldi**, Product Manager for Cell & Gene Therapy at SKAN AG*

17:30

Chairperson Closing Remarks and end of the 1st day sessions

19:30 - 22:00

Gala dinner - with Live Portuguese FADO Music at Meliá Milano Hotel

DAY 2 FEBRUARY 24, 2023

APT TRACK

Morning Sessions Chairperson:
Michele Simone, Bracco

8:30 - 9:00

Registration and Welcome Coffee

9:00 - 9:30

Contamination Control with Efficiency – Integrating Annex 1, Automation and Microbiology

*By **Donald Singer** | **Chris Berridge**, Ecolab Life Sciences*

9:30 - 10:00

Vaporized hydrogen peroxide (VHP) sterilization and biodecontamination technologies – implications from new regulatory and standards developments (EU Annex 1:2022 and ISO 22441:2022)

*By **Juha Mattila**, Director Sterilization Technologies at STERIS Life Sciences*

10:00 - 10:30

Morning Coffee-Break

10:30 - 11:00

Microbial data investigations and effective implementation roadmap of Contamination Control Strategy

*By **Michele Simone**, Corporate Quality Management Director at Bracco*

11:00 - 11:30

Pattern Recognition and Trending for Regulatory Compliancy and Contamination Control Strategy

*By **Susan Cleary**, Director Product Development at Novatek International*

11:30 - 12:00

The Facility Evolution of Small-Scale Cell Therapy

*By **David Estapé**, DSenior Process Specialist & Senior Fellow at CRB*

12:00 - 13:00

Panel Discussion

• EU GMP Annex 1 Revision Implementation
• Aseptic Packaging Sustainability
• Contamination Control Strategies

*Panelists: **James Drinkwater; Zhihao Peter Qiu; Fabian Stutz; Michele Simon***

*Moderated by **Richard Denk***

13:00 - 14:00

Lunch & Networking Break

GCT TRACK

Morning Sessions Chairperson:
Michele Simone, Bracco

14:00 - 14:30

Novel Concept for Isolators to Manufacture ATMP and Biologics

*By **Silvia Aldi**, Product Manager for Cell & Gene Therapy at SKAN AG*

14:30 - 15:00

Comparability for genetically modified cells: challenges for vectors and cells

*By **Christiane Niederlaender**, Vice President Technical CMC at Parexel*

15:00 - 15:30

Viral vector development and manufacture

*By **Magnus Gustafsson**, Chief Business Officer at Biovian*

15:30 - 16:00

Alternative in vitro models to animal testing : what are the new challenges and opportunities?

*By **Edith Filaire**, Professor and Scientific Director at ICARE GROUP*

16:00 - 16:05

Chairperson Closing Remarks and end of the GENAP Summit

BIOGRAPHIES

Alison Armstrong, Senior Director, Global Head Technical and Scientific Solutions at Merck KGaA

Dr. Alison Armstrong is Senior Director , Global Head of the Technical and Scientific Solutions team. Dr Armstrong has a long history in academic research as a postdoctoral scientist and Research fellow and has been involved in examining the role of viruses in various pathogenic conditions. She has led a number of teams in different divisions within Merck; operational teams, validation and scientific development, and she is currently responsible for a scientific consultancy team with the remit to support clients in technical, scientific, and regulatory issues.

Chiara Pacini, Bioprocess Specialist at Pall Corporation

Chiara Pacini is a Bioprocess Specialist based in Milan and covers Italy, Switzerland and UK. She joined Pall in 2019 as an Associate Scientist in the Aspetic team for a year and then moved to the Bioprocess Specialist team. She graduated in Industrial Biotechnology at Bicocca University. She works on the DSP purification of development processes from benchtop to industrial scale. Her expertise is focused mainly on nps, lnps and EVs in the GT field.

Chris Berridge, Global Technical Consultant, Bioquell Specialist at Ecolab Life Sciences

Chris has over 7 years of experience working in graded cleanrooms for pharmaceutical manufacturing as well as biosafety laboratories and biomedical facilities. He is a bio-decontamination specialist and subject matter expert on Bioquell technology, products and services and their uses in the Life Sciences and Healthcare markets. He also manages projects focusing on the implementation of Bioquell's more complex integrated decontamination systems including detailed design, building of bespoke documentation, and managing the validation and other siteworks.

Christiane Niederlaender, Vice President Technical CMC at Parexel

Christiane joined Parexel in January 2021 as Vice President Technical for CMC and now works with developers to get advanced therapies into the clinic and to market. Since joining Parexel, Christiane has done substantial amount of work within the US system and and has knowledge about EU, UK and US CMC regulatory requirements.

David Estapé, Senior Process Specialist & Senior Fellow at CRB

David Estapé is a senior biotechnology expert who holds a PhD in chemical engineering and brings more than 25 years of experience to every project. He is spezialised in facility design and GMP consulting within the vaccine, biotech and plasma pharmaceutical industry. His expertise and experience, as well as his interest and passion in new technologies have made him a recognized biotechnology thought leader that participates strongly in organizations like BioPhorum, Parenteral Drug Association and the International Society for Pharmaceutical Engineering.

Donald Singer, Senior Microbiology Technical Consultant at Ecolab Life Sciences

Don Singer is Senior Microbiology Technical Consultant, North America, for Ecolab, and a Fellow in the American Society for Quality. He was formerly a GSK Senior Fellow. Don was Chair of the USP Microbiology Committee of Experts and has been a member since 2000. Don is also a member of the European Pharmacopeia Group 1 Microbiology Committee. He was chair of the PDA Task Force for the TR 86, “Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing”, and was co-author of the TR 67, “Exclusion of Objectionable Microorganisms”, and is a co-author of the PDA TR for “Contamination Control Strategy”.

Edith Filaire, Professor and Scientific Director at ICARE GROUP

Edith Filaire obtained her PhD from the University of Clermont-Ferrand in 1997. She has worked in major French universities (Lyon 1, Clermont-Fd, Orleans-Paris Saclay). From 2006 to 2018, she was Professor and -co director of a Research laboratory at Orleans-Paris Saclay. Her research focused in nutrition- health using a psychophysiological approach. She is author/co-author of more than 150 contributions to scientific international journals and 6 chapter books. In November 2018 (Lisbon), she was nominated for the Women in Tech International Award that recognises people around the world who innovates, inspires and transforms the technology.

Fabian Stutz, CEO at Pharmabotix AG

Fabian Stutz is CEO & Head of Sales with Pharmabotix AG, a company that provides clients with innovative robotics and automation solutions for the pharmaceutical industry. From building an effective team to maintaining a large customer network, he is adept at driving business development while delivering exceptional service to customers with a direct communications approach.

Frank J.T. Staal, Professor at Leiden University Medical School

Frank Staal received his training at Utrecht University (Netherlands) studying Medical Biology receiving his Bachelor of Science (BSc) and Master of Science degrees both with distinction (cum laude). He obtained his PhD degree from Stanford University Medical School in Genetics under the guidance of professors Leonard and Lenore A. Herzenberg. He moved back to his native country working at the Dutch Cancer Institute (Amsterdam) and subsequently at Utrecht University as Fellow of the Dutch Royal Academy of Sciences (KNAW) with professor Hans Clevers.

James Drinkwater, Head of GMP Compliance at Franz Ziel

James Drinkwater is the Head of GMP Compliance at Franz Ziel Germany and lead of the PHSS: Pharmaceutical and Healthcare Sciences Society Aseptic processing special interest group. Franz Ziel are the largest barrier and cleanroom technology manufacturer in Germany with international projects that include filling lines (with partners) and Gene & Cell Therapy manufacturing platforms. James engages at a consultancy level through facility and process design then oversees and supports GMP compliance through project execution.

Juha Mattila, Director, Sterilization Technologies at STERIS Life Sciences

Juha Mattila is Director, Sterilization Technologies, responsible for the STERIS Life Sciences Finland portfolio, including GMP steam and VHP sterilization and biodecontamination technologies, and WFI and Pure Steam generation systems. He has B. Sc. in HVAC and Process Engineering, and Master of Engineering in Business Informatics. He has over 22 years of experience with pharmaceutical and research technologies, including R&D, engineering, and product management.

Kate Marshall, Technical Director at Protak Scientific

A Microbiologist by profession, Kate has extensive experience in aseptic manufacture of medicinal products that was gained in roles aligned to Quality, Validation and Operations specialising in sterilisation and decontamination processes. Kate takes overall responsibility for technical operations at Protak Scientific, ensuring the successful implementation of the Enzyme indicator technology within diverse applications around the world.

Lutz Ehrhardt, Senior Marketing Manager Centrifugation at Beckman Coulter Life Sciences

Dr. Lutz Ehrhardt is an educated physicist who was pulled into biophysics by his interest in membrane transport and methods in biophysics. His scientific experience at the JWG University Frankfurt and the Max-Planck Institute for Biophysics includes membrane transport, membrane proteins, reconstitution, vesicles, lipid-protein- and protein-protein interactions and biophysical characterization. Lutz is working at Beckman Coulter for > 25 years in different positions including Lab automation, Particle Characterization and Genetic Analysis and Protein Characterization.

Magnus Gustafsson, Chief Business Officer at Biovian

Magnus Gustafsson works as Chief Business Officer at Biovian, a premium Nordic Bio-CDMO providing Manufacturing Happiness for its global clients. In addition to solid business experience, Gustafsson has a scientific background, with more than 20 peer-reviewed articles, and has spent 20 years in various commercial positions executing academic and corporate collaborations, sales management, project management, business development, partnership negotiations and agreements.

Michele Simone, Corporate Quality Management Director at Bracco

Dr. Michele Simone is Director of Corporate Quality Management for Bracco Suisse SA in the pharmaceutical imaging product operations in Lugano, Switzerland, where he is responsible for Quality Management Review, complaints management, auditing, quality risk management, knowledge management, CAPA management and Continual Improvement. Over 28 years' experience in the pharma/biopharma industry. Michele hold a number of different roles during his career, including: Microbiology and Environmental Monitoring Supervisor, QA GMP Compliance Site Manager of a sterile fill-finish facility (liquids, lyophilized vials, pre-filled syringes, cartridges), QA/QC Senior Site Manager of a medical device J&J facility (coronary coated stents) with a broad international scope, Global Quality and Training Senior Manager (site and corporate quality) of a Parenteral network of J&J facilities, Head of Quality System and Compliance of a Vaccines fill-finish facility, QP and Quality Unit Head of an API plant, Corporate Quality Auditor for API, Finished products, Chemical, Consumer, Commercial Affiliates, Vendors.

Richard Denk, Senior Consultant Aseptic Processing & Containment at SKAN AG

Richard Denk is working at the company SKAN AG, headquartered in Allschwil Switzerland in the position Senior Consultant Aseptic Processing & Containment. Richard is Member of the PDA ATMP Advisory Board and chair of the PtC of the Manufacturing of ATMPs. Richard is member of the PDA Isolator Expert Group and publisher of the PDA Paper "Isolator Surfaces and Contamination Risk to Personnel and Patient". Furthermore, Richard is member of the ISPE Annex 1 and PIC/s Annex 2A commenting group, Founded the ISPE CoP Containment and SIG Future Robotics. Richard is Member of the ISPE European Leadership Team and Member of the ISPE CoP Sterile Product Processing. Richard is a global recognized subject matter expert on Aseptic Processing, ATMPs and Containment and has developed the containment pyramid.

Silvia Aldi, Product Manager for Cell & Gene Therapy at SKAN AG

As SME in Cell and Gene Therapy / Advanced Therapy Medicinal Products (ATMPs) manufacturing, Dr. Aldi has more than 10 years of expertise in R&D management and coordination of translational and pre-clinical multidisciplinary research projects. As Research Coordinator at Karolinska Institutet Stockholm, Sweden, she led the development of In Vitro Medical Device (IVD) to diagnosis of autoimmune diseases, such as rheumatoid arthritis and lupus erythematosus.

Susan Cleary, Director Product Development at Novatek International

Susan Cleary, B.Cs, EMBA. is the director of product development at Novatek International. Susan has more than 20 years of experience in designing, developing, and implementing large-scale quality management and contamination control systems. Susan works with pharmaceutical, biotech, and medical device companies and specialises in data integrity and regulatory compliance. She is highly experienced working with clients to streamline their procedures and digitise their data.

Zhihao Peter Qiu, External Advocacy Lead China at Roche Genentech

Peter joined Roche/Genentech in 2022 from Innovent Biologics, China, where he was Chief Quality Officer. Prior to Innovent, Peter spent 14 years at FDA in multiple roles of increasing leadership responsibilities in the Office of Compliance and Biological Quality (OCBQ), Center for Biological Evaluation and Research (CBER), Office of In vitro Diagnostic Devices, Center for Devices and Radiological Health (CDRH), and the Office of Compliance (OC) and the Office of Pharmaceutical Sciences (OPMA), Center for Drug Evaluation and Research (CDER), where his most recent role was Division Director of the Division of Biotechnology Manufacturing in OPMA, responsible for managing the scientific review and quality evaluation of the manufacturing controls and facilities for Biologics license applications (BLA) and conducting pre-license/pre-approval inspections for CDER regulated biological products. Before joining FDA, Peter spent ten years in biotech and device industry, primarily, in R&D and GMP manufacturing.

Zsuzsanna Izsvák, Group leader at Max Delbrück Center of Molecular Medicine, Berlin

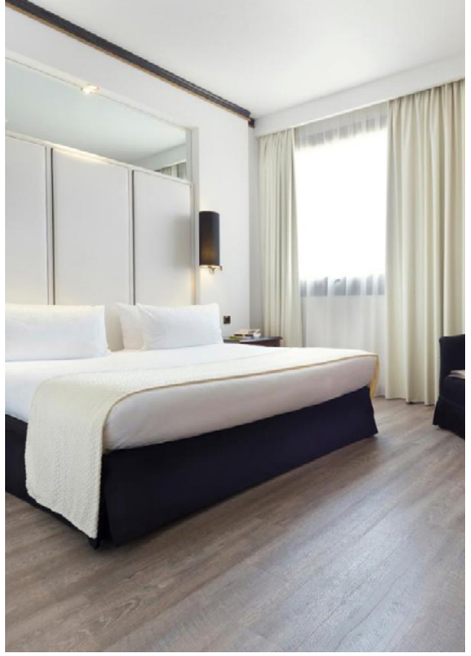
Zsuzsanna Izsvák received her PhD in 1993 from the Hungarian Academy of Sciences in Budapest, Hungary. After a postdoctoral period at the University of Minnesota, St. Paul, USA, she returned to Europe. She held a long–term fellowship from EMBO and worked at the Netherlands Cancer Institute in Amsterdam between 1997 and 1999. She joined the Max–Delbrück–Center for Molecular Medicine in Berlin in 1999. In 2004, her research was evaluated by the European Science Foundation (ESF) as “strategically important” for Europe and was awarded by the European Young Investigator Award (EURYI) in 2004. Zsuzsanna Izsvák is the inventor of the Sleeping Beauty transposon–based non–viral vector system. Her goal is to integrate basic knowledge and its translation to establish a technology platform, including stem cell research, gene and cell therapy, transgenesis, cancer research and functional genomics.

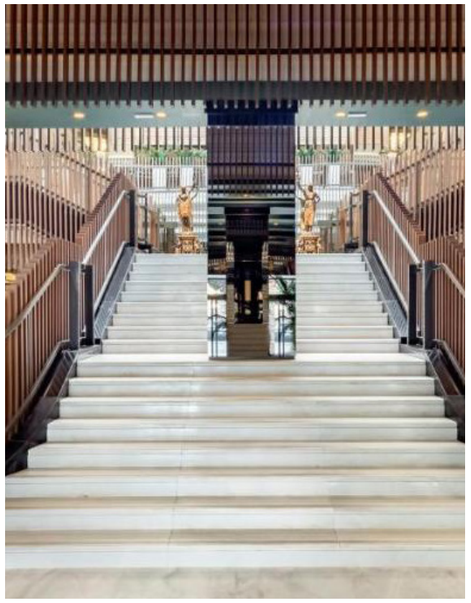
NOTES

MELIÃ MILANO*****

The charm of Milanese elegance

Milan is a vibrant city, capital of fashion, glamour and the latest trends. The booming district of Zona Lotto is home to the Meliá Milano. Fully renovated, it reflects the innovative design and elegance for which the capital of Lombardy is famous and also offers facilities that can only be admired. Exclusive suites and rooms plus the added benefits of The Level service.





genapsummit.com