



2023

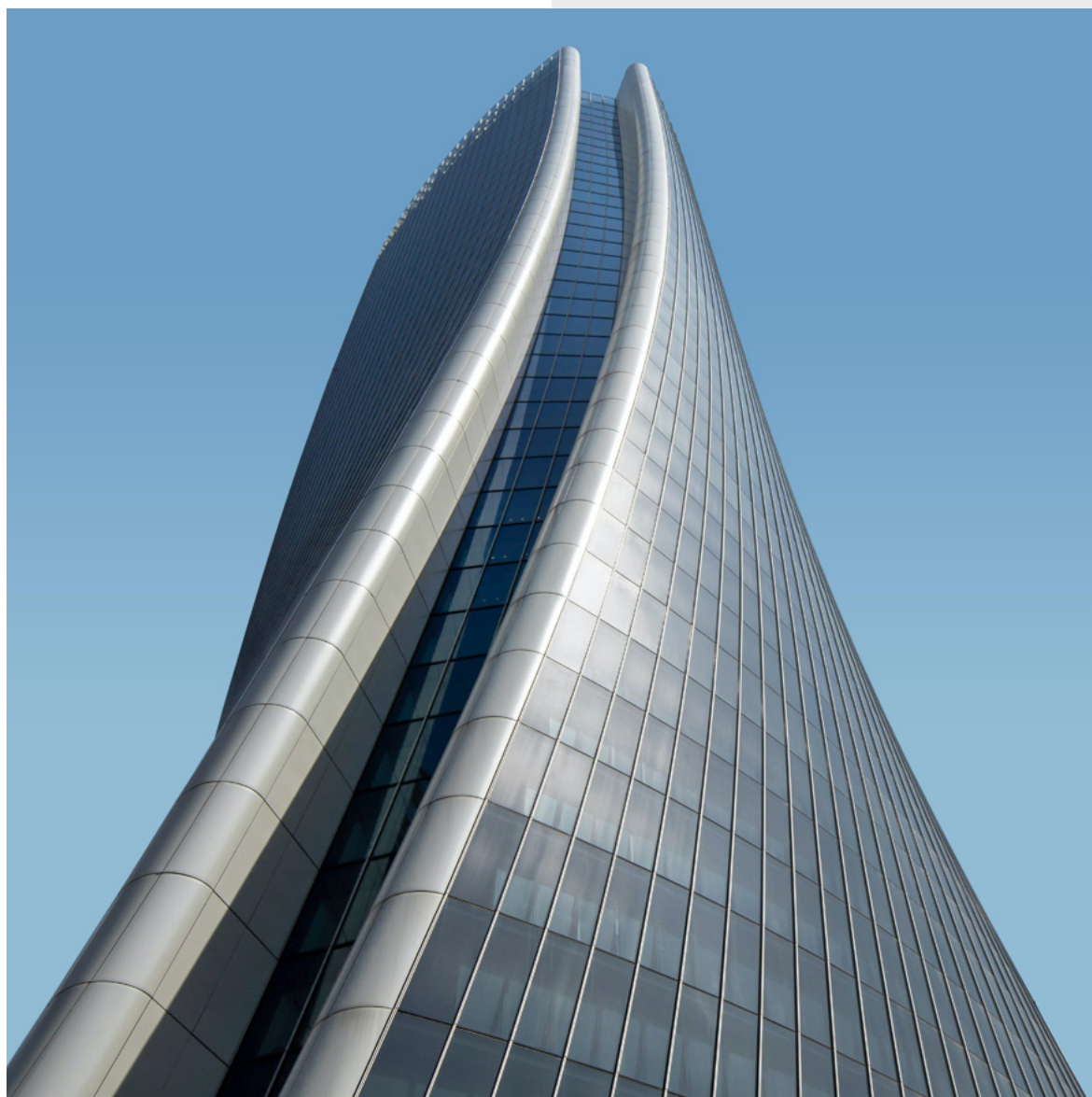
Aseptic Processing Technology | Gene
& Cell Therapy: CMC & Vector Development

Meliá Milano*****

Via Masaccio, 19 - Milano, Italy

23 - 24 February

B



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



Gregory Fiore
Chief Executive Officer
at Exacis Biotherapeutics



James Drinkwater
Head of GMP
Compliance
at Franz Ziel



Michele Simone
Corporate Quality
Management Director
at Bracco



Richard Denk
Senior Consultant
Aseptic Processing &
Containment
at SKAN AG



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



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



Christiane Niederlaender
Vice President Technical
CMC
at Parexel



David Estapé
Senior Process
Specialist & Senior
Fellow
at CRB



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



Zhihao Peter Qiu
External Advocacy Lead
China
at Roche Genentech



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



Donald Singer
Senior Microbiology
Technical Consultant
at Ecolab Life Sciences



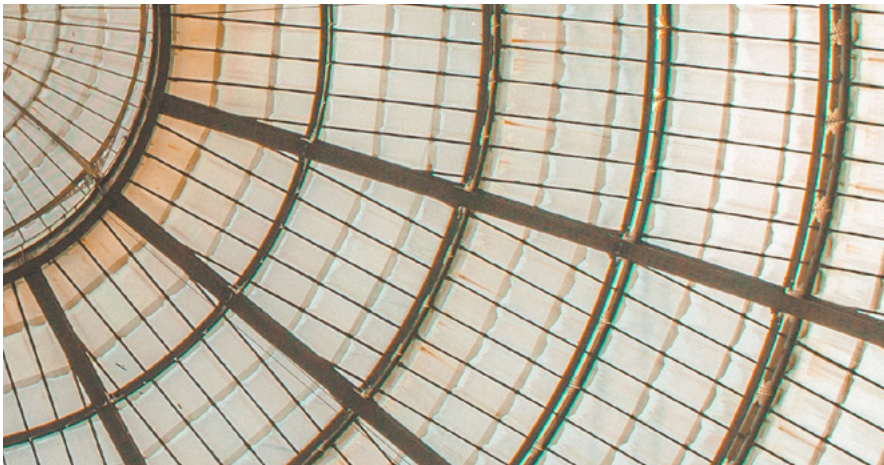
Edith Filaire
Professor and Scientific
Director
at ICARE GROUP



Fabian Stutz
CEO
at Pharmabotix AG



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



SCIENTIFIC AGENDA

DAY 1 FEBRUARY 23, 2023

8:30 - 9:00

Registration and Welcome Coffee

9:00 - 9:40

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

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

9:40 - 10:00

Speed Networking

10:00 - 10:30

Morning Coffee-Break

10:30 - 11:10

Aseptic processing applied in Gene & Cell therapy following QRM principles

By James Drinkwater, Head of GMP Compliance at Franz Ziel

11:10 - 11:50

Microbial data investigations and effective implementation roadmap of Contamination Control Strategy

By Michele Simone, Corporate Quality Management Director at Bracco

11:50 - 12:30

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

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

13:00 - 14:00

Lunch & Networking Break



14:00 - 14:40

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

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

14:40 - 15:20

Topic to be announced - Zsuzsanna Izsvák

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

15:20 - 16:00

Comparability for genetically modified cells: challenges for vectors and cells

By Christiane Niederlaender, Vice President Technical CMC at Parexel

16:00 - 16:30

Afternoon Coffee Break

DAY 2 FEBRUARY 24, 2023

16:30 - 17:00

Panel Discussion (GCT)

9:00 - 9:40

Chairperson Closing Remarks and end of the 1st day sessions

20:00 - 21:00

Gala dinner



8:30 - 9:00

Registration and Welcome Coffee

9:00 - 9:40

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

By Donald Singer | Chris Berridge, Ecolab Life Sciences

9:40 - 10:00

Poster Presentations (APT & GCT)

Submit your Poster Presentation

10:00 - 10:30

Morning Coffee-Break



10:30 - 11:10

Modular and Flexible Robotics Systems for CGT

By Fabian Stutz, CEO at Pharmabotix AG

11:10 - 12:00

The Facility Evolution of Small-Scale Cell Therapy

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

12:00 - 13:00

Panel Discussion (APT)

13:00 - 14:00

Lunch & Networking Break

14:00 - 14:40

Introduction to Cell and Gene Therapy market | ATMP manufacturing | Validated Cell and Gene Therapy processes in isolators

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

14:40 - 15:20

CMC considerations for Cell and Gene therapy products

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

15:20 - 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 - 16:30

Chairperson Closing Remarks and end of the GENAP Summit

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Package Name

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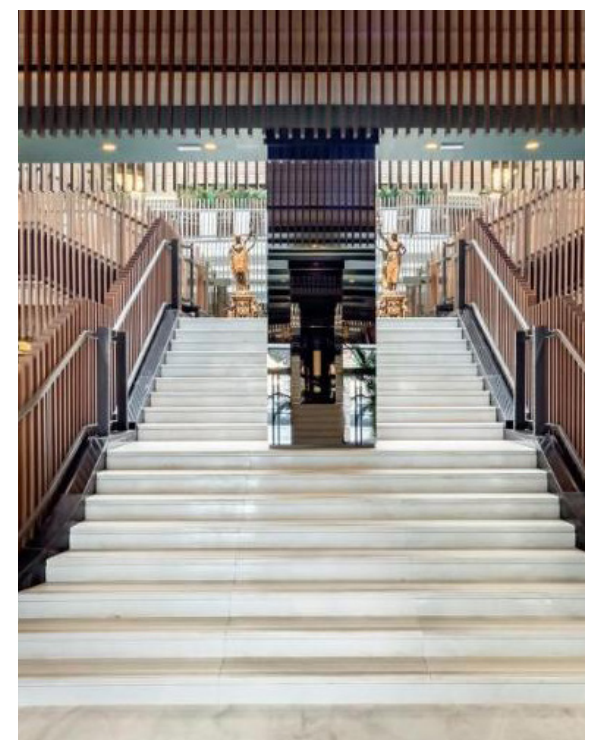
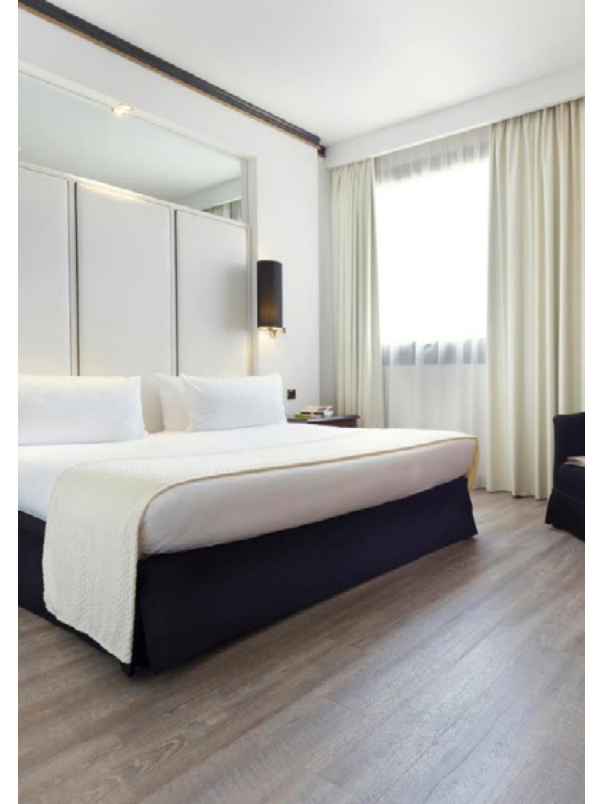
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