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

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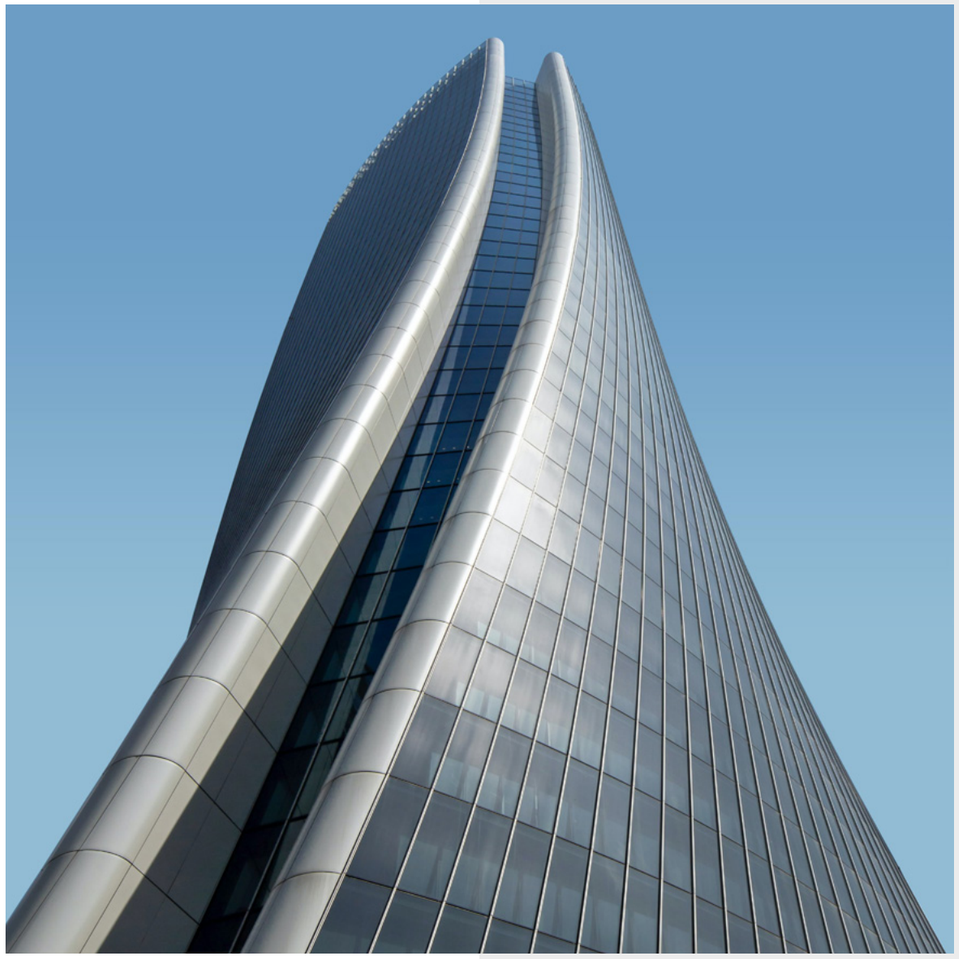


GENNAP SUMMIT

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

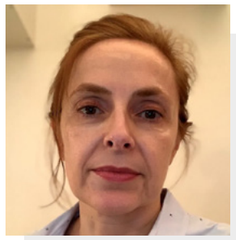
SPEAKERS

Alison Armstrong

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

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

Michele Simone

Corporate Quality Management Director
at Bracco

Richard Denk

Senior Consultant Aseptic Processing & Containment
at SKAN AG

Silvia Aldi

Product Manager for Cell & Gene Therapy
at SKAN AG

Susan Cleary

Director Product Development
at Novatek International

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

Zhihao Peter Qiu

External Advocacy Lead China
at Roche Genentech

Zsuzsanna Izsvák

Group leader
at Max Delbrück Center of Molecular Medicine, Berlin

Gregory Fiore

Chief Executive Officer
at Exacis Biotherapeutics

James Drinkwater

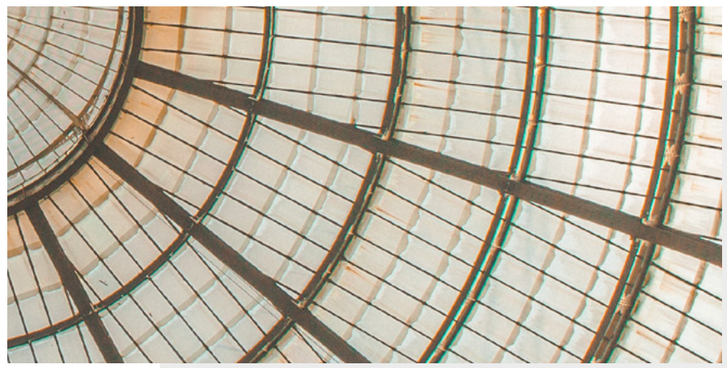
Head of GMP Compliance
at Franz Ziel

Juha Mattila

Director, Sterilization Technologies
at STERIS Life Sciences

Magnus Gustafsson

Chief Business Officer
at Biovian



DAY 1 FEBRUARY 23, 2023

APT TRACK

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 - 12:00
Protak Scientific Presentation

12:00 - 13:00
Pall Corporation Presentation

13:00 - 14:00
Lunch & Networking Break

GCT TRACK

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
Topic to be announced - Zsuzsanna Izsvák

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

15:00 - 15:30
Comparability for genetically modified cells: challenges for vectors and cells

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

15:30 - 16:00
CMC considerations for Cell and Gene therapy products

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

DAY 2 FEBRUARY 24, 2023

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; Gregory Fiore; 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
Gala dinner

APT TRACK

8:30 - 9:00
Registration and Welcome Coffee

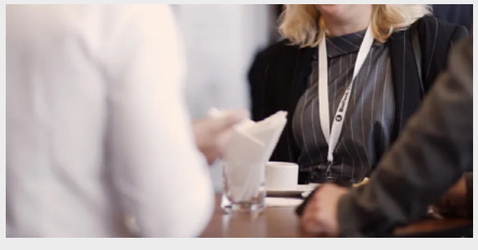
9:00 - 9:30
Contamination Control with Efficiency – Integrating Annex 1, Automation and Microbiology

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

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*

14:30 - 15:00
Viral vector development and manufacture

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

15:00 - 15:30
Alternative in vitro models to animal testing : what are the new challenges and opportunities?

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

15:30
Chairperson Closing Remarks and end of the GENAP Summit

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- Extra delegate registration for only €1000
- Poster Presentation Submission
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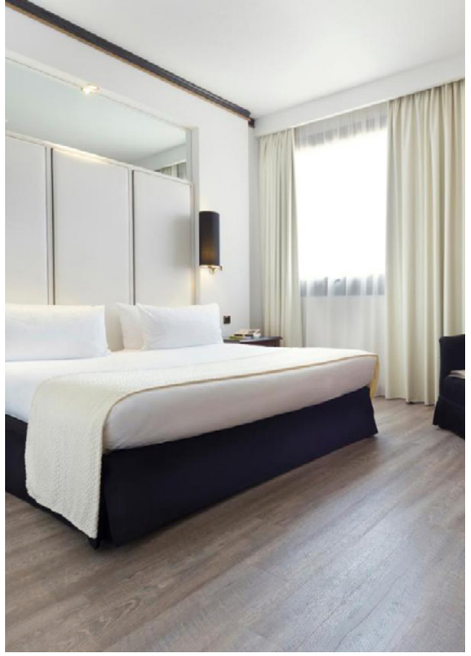

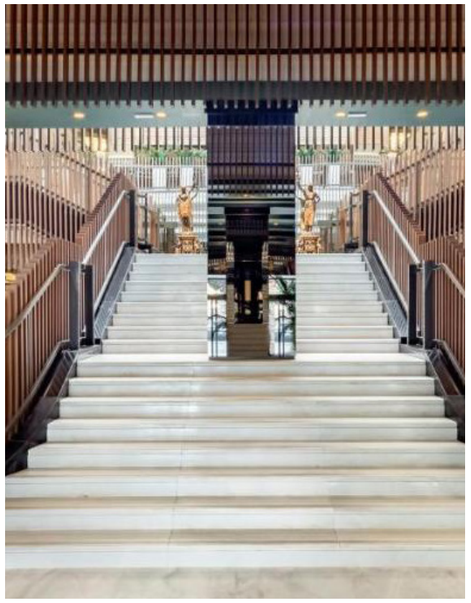

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