Program

Advancing Manufacture of Cell and Gene Therapies VIII

February 4 – 8, 2024
Loews Coronado Bay Hotel
Coronado, CA, USA

Conference Chairs:

Fernanda Masri
Cytomos, UK

Carolyn Yeago
CY Solutions LLC, USA

Gargi Maheshwari
BMS, USA

John Moscariello
BMS, USA

Engineering Conferences International
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New York, NY 10017, USA
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Loews Coronado Bay Hotel
4000 Coronado Bay Road
Coronado, California, 92118
Phone: 619-424-4000
www.loewshotels.com/coronado-bay-resort

Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program, originally established in 1962, that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines.

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Gargi Maheshwari, BMS, USA
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Student Liaison

Bryan Wang, TreeFrog Therapeutics

Previous conferences in this series:

Scale-Up and Manufacturing of Cell-Based Therapies
January 11-13, 2012
San Diego, California
Conference Chairs:
Chris Mason, University College London, UK
Lars Nielsen, University of Queensland, Australia
Greg Russotti, Celgene, USA

Scale-Up and Manufacturing of Cell-Based Therapies II
January 21-23, 2013
San Diego, California
Conference Chairs:
Chris Mason, University College London, UK
Lars Nielsen, University of Queensland, Australia
Greg Russotti, Celgene, USA

Scale-Up and Manufacturing of Cell-Based Therapies III
January 5-9, 2014
San Diego, California
Conference Chairs:
Chris Mason, University College London, UK
Greg Russotti, Celgene, USA
Peter Zandstra, University of Toronto, Canada

Scale-Up and Manufacturing of Cell-Based Therapies IV
January 18-22, 2015
San Diego, CA USA
Conference Chairs:
Chris Mason, University College London, UK
Greg Russotti, Celgene Cellular Therapeutics, USA
Peter Zandstra, University of Toronto, Canada
Thomas Brieva, Celgene Cellular Therapeutics, USA

Scale-Up and Manufacturing of Cell-Based Therapies V
January 15-19, 2017
San Diego, California
Conference Chairs:
Thomas Brieva, Celgene Cellular Therapeutics, USA
Chris Mason, University College London, UK
William Miller, Northwestern University, USA

Scale-Up and Manufacturing of Cell-Based Therapies V
January 27-31, 2019
San Diego, California
Conference Chairs:
Dolores Baksh, GE Healthcare
Ivan Wall, Aston University
Rod Rietze, Novartis

Previous conferences in this series:

Scale-Up and Manufacturing of Cell-Based Therapies VI
Feb 6-10, 2022
San Diego, CA
Conference Chairs:
Sean Palecek, University of Wisconsin, USA
Damian Marshall, Achilles Therapeutics, UK
Fernanda Masri, Cell & Gene Therapy Catapult, UK

2024 Cell Therapies Award Recipient

Paula M. Alves

Paula Alves has been working in the advancement of cell culture technologies for more than 30 years. Her research integrates cell metabolism understanding with biochemical engineering tools for the improvement of bioprocesses efficiency. Paula´s work has contributed for the development of industrially relevant and academically recognized tools and technologies for production of biopharmaceuticals and ATMPs (Advanced Therapy Medicinal Products) in particular pluripotent stem cells and viral vectors for cell and gene therapy.

Key contributions include:

- Establishing 3D culture systems for expansion and differentiation of stem cells in bioreactors for cell therapy and as tools for drug development and pre-clinical research
- Better understanding the complex interplay of cell metabolism and stem cells differentiation and maturation
- Determining key factors in the “Cell Density Effect” for improved viral vectors yields through manipulation of host cells energetic metabolism
- Developing bioanalyticals for bioprocess understanding and cell- and viral- based products characterization

Since 2012, Paula has been the CEO of iBET – Instituto de Biologia Experimental e Tecnológica, a private not-for-profit research organization (www.ibet.pt) located in Oeiras, near Lisbon. Created in 1989 by Prof. Manuel Carrondo, iBET is active in bridging university and industry through R&D projects for the global biopharmaceutical industry, also advancing innovative therapies. Over the last 5 years iBET has grown to more than 200 employees, from which >100 are PhDs, and attracted >60 M€ in industry funding.

Paula is also a professor at NOVA University of Lisbon (ITQB NOVA and FCT NOVA) where she teaches cell culture technologies for biopharmaceuticals and cell-based therapies and biotechnology. Attracting, training and, whenever possible, maintaining highly qualified and committed students and scientists at iBET has been a key goal. The 40 PhD students, plus masters and postdocs she supervised contributed to Paula´s exciting research career. She is

co-author of more than 300 papers that, together with many communications in scientific conferences, contributed to the global recognition of iBET.

Paula was elected member of National Academy of Engineering in 2021 for her leadership in biomanufacturing, advanced biotherapeutics, and bridging the gap between academia and industry. She received the Scientific Merit Award from NOVA University of Lisbon in 2009. Paula has been strongly dedicated to ESACT European Society for Animal Cell Technology, was president for 5 years and started, with Prof Francesc Godia (UAB), the ESACT Advanced Courses Series, that annually runs advanced courses since 2010 (more than 600 students were already trained in ACT and related areas).

Paula is also committed to Engineering Conference International (ECI). She was co-chair of Vaccine Technology and Integrated Continuous Biomanufacturing and has been contributing, as session chair, to other conferences in the biotechnological series. In the European Commission Paula was member of the Scientific Committees of IMI (Innovative Medicines Initiative) and Horizon 2020 (SC1 – Health) and of the EURL ECVAM (EU Reference Lab for alternatives to Animal testing) Advisory Board.

Paula actively promotes women in science and is enrolled in mentoring programs for Girls and Women in Engineering.

This award, sponsored by NIIMBL and Engineering Conferences International, recognizes outstanding contributors to the development and commercialization of cell-based therapies. Past recipients include Bob Nerem, Kim Warren, Peter Zandstra, and Greg Russotti.

Christopher Hewitt Outstanding Young Investigator Award

Aaron D. Simmons, University of Wisconsin at Madison

ECI is pleased to announce that Aaron D. Simmons is the winner of the Christopher Hewitt Outstanding Young Investigator Award.

Aaron received his B.S. and M.S. in Chemical Engineering at the University of Oklahoma, researching novel methods for process monitoring of bone tissue engineered constructs under the direction of Dr. Vassilios Sikavitsas.

He then worked as a senior research technician at the Oklahoma Medical Research Foundation studying molecular contributions of SIRT3 in the development and progression of osteoarthritis in the context of aging and obesity under the direction or Dr. Timothy Griffin.

Currently, Aaron is finishing up his PhD in Chemical Engineering at the University of Wisconsin at Madison in the laboratory of Dr. Sean Palecek. There, his research focusses on process monitoring and process enhancement for stem-cell differentiation. Specifically, he is applying integrative multi-omic and metabolic discovery techniques to identify novel mechanisms and markers of pluripotent stem cell differentiation into cardiomyocytes with the underlying goals of developing novel mid-process monitoring schemes for continual prediction of batch outcomes and improved protocols to increase differentiation process robustness.

During his thesis, he has been an active member and leader within several organizations, mentored numerous trainees, and participated in many public outreach events. Namely among these, he has initiated and led several collaborative projects and standardization initiatives within the National Science Foundation Engineering Research Center for Cell Manufacturing Technologies (CMaT). His broad and growing publication record is a testament to his collaborative nature and continuing impacts on the field.

Outside of his own research, Aaron was also a founding member of the Innovators in Training program of the Forward BIO Institute at UW where he has helped to facilitate process

development/scalability studies and provide non-technical guidance to identify and pursue funding and regulatory milestones for product advancement.

On track to graduate in early 2024, Aaron is excited to further his career in CGT and is looking for opportunities where he can continue to contribute meaningfully to the field.

About This Award

This award is in honor of Christopher Hewitt. He was a leading biological engineer, distinguished for his research using flow cytometry and cell sorting to understand the interaction of the cell with the bioreactor environment within such diverse areas as microbial fermentation, bio-remediation, bio-transformation, brewing and cell culture. He was also the co-founder of the Centre for Biological Engineering at Loughborough University, where he developed a world-leading team in regenerative medicine bioprocessing. In particular, his team made a significant contribution to the literature on the culture and recovery of fully functional human mesenchymal stem cells in stirred bioreactors based on sound biochemical engineering and fluid dynamic considerations essential to scale-up for commercialization. In recognition of his achievements, he was elected Fellow of the Royal Academy of Engineering in 2018. Chris Hewett was an active contributor to the ECI conference series “Advancing Manufacturing for Cell based and Gene Based Therapies”.

The award is given to a promising young scientist whose work shows exceptional promise in the field of process development of cell based and gene-based therapies. The award includes the opportunity to make a presentation at the conference.

Conference Sponsors

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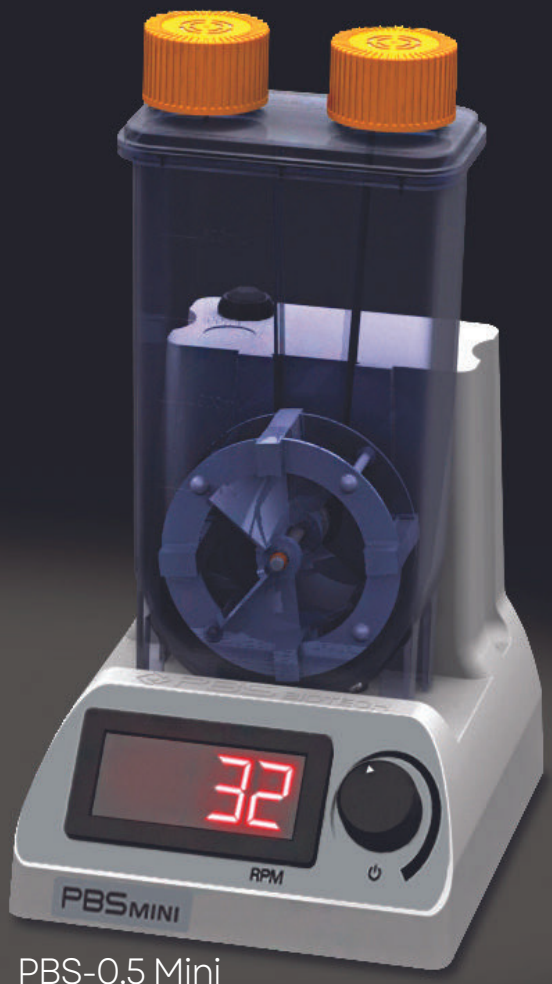

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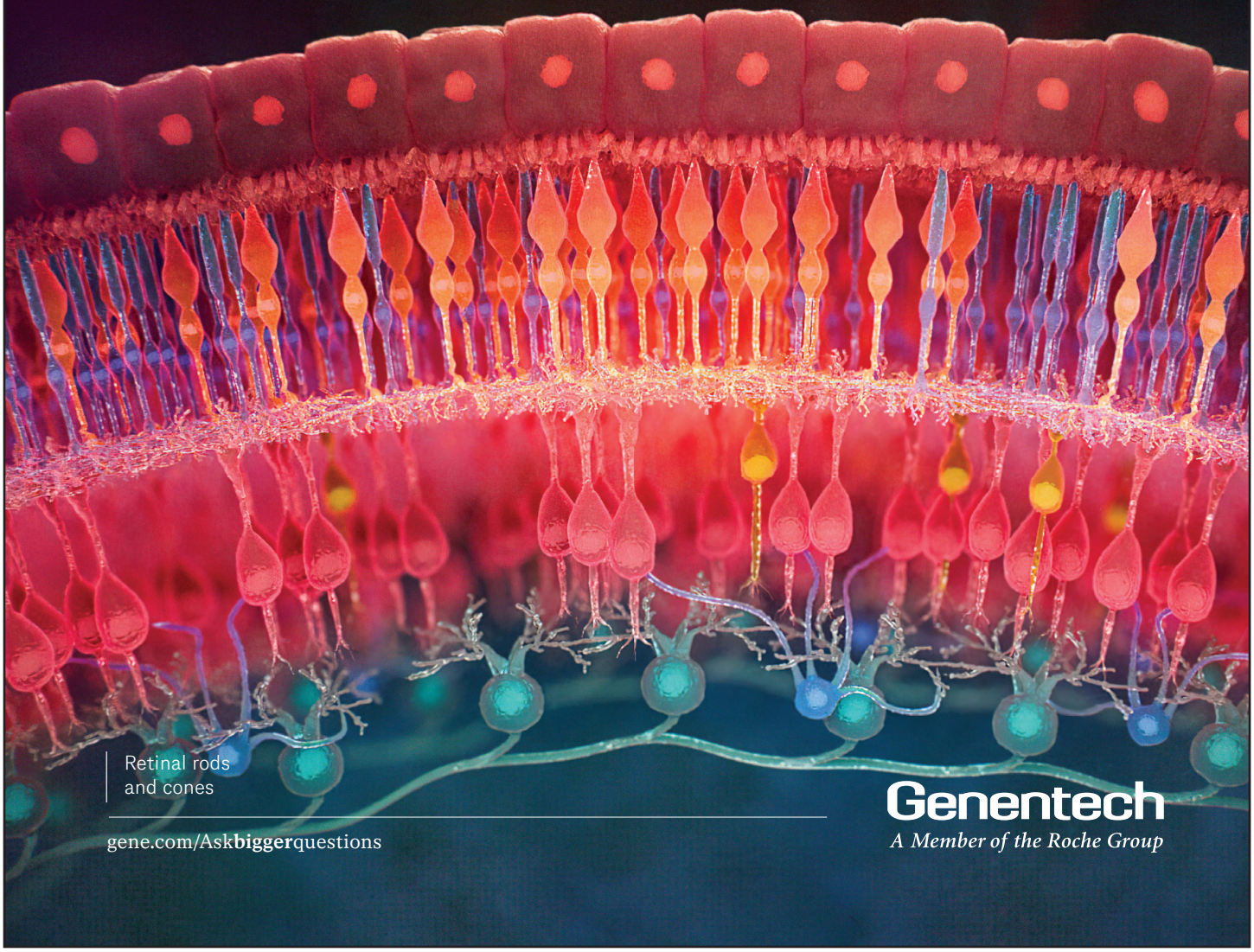

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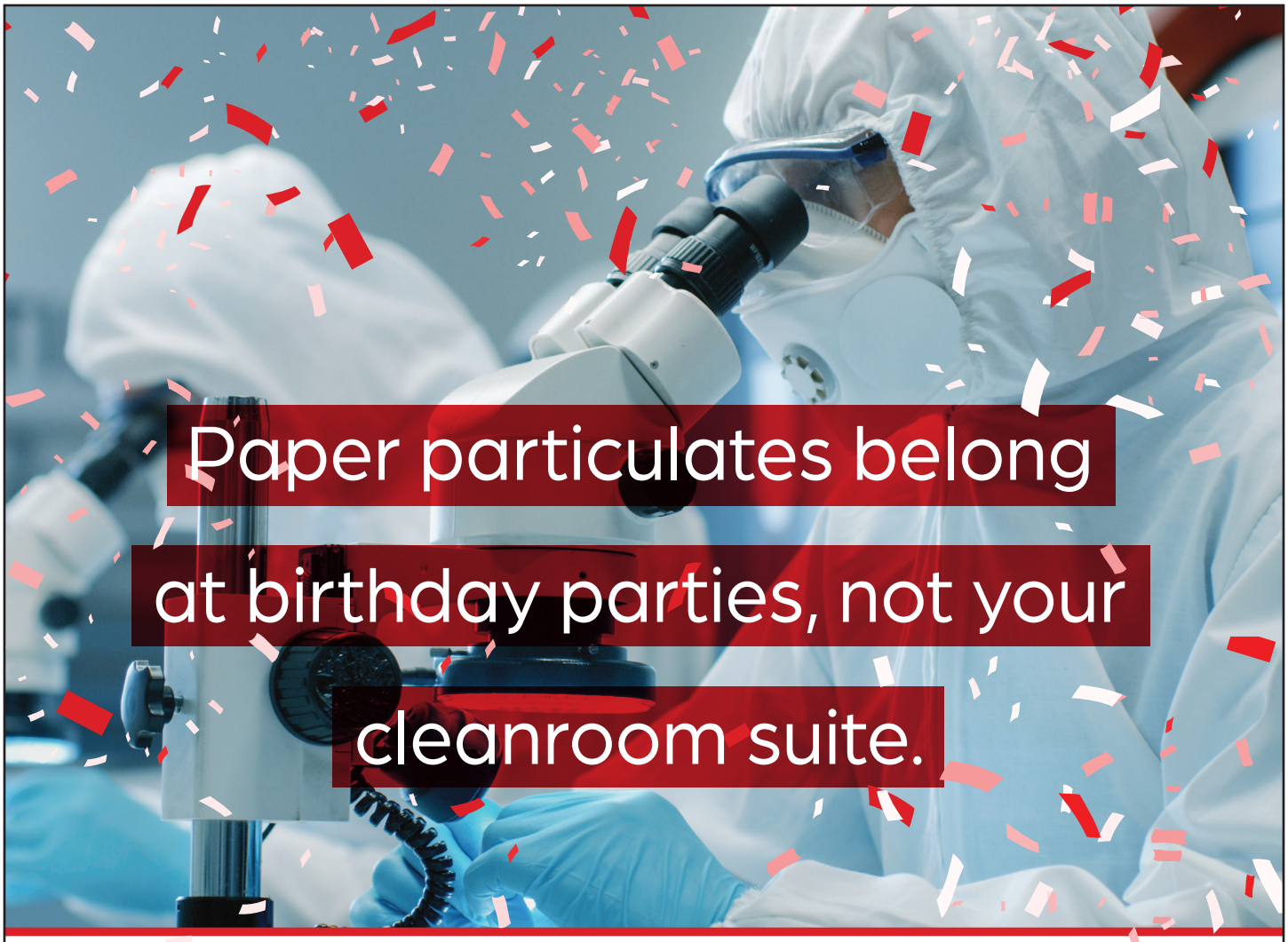

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CATAPULT
Cell and Gene Therapy

The Cell and Gene Therapy Catapult, an independent innovation and technology organisation committed to the advancement of cell and gene therapies, have recently launched two new reports that highlight the growth of the UK advanced therapies sector.

GMP Manufacturing Survey

Our annual GMP Manufacturing Survey identifies the capability and capacity for MHRA licensed cell and gene therapy manufacturing sites in the UK.

GMP Manufacturing Survey 2023

Skills Demand Survey

Our biennial Skills Demand Survey captures anticipated levels of employment in the advanced therapies sector for the next five years and highlights the industry skills requirements to support this workforce.

Skills Demand Survey 2023

ct.catapult.org.uk

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Upcoming ECI Biotechnology Conferences

For complete details on the conferences below,
please visit the ECI web site: www.engconfintl.org

Delivery Of Nucleic Acid Therapeutics II: Biology, Engineering And Development

An ECI Conference Series

April 4 – 8, 2024 Siracusa, Sicily

Co-Chairs

- Steven F. Dowdy, UCSD School of Medicine, USA
- Laura Sepp-Lorenzino, Intellia Therapeutics, USA
- Matt Stanton, Generation Bio, USA

The ECI "Delivery of Nucleic Acid Therapeutics: Biology, Engineering and Development" conference will provide a forum for increasing our mechanistic understanding of the biological processes underpinning non-viral NAT delivery, including molecular and cellular biology, in vivo pharmacology and toxicology, rational optimization strategies, targeting, formulation, bioengineering and process development solutions for scale-up manufacturing, regulatory considerations and preclinical and clinical NAT programs. The conference will bring together biologists, chemists, pharmacologists, biophysicists, drug developers, nanotechnologists, process engineers from academia and industry developing delivery strategies for the antisense, RNA interference, mRNA, Gene Therapy and Genome Editing, ex vivo and in vivo.

Conference Topics:

- Nucleic acid chemical modifications and conjugates to enable and enhance delivery
- Liposomes and polymeric nanoparticle delivery vehicles
- Targeting
- Mechanisms of cellular uptake
- Enhancing endosomal escape
- Biophysical characterization methods
- NAT delivery vehicle toxicology and ADME
- Local and systemic NAT delivery case studies

Vaccine Technology IX

An ECI Conference Series

May 19-24, 2024 Los Cabos, Mexico

Co-Chairs

- Francesc Gòdia, Universitat Autònoma de Barcelona (UAB), Spain
- Linda Lua, The Growth Impact, Australia
- Charles Lutsch, Sanofi-Vaccines, France
- Tara Tagmyer, CMC Leader, USA

The Vaccine Technology Conference focuses on the discovery, development and manufacture of vaccines. A unique conference series that convenes and connects global experts in the vaccine field to discuss and address the technologies to advance vaccines for global needs. The conference offers high-quality scientific content from leaders in academia, industry, government and not-for-profit global health organisations. The participants at these conferences share a common goal – Advancing Vaccine Technologies for a Healthier World.

Conference Topics:

- Novel expression systems and innovative platforms
- Nucleic acid-based vaccines
- Regional development and manufacturing of vaccine
- Vaccine manufacturing
- Analytical technology
- Formulation and stability
- Devices and delivery
- One-health

Upcoming ECI Biotechnology Conferences

For complete details on the conferences below,
please visit the ECI web site: www.engconfintl.org

Biochemical and Molecular Engineering XXIII: Accelerating Biotech Solutions to aid a Changing World

An ECI Conference Series

July 21 – 25, 2024 Dublin, Ireland

Co-Chairs

- Michelle O'Malley, University of California at Santa Barbara
- Brian Pfleger, University of Wisconsin
- Varnika Roy, GSK

Nature hosts an impressive array of chemical structures, proteins, and pathways that humanity has leveraged to make medicines, solvents, materials, and fuels. Advances in synthetic biology have dramatically reduced the cost of DNA synthesis, and enabled rapid prototyping and screening across a wide range of useful hosts. These synthetic tools have advanced the complexity of questions that can be asked and supported the development of systems biology models that more accurately predict phenotypes and facilitate design. Chemical and biological engineers are now using these tools and the knowledge gained with them to tackle Grand Challenges facing society – such as the need for new medicines to fight disease and prevent pandemics, the need for new technologies to improve the sustainability of our industries and address climate change, and the barriers preventing expansion of modern biomanufacturing across the world. The Biochemical and Molecular Engineering conference series brings together researchers from across engineering disciplines and the natural sciences to discuss recent progress in this broad field, network with experts across a wide range of specialties, and brainstorm new approaches to address global challenges facing biotechnology and society at large. This will be the twenty third edition of a conference series dating back to the dawn of the recombinant DNA era. This year the steering committee is thrilled to hold the meeting in Ireland – an emerging hub for biotechnology and biopharma, where we aim to expand our network and form a bridge between North American and European biotech.

Integrated Continuous Biomanufacturing VI

An ECI Conference Series

October 20 – 24, 2024 Leesburg, Virginia

Co-Chairs

- Ana Azevedo, Instituto Superior Técnico, Portugal
- Aaron Noyes, CodiakBio, USA
- Kevin Brower, Sanofi, USA

The Integrated and Continuous Biomanufacturing (ICB) Conference is ECI's premiere international conference in continuous and integrated biomanufacturing. As global competitive pressures continue to force companies to innovate to succeed, integrated continuous processing creates opportunities to accelerate process development and reduce manufacturing costs while enhancing flexibility and product quality. Ultimately, these collective improvements in efficiency and quality will help us better achieve our primary objective in the field – to increase patient access to transformative therapies. Impressive technological advances have been made over the past decade to enable the implementation of continuous bioprocessing. ICB VI aims to build on the strong momentum generated in previous conferences of this series by developing an exciting and engaging program showcasing progress in implementation of integrated continuous biomanufacturing technologies for GMP biomanufacturing via case studies of clinical and commercial bioprocesses. ICB VI will highlight progress across the ICB discipline, including areas related to Regulatory Affairs, Simplification, Emerging Therapeutic Modalities, Process Analytical Technology (PAT), Sustainability, as well as Modeling, Automation, and Control.

ICB VI will bring together leading scientists and engineers from academia, industry and regulatory who are actively engaged in creating and enabling integrated continuous biomanufacturing.

Upcoming ECI Biotechnology Conferences

For complete details on the conferences below,
please visit the ECI web site: www.engconfintl.org

Cell Culture Engineering XIX

An ECI Conference Series

April 27 – May 2, 2025 Tucson, Arizona

Co-Chairs

- Anurag Khetan, BMS
- Marcella Yu, Sutro Biopharma
- Michael Betenbaugh, Johns Hopkins University

The CCE XIX conference will bring together about 400 selected participants of top academic, industrial, and governmental researchers from all over the world. We will celebrate the tradition of high quality and relevant accomplishments and debate future solutions in the area of animal cell culture science and engineering. An international organizing committee has been assembled to help us put together a top-tier program to attract the leading researchers and practitioners in the cell culture technology field, and sustain this meeting's excellent tradition. In addition to a comprehensive series of oral sessions, with a balance of speakers from both leading academic and industrial groups, this conference will again be designed to foster networking and facilitate informal discussion of key cell culture issues among participants through the inclusion of several poster sessions and many workshops.

Microbial Engineering III

An ECI Conference Series

April 2025 Porto, Portugal

Co-Chairs

- Eli Keshavarz-Moore, University College London
- Thomas Sauer, Sanofi

The conference will bring together leaders in Synthetic Biology, Metabolic Engineering and Fermentation Technology both from industry and the academic community. Examples of applications included natural products, therapeutic proteins, vaccines and biosynthesis of a great variety of organic chemicals.

We are confident that this will capture the exciting progress being made on many fronts and highlight practical applications.

Schedule

Advancing Manufacture of Cell and Gene Therapies VIII

February 4 – 8, 2024
Loews Coronado Bay Hotel
Coronado, CA, USA

Engineering Conferences International

Locations and Notes

- *Technical and poster sessions will be in the Commodore Ballroom.*
- *Meals will be in the Constellation Ballroom.*
- *The ECI on site office will be the Sovereign Room (2nd floor).*
- *A room will be available for ad hoc meetings. See ECI staff to reserve a time.*
- *Audio, still photo and video recording by any device (e.g., cameras, cell phones, laptops, PDAs, watches) is strictly prohibited during the technical sessions, unless the author and ECI have granted prior permission.*
- *Speakers – Please have your presentation loaded onto the conference computer prior to the session start (preferably the day before).*
- *Speakers – Please leave at least 3-5 minutes for questions and discussion.*
- *Questions can be submitted via Slido at the sessions. Microphones will be available for questions as well.*
- *Please do not smoke at any conference functions.*
- *Turn your mobile telephones to vibrate or off during technical sessions.*
- *After the conference, ECI will send an updated participant list to all participants. Please check your listing now and if it needs updating, you may correct it at any time by logging into your ECI account.*
- *Emergency Contact Information: Because of privacy concerns, ECI does not collect or maintain emergency contact information for conference participants. If you would like to have this information available in case of emergency, please use the reverse side of your name badge.*

Saturday, February 3, 2024

17:30 – 19:30 Welcome Reception (Cays Lounge located beyond the grand staircase)
(Please pick up your badge from an ECI staff member in Cays Lounge)

Sunday, February 4, 2024

08:30 – 16:15 **Pre-Conference Workshop** (Avalon Room)
Building a flexible manufacturing strategy to navigate turbulent global markets
Chairs: Taby Ahsan, City of Hope, USA
Anne-Lise Brondel, Kyowa Kirin, USA
Mercedes Segura, Elevate Bio, USA
Veena Warikoo, AstraZeneca, USA

14:30 Conference check-in (Atrium)

16:45 – 17:00 Conference welcome
Chairs: Fernanda Masri, Cytomos, United Kingdom
Carolyn Yeago, CY Solutions LLC, USA
Gargi Maheshwari, BMS, USA
John Moscariello, BMS, USA

ECI Technical Liaison: Barry Buckland, NIIMBL, USA

Student Liaison: Bryan Wang, TreeFrog Therapeutics, USA

17:00 – 18:00 **Fireside Chat**
A recap of the last 2 years and outlook into the future of cell and gene therapies
Moderator: Fernanda Masri, Cytomos, United Kingdom
Panelists: Gregg Nyberg, Landmark Bio, USA
Bryan Poltilove, PBS Biotech, USA
Chris Ramsborg, Flagship Pioneering, USA

18:00 – 18:30 Stretch Break

18:30 – 20:00 Dinner

Monday, February 5, 2024

07:00 – 08:30	Breakfast (Breakfast with VIPs for graduate students)
	Session 1: Viral Vector and Gene Editing Platforms – Progress and Challenges in Process Development, Manufacturing, Product Characterization and Technology Landscape Chairs: Alina Verano, Vvector Bio,Canada Daniel M Marasco, Eli Lilly and Company, USA
08:30 – 09:05	**Keynote** **Time is muscle: Platform advancement for swift time-to-market in AAV manufacturing** Jiuyi Lu, Sarepta Therapeutics, USA
09:05 – 09:25	**Continuous processing of viral gene therapy vectors** Caryn Heldt, Michigan Technological University, USA
09:25 – 09:45	**Leveraging a RNA-based lipid nanoparticle (LNP) gene writer system to generate Chimeric Antigen Receptor T cells (CAR-T) for in vitro and in vivo tumor activity** Jason Rodriguez, Tessera Therapeutics, USA
09:45 – 11:05	Coffee Break / Opportunity to visit sponsor tables
11:05 – 11:25	**Enhancing rAAV biomanufacturing: Process intensification strategies for streamlined upstream and downstream processing** António Roldão, iBET, Portugal
11:25 – 12:00	**Keynote** **Novel single plasmid technology for AAV production in HEK-293 suspension cells** Alina Venereo Sanchez, VVector Bio, Canada
12:00 – 12:20	**Towards a scalable AAV vector production at high volumetric efficiency** Prasanna Srinivasan, Massachusetts Institute of Technology, USA
12:20 – 12:35	Panel Session
12:35 – 14:05	Lunch
	Session 2: Advances in Cell Therapy Manufacturing Technology to Enable Autologous and Allogeneic Applications ***Sponsored by PBS Biotech*** Chairs: Bruno Marques, Century Therapeutics, USA Samin Akbari, Sartorius, USA
14:05 – 14:40	**Keynote** **Fit for purpose, DMSO-free preservation of cellular therapies** Alison Hubel, University of Minnesota, USA
14:40 – 15:00	**High-density microbioreactor process designed for automated point-of-care manufacturing of CAR T cells** Wei-Xiang Sin, Singapore-MIT Alliance for Research and Technology Centre (SMART), Singapore

Monday, February 5, 2024 (continued)

15:00 – 15:20	**Scalable allogeneic CAR-T manufacturing: Perfusion optimization, multi-liter scale-up and automated harvesting in single-use stirred-tank bioreactors** Pierre Springuel, University College London, United Kingdom
15:20 – 15:40	**Producing Ipsc derived functional Cd8+ T-cells in scalable stirred tank bioreactors** Liz Csaszar, Notch Therapeutics, Canada
15:40 – 16:00	**Assessing robust bioprocess design through modulation of process input variables in the expansion of human induced pluripotent stem cell aggregates in Vertical-Wheel(R) bioreactors** Tiffany Dang, University of Calgary, Canada
16:00 – 16:45	Coffee Break / Opportunity to visit sponsor tables ***Sponsored by Cell and Gene Therapy Catapult***
16:45 – 17:20	**Keynote** **Powerful characterization of cell therapies via whole and single-cell next-generation sequencing** Tom Brieva, Resilience, USA
17:20 – 17:40	**Optimizing the generation of hematopoietic progenitor cells from pluripotent stem cells in dynamic suspension culture** Thristan Paulo Taberna, University of British Columbia, Canada,
17:40 – 18:00	**Combined Wnt activation and oxygen modulation enhance the manufacture and scale-up of pluripotent stem cell-derived cardiomyocytes in bioreactors** Pedro Vicente, iBET, Portugal
18:00 – 18:20	**Towards a scalable, closed and automated platform for the production of cost-efficient allogeneic cell therapies: showcase of an exemplar iNK process** Márcia F. Mata, Cell and Gene Therapy Catapult, United Kingdom
18:20 – 18:30	Stretch Break
18:30 – 19:30	**Poster Session** with refreshments & open bar (beer and wine) ***Sponsored by Takeda*** Chairs: Gargi Maheshwari, BMS, USA John Moscariello, BMS, USA
19:30	Dinner on your own

Tuesday, February 6, 2024

07:00 – 08:30	Breakfast
	Session 2: Advances in Cell Therapy Manufacturing Technology to Enable Autologous and Allogeneic Applications (continued) Chairs: Bruno Marques, Century Therapeutics, USA Samin Akbari, Sartorius, USA
08:30 – 09:05	**Keynote** **Bioprocessing of stem-cell derived allogeneic cell therapy products: enabling large-scale manufacturing** Mats Åkesson, Novo Nordisk, Denmark
09:05 – 09:25	**Stem cell-derived pancreatic Islet encapsulation technologies for immobilized culture and transplantation** Corinne A. Hoesli, McGill University, Canada
09:25 – 09:45	**Cell culture media-based cryo-formulations containg dimethyl sulfoxide minimize cryopreservation-induced cell damage in iPSC-derived effector cells** Victoria Karakis, Century Therapeutics, USA
09:45 – 10:05	**Effects of temperature fluctuations on cryopreserved human induced pluripotent stem cells Post-thaw viability and cryo-Raman observation** Jun Okuda, Osaka University, Japan
10:05 – 10:20	Panel Session
10:20 – 11:05	Coffee Break / Opportunity to visit sponsor tables ***Sponsored by Resilience***
	Session 3: Digitization, Process Control, and Closed-system Automation in Cell and Gene Therapies Chairs: Antinea Chair, Cellares, USA Stephen Balakirsky, Georgia Tech Research Institute, USA
11:05 – 11:40	**Keynote** **Modular sensing, automation, and control for the production of cellular therapies** Stephen Balakirsky, Georgia Tech Research Institute, USA
11:40 – 12:00	**Digital twin-enabled feedback-controlled bioreactors with integrated process analytics for biomanufacturing of cell therapies** Bryan Wang, TreeFrog Therapeutics, USA
12:00 – 12:35	**TBA**
12:35 – 12:55	**Scaling AAV viral vector production processes up to manufacturing scale utilizing dynadrive single-use bioreactors** Paula Decaria, Thermo Fisher Scientific, USA
12:55 – 14:25	Lunch with **Poster Session**

Tuesday, February 6, 2024 (continued)

14:25 – 14:45	**Cell placement in culture vessel after seeding is CPP in induction culture of retina pigment epithelial cells derived from iPSC** Masahiro Kino-oka, Osaka University, Japan
14:45 – 15:20	**Keynote** **Metabolic control, adaptive culturing, and AI predictions, a new generation of cell culturing devices, ADVA X3 case study** Ohad Karnieli, ADVA Biotechnology, Israel
15:20 – 15:40	**Towards in-silico scale-up of cell and gene therapy manufacturing** Christian Witz, SimVantage, Austria
15:40 – 15:55	Panel Session
15:55 – 16:40	Coffee Break / Opportunity to visit sponsor tables
	Session 4: In-Process and Analytical Control Strategies for Cell and Gene Therapies ***Sponsored by Genentech*** Chairs: Paula Alves, iBET, Portugal Tomas Kowski, Umoja Therapeutics, USA
16:40 – 17:15	**Keynote** **Evolving CAR cell therapy engineering: Challenges & opportunities** Isabelle Riviere, Takeda, USA
17:15 – 17:35	**Rapid noninvasive analytical tool for cell and gene therapy products** Marc Taraban, University of Maryland, USA
17:35 – 18:00	**Chris Hewitt Award Lecture** **Predicting and enhancing cardiac potential of iPSC-derived cardiac progenitor cells through integrated multi-omic analysis** Aaron Simmons, University of Wisconsin-Madison, USA
18:00 – 18:30	Stretch Break
18:30 – 23:00	Social event – Stone Brewery Bus transportation to be provided

Wednesday, February 7, 2024

07:00 – 08:30	Breakfast
	Session 4: In-Process and Analytical Control Strategies for Cell and Gene Therapies (continued) Chairs: Paula Alves, iBET, Portugal Tomas Kowski, Umoja Therapeutics, USA
08:30 – 09:05	**Keynote** **Release and characterization of VivoVec: Surface-engineered lentiviral vector for in vivo generation of CAR-T cells** Richard Rogers, Umoja Biopharma, USA
09:05 – 09:25	**TBA**
09:25 – 10:00	**Keynote** **Leveraging cell and gene therapy products' quality through a bioanalytics avenue** Patricia Gomes-Alves, iBET, Portugal
10:00 – 10:20	**Novel analytics for rapid adventitious agent detection in cell and gene therapy manufacturing** Stacy Springs, Massachusetts Institute of Technology, USA
10:20 – 11:05	Coffee Break / Opportunity to visit sponsor tables
11:05 – 11:40	**Keynote** **New methods and approaches for the analysis of new therapeutic modalities** Sunny Zhou, Northeastern University, USA
11:40 – 12:00	**Process analytical utility of Raman microscopy for cell therapy manufacturing** James M. Piret, University of British Columbia, Canada
12:00 – 12:15	Panel Session
12:15 – 13:45	Lunch
13:45 – 14:15	**Advancing Manufacture of Cell and Gene Therapies Award Lecture** **R&D supporting translation of cell based biotherapeutics** Paula Alves, iBET, Portugal
14:15 – 15:00	Coffee Break
	Session 5: Critical Early Decisions in Regulatory Strategies and Standards to Facilitate Product Development Chairs: Taby Ahsan, City of Hope, USA Eytan Abraham, Resilience, USA
15:00 – 15:35	**Keynote** **NIST flow cytometry standards consortium enables quantitative and comparable characterization of cell and gene therapies** Lili Wang, NIST, USA

Wednesday, February 7, 2024 (continued)

15:35 – 16:10	**Keynote** **Reducing regulatory risk with CMC strategy using gene therapy platforms** Doris Snow, Resilience, USA
16:10 – 16:45	**Keynote** **Regulatory updates and trends in cell and gene therapy** Kimberly Benton, Dark Horse Consulting, USA
16:45 – 16:50	**Workshop output** Anne-Lise Brondel, Kyowa Kirin, USA and Taby Ahsan, City of Hope, USA
16:50 – 17:30	Panel Discussion
17:30 – 19:00	Break
19:00	Conference Banquet

Thursday, February 8, 2024

07:00	Breakfast and Departure

Posters

Advancing Manufacture of Cell and Gene Therapies VIII

February 4 – 8, 2024
Loews Coronado Bay Hotel
Coronado, CA, USA

Engineering Conferences International

Poster Presentations

1. **Scalable manufacturing of extracellular vesicles from human-induced pluripotent stem cells in stirred-tank bioreactors**
   Margarida Serra, iBET-Instituto de Biologia Experimental e Tecnológica, Portugal

2. **T cell expansion and phenotype can be tuned in stirred-tank bioreactors through temporal control of T cell activation**
   Margarida Serra, iBET-Instituto de Biologia Experimental e Tecnológica, Portugal

3. **Method development for the production of clinically relevant doses of human pluripotent stem cell derived cardiomyocytes**
   Andrew Prowse, The University of Queensland, Australia

4. **Flow-based membrane technology to engineer T-cells**
   Aida López Ruiz, University of Delaware, USA

5. **Development of a xeno free system for scale-up of human bone marrow derived mesenchymal stromal cells using dissolvable microcarriers in a single-use vertical wheel bioreactor**
   Antonio Fernandez-Perez, Corning Life Sciences, USA

6. **Gradient plasma polymer coatings as closed culture vessel surface for manufacturing cell-based immunotherapy products**
   Balaji Ramachandran, McGill University, Canada

7. **Systematic bioprocess engineering used to optimize linear scale-up of size controlled PSC aggregates in vertical-wheel bioreactors**
   Breanna Borys, PBS Biotech Inc., USA

8. **Recombinant carbohydrate binding module fusion proteins for the animal-component-free bioprocessing of stem cells**
   Brett Abraham, University of Calgary, Canada

9. **Ambr250 system for optimization of stem cell aggregate expansion conditions**
   Brian Russell, Astrazeneca, USA

10. **Process optimization in enhancing end-stage iPSC-derived immune-effector cell expansion**
    Chen-Yuan Kao, Century Therapeutics, USA

11. **Process parameter development for the scaled generation of stem cell-derived pancreatic endocrine cells**
    Diepiriye Iworima, University of British Columbia, Canada

12. **An optimized bioprocess for the transplantation of autologous bone-marrow derived mesenchymal stromal cells to treat equine joint injury**
    Emilie Gysel, University of Calgary, Canada

13. **Enabling allogeneic T cell-based therapies: Scalable stirred-tank bioreactor mediated manufacturing**
    Lisa Prendergast, Lonza, United Kingdom

14. **A platform approach for producing engineered extracellular vesicles**
    Lisa Prendergast, Lonza, United Kingdom

15. **Designing a feeder-free expansion system for peripheral blood-derived NK cells**
Janani Narayan, University of Minnesota, USA

16. **Designing a soluble factor-based expansion system through mechanistic understanding of feeder cell-mediated NK cell activation**
Janani Narayan, University of Minnesota, USA

17. **Amino acid analysis indicates metabolic differences in multi-cytokine backpack-manufactured CAR T-cells**
Milla Neffling, 908 Devices, Inc., USA

18. **Optimization of cell culture conditions for high transfection efficiency of HEK293 cells and production of viral vectors**
Milla Neffling, 908 Devices, Inc., USA

19. **Addressing scale-up challenges for the production of allogeneic, shear sensitive cell therapy products within the Vertical-Wheel bioreactor family**
Omokhowa Agbojo, PBS Biotech Inc., USA

20. **Understanding oxygen tension impact for enhanced clinical scale hematopoietic progenitor cell differentiation**
Orchid Poponne, Century Therapeutics, USA

21. **Comparison of growth activity of bone marrow-derived mesenchymal stem cells in normoxic and hypoxic culture conditions through continuous passage**
Rafianto Dwi Cahyo, Osaka University, Japan

22. **Development of mass culture process for human induced pluripotent stem cells in suspension**
Riku Yamamoto, Osaka University, Japan

23. **Investigate the stability of seeding process of mesenchymal stem cell on microcarriers by considering heterogeneity**
Riku Yamamoto, Osaka University, Japan

24. **Verification of built-in calibration function of a pH sensor for sample-free bioprocess operations**
CD Feng, Broadley-James Corp., USA

25. **Building global opportunities between development and quality (Qualified Persons, QPs) for ATMPs**
Tiffany Rau, Biopharma Technical Consulting Ltd (Ireland) and Rau Consulting LLC (USA), Ireland

26. **Automated TruStableTM rAAV production**
Christopher Abeles, Shape Therapeutics, USA

27. **Use of conventional flow cytometry to study extracellular vesicles**
Gregg Nyberg, Landmark Bio, USA

28. **At-line quantitation for the nicontinic acid to nicotinamide ratio as a biomarker for microbial combination of cell cultures**
Kenion Blakeman, 908 Devices, Inc., USA

29. **Improving cell and gene therapy manufacturing processes by automated on-line and in-line bioprocess analytical technologies**
Nick Randall, 908 Devices, Inc., USA

30. **WITHDRAWN**

31. **Adsorptive separation of viral gene therapy vectors**
Nico Lingg, BOKU, Austria

32. **Screen your AAV production process – From high throughput to scalability**
Alyssa Buve, Sartorius Xell GmbH, Germany

33. **Development of a scale down bioreactor model for AAV gene therapy**
Arun Bagale, Rocket Pharmaceuticals, Inc., USA

34. **Utilizing enhancers to elevate AAV productivity**
Brandi Arterberry, Rocket Pharmaceuticals, Inc., USA

35. **Strategies for enhanced Adeno-Associated Virus (AAV) vector formulations**
Braulio Carrillo Sanchez, University College London, United Kingdom

36. **A scalable 3-D printed bioreactor for adherent cell based production of viral vector**
Carlos Cantú, Southwest Research Institute, USA

37. **Optimizing triple transfection for enhanced rAAV production: A Response Surface Methodology approach**
Jesús Lavado García, Technical University of Denmark, Denmark

38. **WITHDRAWN**

39. **WITHDRAWN**

40. **A recombinase-mediated cassette exchange capable stable cell line for configuring inducible AAV production cassettes**
Erica Green, University of Delaware, USA

41. **Mechanistic modeling for efficient manufacturing of rAAV with the Sf9/BEVS platform**
Francesco Destro, Massachusetts Institute of Technology, USA

42. **DNA impurity reduction by a stably integrated staphylococcal nuclease is compatible with high-titer suspension serum-free rAAV manufacturing**
Geoffrey Howe, University College London, United Kingdom

43. **Optimization of scalable rAAV production for gene therapy – Leveraging at-line amino acid measurements for bioprocess modeling-driven approaches**
Graziella Piras, 908 Devices, Inc., USA

44. **Evaluation of small molecule antagonists of cellular innate immunity for efficient manufacturing of T-cell therapeutics**
Andrea Vervoort, Virica Biotech, Canada

45. **Introducing a high-performance T-cell culture medium that is free of animal derived components**
Joanna Kern, Thermo Fisher Scientific, USA

46. **Establishing modularity in AAV manufacturing – Deployment of engineered cell lines and advanced analytics in traditional manufacturing platforms**
Brandon Razooky, Resilience, USA

47. **High-yield AAV production and improved manufacturability across multiple serotypes via a novel cell engineering platform**
Kathy Ngo, CHO Plus, Inc., USA

48. **An efficient plasmid ratio optimization for rAAV production can be achieved using a mixture design**
Konstantina Tzimou, Technical University of Denmark, Denmark

49. **GlutaMAX decay offers a more sensitive indication of cell health than LDH enzymatic activity or Trypan blue exclusion**
Lauren Peters, Solid Biosciences, USA

50. **Metabolic phenotype of high productivity within transient transfection AAV production**
Margaret Moran, Solid Biosciences, USA

51. **A process development approach to a platformable and robust scale up for enrichment of full AAV capsids using membrane chromatography**
Mark Schofield, Cytiva, USA

52. **Process optimization and intensification of AAV2 vector production: Scale down and rapid scale up upstream processes**
Nazgul Wagner, Sartorius, Germany

53. **Informing next-generation cell and gene therapy technologies through an evaluation of currently approved and late clinical stage medicines**
Niah Goudar, Berkeley University, USA

54. **Adventitious agent control in gene therapy processing**
Nicholas Marchand, Cytiva, USA

55. **Assessing the impact of evolutionary pressures on the performance of AAV vector production in HEK293 cells**
Nikolaus Virgolini, University of Natural Resources and Life Sciences, Vienna, Austria

56. **Asymmetrical-flow field-flow fractionation and Taylor dispersion analysis for characterization of Adeno-Associated Viruses for gene therapy**
Nikolaus Virgolini, University of Natural Resources and Life Sciences, Vienna, Austria

57. **Assisting quality by design through design of experiments to overcome industry bottlenecks for Adeno-Associated Virus (AAV) downstream processing**
Paul Cashen, Sartorius, United Kingdom

58. **Continuous rAAV vector production using the baculovirus expression vector system**
John Joseph, Massachusetts Institute of Technology, USA

59. **Therapeutic viral vectors: Manufacturing, challenges, and platform-based innovation**
Rachel Legmann, Repligen, USA

60. **Plasmid engineering to improve AAV productivity and packaging efficiency**
Devarshi Kapadia, Lonza, USA

61. **TruStableTM: A fully integrated inducible stable producer cell line for AAV manufacturing**
Sandhya Pande, Shape Therapeutics, USA

62. **Designing performance membranes for challenging & demanding separation applications through advanced characterization techniques**
Adolfo Nicoloso, Meissner, USA

63. **Animal-origin free peptones enhance adenovirus production**
Wen-Yang Tsai, Thermo Fisher Scientific, USA

64. **Towards a fully defined viral vector production process**
Nelson Ndahiro, John Hopkins University, USA

Engineering Conferences International

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Calendar of ECI Conferences

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2024

January 7-13	**23AI**	**INNOVATIVE MATERIALS & METHODS FOR ADDITIVE MANUFACTURING II (IM2AM)** (Tomar Portugal) D. Schmidt (Luxembourg Institute of Science and Technology (LIST); N. Gupta, New York University; E. Eastwood, KCNSC/Honeywell FM&T; B.G. Compton; University of Tennessee, Knoxville; G.M. Gladysz, Los Alamos National Laboratory
February 4-8	**24AT**	**ADVANCING MANUFACTURE OF CELL AND GENE THERAPIES VIII** (Coronado, CA) F. Masri, Cell & Gene Therapy Catapult; C. Yeager, Georgia Institute of Technology; G. Maheshwari, BMS; J. Moscariello, BMS
April 4-8	**24AC**	**DELIVERY OF NUCLEIC ACID THERAPEUTICS II: BIOLOGY, ENGINEERING AND DEVELOPMENT** (Siracusa, Sicily) L. Sepp-Lorenzino, Intellia Therapeutics; S. F. Dowdy, University of California San Diego School of Medicine; M. Stanton, Generational Bio
April 14-19	**24AI**	**ULTRA-HIGH TEMPERATURE CERAMICS: MATERIALS FOR EXTREME ENVIRONMENT APPLICATIONS V** (Sicily, Italy) D. Sciti, Institute for Science and Technology of Ceramics, CNR; L. Silvestroni and F. Monteverde, ISSMC-CNR; J. Binner, Univ. of Birmingham; R. Savino, Univ. of Naples; G. Thompson, Univ. of Alabama; E. Wuchina, Naval Surface Warfare Center
April 28-May 2	**24AP**	**CHEMREC I: THERMOCHEMICAL RECYCLING OF PLASTICS** (Malaga, Spain) S. Kersten, University of Twente; M. Pilar Ruiz, Maastricht University; E. Heeres, University of Groningen
May 5-10	**20AF**	**SYNTACTIC AND COMPOSITE FOAMS** (Riga, Latvia) G.M. Gladysz and K.K. Chawla, University of Alabama at Birmingham; A. R. Boccaccini, University of Erlangen- Nuremberg; M. Fukushima, National Institute of Advanced Industrial Science and Technology
May 12-16	**24AH**	**NANOTECHNOLOGY IN MEDICINE IV: ENABLING NEXT GENERATION THERAPIES** (Tomar, Portugal) K. Rege, Arizona State University; S. De Smedt, Ghent University S. Varghese, Duke University
May 19-24	**24AA**	**VACCINE TECHNOLOGY IX** (Los Cabos, Mexico) C. Lutsch, Sanofi Pasteur; L. Lua, University of Queensland; F. Godia, Universitat Autònoma de Barcelona; T. Tagmyer, Merck
June TBA	**24AS**	**TRANSITION OF ENERGY SYSTEMS TOWARDS SUSTAINABILITY** (Stavanger, Norway) S. De, S. Bandyopadhyay, IIT, Bombay; M. Assadi, University of Stavanger
July 21-25	**24AM**	**BIOCHEMICAL AND MOLECULAR ENGINEERING XXIII: ACCELERATING BIOTECH SOLUTIONS TO AID A CHANGING WORLD** (Dublin, Ireland) M. O'Malley, University of California at Santa Barbara; B. Pfleger, University of Wisconsin; V. Roy, GSK
Summer	**24AE**	**NANOTECHNOLOGY CONVERGENCE FOR SUSTAINABLE ENERGY, ENVIRONMENT, CLIMATE CHANGE AND HEALTH: A US-AFRICA CONFERENCE** (Casablanca, Morocco) I.C. Escobar, University of Kentucky; A. El-Gendy, University of Texas-El Paso
Oct 6-11	**24AN**	**NANOMECHANICAL TESTING IN MATERIALS RESEARCH AND DEVELOPMENT IX** (Sicily, Italy) M. Sebastiani, Rome TRE University
Oct 20-24	**24AB**	**INTEGRATED CONTINUOUS BIOMANUFACTURING VI** (Leesburg, VA, USA) A. Azevedo, Instituto Superior Técnico; A. Noyes, Apogee Therapeutics; K. Brower, Sanofi

Nov 3-7	**24AO**	**MIXED CONDUCTING AND NONSTOICHIOMETRIC COMPOUNDS VII** (Tainan, Taiwan) W. Chueh, Stanford University; K.-Z. Fung, National Cheng Kung University; R. Waser, RWTH Aachen; H. Takamura, Tohoku University

2025

April TBA	**25AM**	**MICROBIAL ENGINEERING III** (Porto, Portugal) E. Keshavarz-Moore, University College London; T. Sauer, Sanofi
Late Spring	**25AU**	**SINGLE USE TECHNOLOGIES VII** (Europe) N. Montenay, Sartorius; A. Rayat, University College London; A. DiBenedetto, Roche Genentech
April 27 – May 2	**25AC**	**CELL CULTURE ENGINEERING XIX** (Tucson, AZ) A. Khetan, BMS; M. Yu, Sutro Biopharma; M. Betenbaugh, Johns Hopkins University
Late Spring	**25AG**	**ALKALI ACTIVATED MATERIALS AND GEOPOLYMERS: SUSTAINABLE CONSTRUCTION MATERIALS AND CERAMICS MADE UNDER AMBIENT CONDITIONS** (Finland) C. Leonelli, Universita' degli Studi di Modena e Reggio Emilia;
May 2025	**25AB**	**BIO-CHAR IV** (Santa Marta, Colombia) F. Berruti, Western University, Canada
May 18-22	**25AO**	**ADVANCES IN OPTICS FOR BIOTECHNOLOGY, MEDICINE AND SURGERY XVIII** (Cork, Ireland) S. Gibbs, M. Skala and S. Andersson-Engels
June 1-6	**25AP**	**POLYMER REACTION ENGINEERING** XII (Clearwater, Florida) I. Konstantinov, The Dow Chemical Company; P. Iedema, University of Amsterdam; M. Grady, Axalta
June 22-27	**25AT**	**THERMAL AND ENVIRONMENTAL BARRIER COATINGS VII** (Irsee, Germany) B.. Pint, Oak Ridge National Laboratory; E. Opila, University of Virginia; B. Hazel, Pratt & Whitney; Uwe Schulz, German Aerospace Center; Ram Darolia, GE Aviation (retired); B. Harder, NASA
July 2025	**25AW**	**MICRO- AND NANOPLASTICS IN WATER: CHARACTERIZATION, CURE AND PREVENTION** (Switzerland) D. Hunkeler, Aqua+Tech
October TBA	**25AE**	**ENZYME ENGINEERING XXVIII** (Denmark) J. Woodley, DTU; D. Hededam-Welner, DTU
Oct TBA	**25AD**	**ELECTROPHORETIC DEPOSITION VIII: FUNDAMENTALS AND APPLICATIONS** (Torremolinos (Malaga), Spain) B. Ferrari, Institute for Ceramic and Glass, Spanish Research Council; A.R. Boccaccini, University of Erlangen-Nuremberg
October 26-31	**25AS**	**CERAMIC MATRIX COMPOSITES III** (Yamanashi, Japan) R. Darolia, GE Aerospace; K. Goto, JAXA; T. Akatsu, Tokyo University of Technology; S. Kitaoka, Japan Fire Ceramics Center; G. Vignoles, University of Bordeaux
November TBA	**25AI**	**BENEFICIATION OF PHOSPHATES X** (Hanoi, Vietnam) (Chair: Patrick Zhang, Florida Industrial and Phosphate Research Institute, USA; Co-Chairs: Phong Vo, Ardaman & Associates Inc, USA; Erika Rova, Yara Suomi Oy, Finland; André Carlos Silva, Federal University of Goiás, Brazil; Ewan Wingate, Bechtel Australia, Australia)
TBA	**25AF**	**CIRCULAR ECONOMY FOR ORGANIC WASTES AND NUTRIENT MANAGEMENT** (Cartagena, Colombia) Gerardo Ruiz-Mercado, EPA; Karina Angelica Ojeda Delgado, University of Cartagena; Eduardo Luis Sanchez Tuiran, University of Cartagena

2026

May/June	**26-AP**	**PYROLIQ II – 2023: Pyrolysis and Liquefaction of Biomass and Wastes** (TBA) F. Berruti, ICFAR & Western University; A. Dufour, CNRS, ENSIC; M. Garcia-Perez, Washington State University; W. Prins, University of Ghent
June 7-12	**26AW**	**WASTELCA 5: LIFE CYCLE SUSTAINABILITY ASSESSMENT FOR WASTE MANAGEMENT AND RESOURCE OPTIMIZATION** V (Cetraro (Calabria), Italy) U. Arena, University of Campania "Luigi Vanvitelli";

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To initiate conferences that will have a significant impact on engineering education, research practice and/or development.

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- Process all applications and registrations.
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- Contract for the publication of print or electronic proceedings, if any.
- Provide on-site staff during the conference.

For more information, please contact the ECI Director at Barbara@engconfintl.org