Name	BIO
Yoji Sato	Dr. Sato is the Head of the Division of Cell-Based Therapeutic Products at the National Institute of Health Sciences. As a graduate student at the University of Tokyo and as a postdoc at the University of Cincinnati, he conducted research on cardiovascular pharmacology and succeeded in establishing a variety of transgenic mouse models to elucidate mechanisms of cardiac excitation-contraction coupling. His current research area is in the field of regulatory science for the quality, efficacy, and safety of cell therapy products. He also serves as a topic leader of ICH Q5A(R2) and a member of the Pharmaceutical Affairs Council of the Ministry of Health Labour and Welfare.
Glenn Wright	Glenn E. Wright is the President & CEO of the Parenteral Drug Association and serves as Chairman of the Board for the Product Quality Research Institute. Mr. Wright has more than 30 years industry experience, having served in various technical and senior leadership positions at Eli Lilly, Amgen, and Pfizer. He has extensive technical, regulatory, and quality expertise in pharmaceutical manufacturing and has served on the PDA Board of Directors, Science Advisory Board, and Program Advisory Board. In addition, he has chaired numerous industry meetings, Task Forces, and Steering Committees on topics of importance for the industry.
Yasuhito Ikematsu	Yasuhito Ikematsu is an associate professor at the Graduate School of Engineering, Osaka University, and concurrently serves as director of the Osaka University Hitachi Plant Service Regenerative Medicine Collaborative Research Institute. For more than 14 years at J-PDA, he has been engaged in research on sterility and quality control in sterile pharmaceuticals and regenerative medicine products, as well as research and dissemination of rapid microbial testing methods. He also contributes to regulations and guidelines in Japan, conducting regulatory science and human resource development.
Mitsuo Mori	Mitsuo Mori is the General Manager of the Quality Control Department, Takasaki Quality Unit, Quality Headquarters, Kyowa Kirin Co., Ltd. At the same time, he is in charge of overall quality control of the company's biopharmaceuticals. He has more than 20 years of experience in pharmaceutical companies, especially as an expert in microbial control. For more than 6 years at Japan PDA, he has been engaged in research on sterile management of sterile pharmaceuticals and regenerative medicine products, and research and dissemination of rapid microbial testing methods. He is also active in the pharmaceutical industry and has been making recommendations for various regulations including the Japanese Pharmacopoeia for over 13 years.

Tetsuya Karino	Tetsuya Karino belongs to Sumitomo Pharma Co., Ltd. Regenerative Medicine/Cell Therapy Plant Manufacturing Group. He is currently in charge of production management. After three years of experience in quality assurance of sterile pharmaceuticals, he has been involved in manufacturing control operations for the commercialization of cell-based pharmaceuticals for ten years. Since 2020, he has been participating in research on aseptic management of regenerative medicine products at Japan PDA.
Richard Denk	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 the PtC of the Manufacturing of ATMPs. Richard was also chair of the 2022 PDA ATMP Conference in Brussels and is Member of the Program Committee of the PDA 2022 Annex 1 workshops. 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. Richard is a global recognized subject matter expert on Containment and has developed the containment pyramid.
Masahiro Kino-oka	Dr. Masahiro KINO-OKA is the professor in Department of Biotechnology, Graduate School of Engineering, Osaka University since 2009, being the leader in the field of manufacturing for cellular therapy products. He has also established the Research Base for Cell Manufacturability since 2021, performing the developments of cell manufacturing system, guidelines for regulation (by PMDA) with standard (by ISO TC198/WG9 and TC276/WG4) as well as human resources, inviting many companies to gather and make up the core consortium for social implementation.
Tomoko Hongo-Hirasaki	Dr. Tomoko Hongo-Hirasaki is lead expert of virus filtration at Asahi Kasei Medical Co., Ltd.. She is in charge of global scientific activity and leading scientific publication in bioprocess division. She worked with PlanovaTM virus removal filters for over 25 years, including R&D, technical support to customers, and scientific affairs.
Masayoshi Tukahara	Her research has focused on virus filtration mechanisms, viral clearance study design, design space studies for virus filtration and the characterization of virus removal membranes.
Seitaro Mizukami	Seitaro Mizukami joined Takeda Pharmaceutical Co. Ltd in Mar. 2006 and worked for the CMC Division. He engaged in formulation process improvement, facility introduction at Manufacturing Science division in GMS Japan since Jan. 2017. In May .2021 he was assigned Head of Cell Therapy Osaka Manufacturing at Biologics operation unit in GMS.

Sang Yoon	Sang Yoon is Senior Director of Quality at Samsung Biologics, located in Songdo, South Korea. He is responsible for Quality Innovations and Operational oversight of multiple biologic plants. He is passionate about improving healthcare by commercializing therapies to treat rare diseases, and building an engaging company culture to deliver results. Sang Yoon has over 20 years of experience in Product and Process Development, Manufacturing Operations, Quality Systems and Compliance, Quality Engineering, Operational Excellence, and Training in the production of plasma biologics, cell therapy, and medical devices. He has also led cultural transformations at two large healthcare hospital and Clinic organizations in California. Before joining Samsung Biologics, he previously served in Quality leadership positions for two Cell and Gene Therapy startups in California, one which recently achieved EMA approval for the first Allogeneic Cell Therapy product. He will share his lessons learned from his past two C&GT startup companies.
Shingo Sakurai	Dr. Sakurai is the professor of facility of Pharmaceutical Sciences in Tokyo University of Science. After retiring from PMDA as an operating officer of inspection departments of GMP, QMS and GCTP in 2020, he has opened the laboratory of Pharmaceutical Quality Design and GMP in the Univ. His research is the international harmonization of Japanese guidelines in these areas. For the human resource development of students and industries, he conducts develop research on the educational materials of GMP and GCTP. He is also a director of PDA Japan chapter and chief director of NPO Drug and Food Quality Assurance Support Center.
ALISON ARMSTRONG	Dr. Alison Armstrong is Senior Director and Global Head of the Technical and Scientific Solutions team. She established a client facing scientific consultancy team in 2015. This team is responsible for scientific and regulatory advice and fully supports customers worldwide. Dr. Armstrong has authored a number of articles on trends in biosafety testing and is a member of regulatory taskforce groups related to rapid technologies. She is an invited speaker at global conferences.
Prof. Sean Palecek	Sean Palecek is the Milton J. and Maude Shoemaker Professor of Chemical and Biological Engineering at the University of Wisconsin – Madison and the Director of Research for the National Science Foundation Center for Cell Manufacturing Technologies (CMaT). Sean's research lab studies how human pluripotent stem cells (hPSC) make fate choices and uses this information to develop processes for differentiation of human pluripotent stem cells to a variety of lineages, including cardiovascular and neurovascular cell types. His lab strives to engineer fully-defined, scalable, and robust process to generate cells for in vitro modeling and in vivo therapeutic applications.