2025-10-16 BPD Roundtable Dinner _ Table Descriptions and Speaker Info

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Contents (by Table Number)

1. DATA ENABLEMENT FOR AI APPLICATIONS IN BIOTECH AND CELL AND GENE THERAPY

Description	The biotech and Cell and Gene Therapy industry has seen a shift over the last months from a general idea of the importance of AI to the first actual implementations of digital twins for facility design and holistic process execution models with or without AI, studies on how AI can support diagnosis for orphan drugs and AI implementations for drug discovery. While this provides great opportunities, it also creates new challenges. How can we make use of the tons and tons of non-structured data? How do we need to adapt our procedures to allow for efficient data enablement? And where do we stand on validation and control of AI models in specific use cases? The roundtable will come together to discuss what we can do to get ready for efficient and controlled use of AI models, exchange their experiences and lessons learned with AI implementation and discuss recent developments in the industry. The discussion will be suitable for all levels of experience.
Biosketch	After her PhD on the genetic background of autism spectrum disorders, Judith Koliwer led an academic research group, which analyzed the physiological role of proteins associated with cancer and epilepsy by using lenti and retroviral transduction for genetic modification of cell cultures. As leading scientist for BSL2, she supported the development of the virus-based projects of Bielefeld University. In 2019, Judith joined the MES and data analytics company Körber Pharma Software as senior industry advisor and principal consultant for advanced projects. She works closely together with Cell and Gene Therapy manufacturers supporting them in transitioning their manufacturing process from paper to a digital solution, generating their digital ecosystem roadmap as well as optimizing their process data management.

2. CDMO AND CLIENT SUCCESS: A TWO-WAY STREET

Description	To explore the key drivers of successful collaborations between CDMOs and their clients—from startups to large pharma—by focusing on alignment, trust, quality, and scalability. Participants should leave with clear strategies to optimize outcomes on both sides of the partnership. Key Takeaways Strong partnerships begin with shared definitions of success and transparent planning—early. A great CDMO is more than a vendor; it's a co-strategist and risk-sharing partner. Consistent communication, clear governance, and aligned quality systems prevent surprises. Cultural and operational compatibility is just as important as technical capability. Success is mutual: when one side fails, both do—when one wins, both scale.
Biosketch	Troy Fugate is Vice President of Compliance Insight, Inc., a leading global Quality and Regulatory Service Provider for FDA and GxP regulated industries. With over three decades of experience in pharmaceutical, biologics, medical device, and OTC compliance, he specializes in embedding systems of high-quality across workforces, practices, and environments. Troy began his career in industry working with the FDA directly on compliance issues, partnering with Cynthia Ipach to grow Compliance Insight into a respected international firm by 2016, renowned for its deep expertise and client-first literature. Under his leadership, the company has been honored multiple times—including recognition as a Top 10 Pharmaceutical Compliance Solution Provider and "Company of the Year" by Industry Era. A prolific thought leader, Troy regularly speaks at events, hosts GMP-focused webinars and podcasts, and shares insights through LinkedIn posts and short articles on GMP best practices.

3. QUALITY BY DESIGN AND PROCESS VALIDATION -- KEY CONCEPTS AND METHODS

Description	As guidance for industry, FDA published Q8(R2) Pharmaceutical Development (2009), which states "The aim of pharmaceutical development is to design a quality product and its manufacturing process to consistently deliver the intended performance of the product. ... It is important to recognize that quality cannot be tested into products, i.e., quality should be built in by design." In addition, FDA also published Process Validation: General Principles and Practices (2011), which outlines a three-stage approach to process validation that ensures that "a process is capable of consistently delivering quality product." Most life sciences organizations have not implemented Quality by Design (QbD) but still depend largely on inspection and testing to ensure product quality. Many scientists and engineers are still unaware of the concepts of QbD and process validation, and most lack training and experience in statistical methods used in QbD and process validation. The roundtable will introduce some basic concepts and methods and facilitate discussion about the challenges and lessons learned.
Biosketch	Fang Zhou has worked in R&D, manufacturing, quality, and Continuous Improvement in the life sciences industry since 2001. In addition, he has over a decade of experience delivering training and consulting to global clients in the areas of Quality by Design, statistical methods, Operational Excellence, and organizational change management. Fang Zhou is a certified Lean Six Sigma Master Black Belt and PMP. He has a Bachelor's degree in Chemical Engineering and MS in Analytics from Georgia Tech and a Ph.D. in Molecular Biophysics & Biochemistry from Yale.

4. FORMULATION CONSIDERATIONS FOR BIOLOGICS

Description	The discussion topic will focus on the product development and formulation considerations for biologics, focusing on understanding the behavior of the developing asset, formulation challenges, and planning for advanced stages of development via risk mitigation strategies. Interested parties would be downstream manufacturing scientists, analytical scientists, formulators, and professionals in preclinical research. The group's shared experience and questions will guide the discussion.
Biosketch	Michael Doherty has been a pharmaceutical development professional for over 20 years, holding leadership positions at innovator companies and CDMOs, and is the founder and principal consultant at Pharmosaic Consulting LLC. He advises biotech and pharma companies on strategy and development, and has had extensive experience with emerging technologies and innovative drug delivery systems, as well as product development for biologics, topicals, and liquid and semisolid dosage forms.

5. BUILD-VS-BUY DECISIONS FOR GMP LIQUID MANUFACTURING IN EARLY- TO MID-STAGE BIOMANUFACTURING PROGRAMS.

Description	**Who Should Participate:** Biotech/CGT executives, CDMO ops leaders, facility & MSAT engineers, procurement, and project/program managers shaping manufacturing strategy and site design. **Learning Objectives:** 1. Examine total cost of ownership for in-house versus outsourced buffer/media preparation. 2. Identify decision thresholds for building out capacity (brick-and-mortar or stick-build) versus outsourcing. 3. Apply design levers—such as single-use technologies, modularization, and right-sizing classified space—to reduce capital expenditure and accelerate start-up timelines. 4. Develop supplier qualification criteria for critical raw materials to mitigate outsourcing risk. **Experience Level:** Intermediate to Advanced **Why This is Timely and Important:** With construction costs increasing more than 85% since 2009, the ability to optimize facility footprint and capital allocation is a critical competency for today's manufacturing leaders. Leveraging qualified partners for non-core functions—such as buffer/media preparation and purified/WFI water—can deliver measurable reductions in CapEx and OpEx while maintaining GMP compliance. Drawing on 15 years of biotechnology facility design and operations experience, the speaker will lead a discussion on practical decision-making framework, proven design approaches, and supplier qualification strategies that strengthen ROI and operational resilience in a resource-constrained environment.
Biosketch	David joined GeminiBio in February 2023 as VP of Sales bringing deep bioprocess expertise and a proven track record of building and scaling successful companies. As a founding member of Intermountain Life Sciences, he played a pivotal role in driving growth and positioning the for acquisition by Cytiva in 2021. Earlier in his career, David also meaningfully contributed to the successful exit of an additional cell culture focused outsourcing company, further cementing his experience in guiding small to mid-sized organizations through high value transactions with efficient capital deployment and rapid scale. At GeminiBio, David leads the strategic commercial expansion of the company's extensive media and buffer contract manufacturing services, delivering cGMP scalable liquid workflows that help biopharmaceutical clients efficiently optimize processes from development through full commercial production.

6. BRIDGING THE GAP: INNOVATING DOWNSTREAM BIOPROCESSING FOR INTENSIFIED AND CONTINUOUS MANUFACTURING

Description	This roundtable will focus on addressing the critical bottleneck between advanced upstream processes and current downstream capabilities in biomanufacturing. We'll discuss the technological needs and potential innovations required to handle the high cell densities and product concentrations generated by intensified and continuous upstream systems. Anyone working to optimize production, reduce costs, and implement next-generation manufacturing strategies will find this discussion highly relevant. It will be particularly valuable for those directly encountering the limitations of current purification technologies when paired with high-productivity upstream processes. The topic is timely and important because the biopharmaceutical industry is actively moving towards intensified and continuous manufacturing to reduce costs and facility footprints. However, the success of these upstream advancements is currently capped by downstream processing limitations. Solving this bottleneck is crucial for realizing the full economic and operational benefits of modern biomanufacturing. This session is suitable for professionals with an intermediate to advanced level of experience in bioprocessing. A foundational understanding of both upstream and downstream unit operations is expected to contribute effectively to the discussion.
Biosketch	Sunil Mehta is a scientist inventor and global entrepreneur with over 25 years of experience in biopharmaceuticals cell and gene therapy and vaccines. A proven leader Dr. Mehta has a successful track record of transforming innovative technologies into high-quality products. Dr. Mehta's experience is vast spanning leadership and scientific roles at KBI Biopharma Johnson & Johnson and Roche. He possesses a deep understanding of the entire bioprocessing workflow from R&D to commercial cGMP manufacturing of biologics. Dr. Mehta's entrepreneurial spirit is evident in his co-founding of kSep Systems in 2011. As President and CEO he spearheaded kSep's remarkable growth transforming it into a global leader before its successful acquisition by Sartorius Stedim Biotech in 2016. Dr. Mehta holds a Ph.D. from Brown University and gained valuable early research experience at the Uniformed Services University of the Health Sciences. His expertise is further bolstered by several key patents in diverse bioprocessing technologies and cancer therapies.

7. BUILDING A SCALABLE COMMERCIALIZATION ROADMAP

Description	As life sciences companies transition from clinical to commercial or expand their product portfolios and enter new markets, the complexity of commercialization increases. This roundtable will explore how to build a scalable, patient-centric commercialization roadmap, including aligning systems and platforms with growth strategies, mapping the patient journey to guide engagement models, and leveraging orchestration platforms to enable cross-functional collaboration. Geared toward commercial, operations and IT leaders, the discussion will draw on two real-world project examples to uncover practical insights and best practices. As speed-to-market and patient engagement become increasingly critical, this session offers a timely opportunity to share challenges and strategies with peers working to scale their commercialization efforts.
Biosketch	Lynette Nazabal is an associate partner with Clarkston and serves as the firm's pharmaceutical, biotech, and contract manufacturing and research organization lead. In her role, Lynette provides strategic oversight and input into the firm's services and solutions relative to those industries. Lynette has worked within the pharmaceutical and biotech industry for almost 20 years, with differentiated experience that includes quality systems, manufacturing, commercialization, laboratory operations and technology, validation, and regulatory operations and compliance. She also has considerable expertise in manufacturing execution systems, with specific focus on batch record design, master data management, business process flow, training, and project management. In addition, Lynette has also worked with Infrastructure and Information Security teams to provide innovative cloud-based solutions to support IT needs within the life sciences industry.

8. SMARTER CAPAS: QUALITY OVERSIGHT THAT ACTUALLY IMPROVES PROCESSES

Description	Proposed Topic: This roundtable will explore smarter CAPA strategies that go beyond checkbox compliance to drive real process improvements. We'll discuss root cause analysis, cross-functional investigations, and how to create CAPAs that prevent recurrence rather than recycle paperwork. Who It's For: Quality professionals, operations leaders, and scientists involved in bioprocess development or manufacturing. Learning Objectives: Identify common CAPA pitfalls and how to avoid them Learn effective strategies for investigation and follow-up Discuss how QA can partner with teams to improve outcomes Experience Level: Intermediate to Advanced Why It Matters: As regulatory expectations rise, CAPAs must evolve from reactive fixes to proactive tools for quality and efficiency. This session will be valuable for those seeking practical, scalable solutions that work in real-world biomanufacturing environments.
Biosketch	Ronke Adetolu is a Quality Assurance Manager at SC Johnson with over a decade of experience in regulated industries, including pharmaceutical manufacturing and consumer goods. She previously led QA consulting efforts for multiple pharmaceutical clients, specializing in deviations, CAPAs, batch record review, and compliance training. Ronke has a strong track record of driving continuous improvement through quality systems and cross-functional collaboration. Her expertise spans cGMP, root cause analysis, audit readiness, and regulatory compliance. She is passionate about making quality a value-add across teams, not just a requirement.

9. ANALYTICS FOR CELL THERAPY: CHARTING A DIFFERENT PATH WITH DIFFERENT CHALLENGES.

Description	The focus of the discussion will be analytics for cell therapy. While there is an overlap between the more established monoclonal antibody and viral vector industries, this is not the case for cell therapy. Discussions will focus types of assays, assay design, differences from vector or mAb assays products, assay qualifications, and stability studies. Discussions will cover the standard autologous cell therapies and the emerging allogenic cell therapies. Learning objectives will include increasing awareness and understanding the differences for analytical development and assay design for cell therapy. Understanding the distinct set of challenges, recent progress, and future outlook. Suitable experience for engaging conversation would include intermediate and advanced experience in the cell and gene therapy industry or beginners with educational background covering molecular biology and/or immunology. This would provide a timely and interesting discussion given the recent growth of the cell therapy industry. Those in either the cell or gene therapy industries would benefit and find the discussion valuable.
Biosketch	Patrick Kellish, Ph.D. is a Senior Scientist in Analytical Development at Kincell Bio, a cell therapy CDMO with facilities in North Carolina and Florida. In his current role, Dr. Kellish leads analytical development efforts that support cell therapy programs from early-stage process development through clinical supply manufacturing. His work focuses on designing and qualifying critical assays for cell identity, potency, and safety to ensure robust product characterization and regulatory readiness. Before joining Kincell Bio, Dr. Kellish served as a faculty member at the University of Florida, where he was director of the flow cytometry core. In that role, he led immune monitoring initiatives supporting early-phase clinical trials. Specializing in early phase cell therapy production and characterization, his background includes the immunology of viral vectors, oncolytic virotherapy, and cell therapies for solid tumors and hematological malignancies. His expertise bridges discovery research and translational development, with a focus on enabling the clinical advancement of novel therapeutic platforms.

10. A NEW APPROACH TO COMPLIANCE DOCUMENTATION FOR AUTOMATION, BIOPROCESS, AND CQV TEAMS.

Description	This discussion will address common challenges, gaps, and best practices in developing and executing compliance documentation and testing protocols for biomanufacturing projects. Focus areas include key deliverables such as Functional Specifications (FS), Design Specifications (DS), Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), Installation and Operational Verification (IOV), Installation and Operational Qualification (IOQ), and Performance Qualification (PQ). Process Engineers, Automation Specialists, and CQV Professionals are encouraged to participate in a cross-functional dialogue to promote alignment across disciplines. The session will conclude by introducing a streamlined methodology I have developed and applied across capital projects for companies including Pfizer, Eli Lilly, Exela, and Alnylam—aimed at improving turnover efficiency, transparency (traceability), and regulatory/production readiness.
Biosketch	Aershen Muheyati is a biomanufacturing systems engineer with expertise in automation, commissioning and qualification (CQV), and digital transformation in GMP-regulated environments. He currently serves as Program Chair of ISA Raleigh-Durham and is a member of the ISPE CaSA IT/Media Committee. His background combines a B.S. in Chemical and Biomolecular Engineering with an M.S. in Information Science, enabling a cross-functional approach to data integrity, process automation, and compliance. Aershen's work spans full-lifecycle CQV execution, ISA-88/95-based batch automation design, and risk-based validation per ASTM E2500 and GAMP 5. He has contributed to the startup of large-scale biologics and cell therapy facilities by integrating manufacturing execution systems (MES), process control systems (PCS), and equipment automation with regulatory-ready strategies.

11. LEVERAGING SECRETOMICS TO IDENTIFY POTENCY MARKERS

Description	The discussion pertains to leveraging the secretome to identify a potency test for cell-based therapies. Correlating members of the cell or organoid secretome with function may inform mechanism of action in vivo and meet FDA-2023-D-4299. The discussion should interest stakeholders developing cell-based therapies for solid organ rescue. The learning objective is to leverage existing technologies and knowledge bases to arrive at tangible solutions. This session is intermediate to advanced.
Biosketch	Prakash Narayan _ Transformative concept to clinical trial executive in the cell and small molecule space. I spent > 22 years in publicly traded pharma advancing therapies through IND filings across multiple TAs. Most recently I have been leveraging omics and tissue atlases to identify potency markers for BLA filings and precision medicine-based inclusion criteria. Aside from work I enjoyed a public facing role as Member, National Kidney Foundation - Serving the Carolinas and championing therapies for patients with systemic lupus erythematosus.

12. BUILDING AN AGILE YET RELIABLE OPERATIONS TEAM

Description	We will explore practical strategies for building a flexible operations workforce that can effectively respond to the capacity fluctuations often experienced in manufacturing, quality control (QC), quality assurance (QA), and other key operational areas. This roundtable will focus on how fractional, cross-trained and project-based talent can be used to meet short-term or variable demand without the long-term cost burden of full-time employees. This approach is especially useful for CDMOs and smaller companies navigating clinical development timelines, shifting production schedules, or constrained budgets. Attendees will discuss real-world applications, potential challenges, and the benefits of adopting flexible staffing models to maintain performance and agility during both high-activity and slower periods.
Biosketch	Lisa Cozza is principal consultant at Tunnell Consulting and a seasoned executive with over 35 years' experience in biomanufacturing cGMP operations, QC, PD, and business development for bulk drug and final drug product in all stages of clinical and commercial production in both contract and innovator companies. Currently she is supporting CDMO business transformations to improve sitewide performance with a positive mindset.

13. PROCESS VALIDATION SIMPLIFIED USING STANDARD TERMINOLOGIES

Description	The topic of discussion is to present a simplified approach towards process validation after systematically selecting, refining and applying terminologies listed in multiple regulatory guidelines. Scientists and Engineers from Process Characterization/Validation involved in late phase/stage at-scale manufacturing of biologics having skills ranging from intermediate to advance level will benefit from this discussion, as this discussion is a 2-way street. This discussion is important, critical and timely because a consistent process validation in the industry is needed to facilitate quick site to site transfer, in this global market. Currently, the validation of therapeutic protein manufacturing processes follows different paths/procedures with the final goal of commercializing a product via regulatory approvals quickly.
Biosketch	Brij Singla drives early phase/clinical projects and technology transfers from development to at-scale manufacturing, in addition to leading (and/or involved in) more than 10 late phase/stage process validation campaigns over the past 2 decades, co-partnering with clients on BLA review, and regulatory audits and inspections.

14. INVESTIGATION STRATEGIES FOR MICROBIAL DEVIATIONS IN BIOMANUFACTURING

Description	This discussion provides a focused look at effective strategies for investigating microbial deviations within biomanufacturing and process development environments. With microbial control being critical to product quality and regulatory compliance, we will look at a systematic approach to identifying, assessing, and addressing contamination events. Attendees will gain insights into root cause analysis methods tailored to complex biologics processes and how to apply meaningful corrective and preventive actions (CAPAs).
Biosketch	Kim Sobien is a Senior Microbiology Consultant at ValSource. Her 25-year pharmaceutical industry career encompasses a breadth of Quality, Compliance, and technical experience with injectable pharmaceutical products. Her expertise is in microbiology, sterility assurance, contamination control, investigations, capability building, and inspection readiness.

15. HARNESSING DIGITAL TWINS AND ARTIFICIAL INTELLIGENCE (AI) TO REVOLUTIONIZE REAL-TIME PROCESS OPTIMIZATION IN CGT SUPPLY CHAIN

Description	This roundtable will explore the transformative potential of digital twin and AI technologies in cell and gene therapy (CGT) supply chain. The discussion will focus on how real-time process replication can revolutionize process optimization in autologous therapies by enhancing end-to-end visibility, slashing lead times, and proactively tackling bottlenecks real-time digital twins. Target audience: Manufacturing and supply chain, process optimization, and digital transformation leaders, quality assurance professionals in the CGT space. Professionals from pharmaceutical companies, biotechnology firms, CDMOs, and technology providers focused on advanced therapies. Suitable for professionals seeking to understand and implement next-generation digital technologies. Basic understanding of cell and gene therapy manufacturing processes is recommended. Learning objectives: - Review the critical challenges in CGT supply chain process optimization - Explore real-world applications of digital twins and AI for optimizing CGT supply chain - Examine implementation challenges A critically important discussion as the CGT industry faces unprecedented scaling challenges while striving to reduce manufacturing costs and improve patient access.
Biosketch	Basia Coulter, Ph.D., M.Sc. serves as a global digital & AI enablement leader at Globant, specializing in healthcare and life sciences digital transformation. With a unique background spanning neuroscience, strategy consulting, and technology implementation, Dr. Coulter bridges the critical gap between scientific expertise and digital innovation in biopharma. Her educational foundation includes a Ph.D. in neuroscience, AI in Pharma and Biotech training from MIT Sloan School of Management, as well as AI in Healthcare Specialization from Stanford University, Center for Continuing Medical Education. At Globant, she leads cross-functional global teams in implementing AI-driven solutions for life sciences organizations, with particular expertise in harnessing digital technologies to accelerate breakthrough innovations across R&D and commercial domains. She has contributed to industry publications on clinical study design optimization and has extensive experience in implementing digital transformation strategies across the pharmaceutical value chain.

16. DESIGNING FOR CHAOS: HOW TO BUILD FLEXIBILITY INTO CGT FACILITIES

Description	Cell & Gene therapy facilities rarely go according to plan and that's before the process changes, timelines shift, or someone decides to double the batch size mid-project. This roundtable is all about designing for chaos: how do we build flexibility into our cleanrooms, utilities, and schedules so we don't have to start over every time the goalposts move? We'll use a set of "chaos cards" to spark discussion, each one posing a real-world scenario like a late process change, a space crunch, or an unexpected scale-up. The goal is to trade ideas and experiences on how to design facilities that can flex when reality hits. This is a practical, interactive session for engineers, project managers, and operations folks. Intermediate level, but open to anyone who's had to deal with shifting targets on a regular basis.
Biosketch	Faryal Khan is a process engineer with over 12 years of experience in the pharmaceutical and cell & gene therapy space, specializing in the design and optimization of manufacturing facilities ranging from $50K to $1.5B. She brings expertise in modular cleanroom design, single-use systems, and process automation. Faryal is passionate about bridging the gap between process development and manufacturing, and works closely with clients to streamline operations, eliminate bottlenecks, and improve tech transfer outcomes. Known for her practical, results-driven approach, she is a frequent collaborator with biotech vendors and stays actively engaged with emerging trends in CGT facility design and operations.