Second Annual Roundtable Dinner, October 16, 2026

At the North Carolina Biotechnology Center. 15 TW Alexander Drive, Durham NC

Contents

Table 1: Translating Plant-Based Nanotherapeutics into Scalable Manufacturing: Process Development Strategies and Future Directions

Speaker: Nazanin Ghareh Khani (independent consultant)

Description of Talk

The advancement of plant-derived nanotherapeutics offers promising opportunities for sustainable and next-generation drug delivery; however, translating these innovative platforms from laboratory research into scalable, reproducible, and manufacturable products remains a significant challenge.

This discussion will focus on process development strategies for plant-based nanotherapeutics, including scale-up challenges, critical quality attributes, characterization approaches, process optimization, and opportunities for sustainable biomanufacturing.

This topic will be valuable for professionals in Process Development, Manufacturing, MSAT, Quality, and R&D who are interested in emerging therapeutic platforms and innovative manufacturing approaches. Participants will gain insights into key barriers affecting manufacturing translation and strategies to improve process robustness and commercialization readiness.

This intermediate-level session is designed for professionals seeking to understand the challenges and future opportunities in developing scalable nanotherapeutic manufacturing processes.

Speaker Biosketch

I am a chemist with a Master's degree in Nanochemistry and over six years of research experience in developing nanotechnology-based therapeutic platforms. My research has focused on the design, synthesis, characterization, and biological evaluation of nanomaterials for biomedical applications, including drug delivery and neurotherapeutic approaches.

I have experience with nanomaterial characterization techniques, including DLS, SEM/TEM, FTIR, and UV–Vis spectroscopy, as well as biological evaluation methods. My research interests include translating innovative nanomedicine technologies into scalable and sustainable manufacturing processes. I am currently expanding my expertise in biopharmaceutical process development and manufacturing through professional training and industry-focused programs.

Table 2: Driving Innovation Through Use of NGS to Replace Animal-Based Assays

Speaker: Athenesia Faggins (Minaris)

Description of Talk

This roundtable will explore the evolving regulatory landscape for replacing in vivo testing in antibody development and release testing, with a focus on adventitious agent detection and MAP, HAP, and RAP strategies. We will discuss how next-generation sequencing (NGS) and complementary in vitro methods can support or replace traditional animal-based assays and share key insights and outcomes from the FDA Scientific Public Workshop on NGS for Adventitious Agent Detection in Biologics held on September 23rd.

Participants from regulatory affairs, analytical development, quality, CMC, and process development will benefit from an open discussion on regulatory expectations, validation considerations, comparability strategies, and global alignment.

Learning objectives include:

- Understanding current FDA perspectives on NGS for biologics safety testing
- Identifying opportunities and challenges in replacing in vivo assays
- Discussing practical implementation and validation strategies
- Sharing lessons learned and case experiences

Suitable for intermediate to advanced professionals, this session is timely as industry and regulators increasingly seek science-based, animal-free approaches to ensure antibody safety while improving efficiency and innovation.

Speaker Biosketch

Dr. Athenesia Faggins is a biopharmaceutical leader specializing in raw material risk control and analytical sciences for cell and gene therapy development and manufacturing. With more than 10 years of experience at Minaris Advanced Testing, she has led raw material risk control and analytical strategy, method development, qualification, and GMP testing supporting process development and technology transfer for many clients. Her expertise includes assay lifecycle management, comparability studies, and regulatory-aligned raw material and analytical control strategies that enable scalable manufacturing of advanced therapies. Dr. Faggins is recognized for translating scientific rigor into operational excellence to accelerate safe, effective therapies to patients.

Table 3: Quality Systems & Compliance: Challenges, Trends, and Best Practices

Speaker: Tania Ramos (PACIV)

Description of Talk

This interactive roundtable will bring together professionals from the life sciences industry to discuss current challenges, best practices, and emerging trends in Quality Systems and regulatory compliance. Topics will include inspection readiness, data integrity, computerized systems validation (CSV), digital quality transformation, AI in regulated environments, and fostering a strong quality culture. The session is intended for quality professionals, validation engineers, manufacturing and automation engineers, compliance specialists, IT/OT professionals, and managers. Suitable for intermediate to advanced participants, the discussion will encourage peer-to-peer learning and knowledge sharing. Participants will leave with practical insights, real-world examples, and strategies they can apply within their organizations while expanding their professional network. As digital transformation and evolving regulatory expectations continue to reshape the industry, this discussion provides a timely opportunity to exchange experiences and collaborate on solutions.

Speaker Biosketch

Tania Ramos is a Principal Validation Engineer and North Carolina Regional Lead at PACIV with over 20 years of experience supporting the pharmaceutical, biotechnology, and medical device industries. She specializes in Computer System Validation (CSV), Data Integrity, Quality Systems, Digital Transformation, Automation, and GMP regulatory compliance. Throughout her career, Tania has led validation and compliance initiatives for complex manufacturing and laboratory systems, supported regulatory inspections, and implemented risk-based quality solutions aligned with FDA, EMA, GAMP 5, and 21 CFR Part 11 requirements. She is passionate about connecting professionals, sharing practical industry insights, and fostering collaboration to advance quality, compliance, and innovation across the life sciences industry.

Table 5: Modernizing Modular Biotech Facility Automation

Speaker: John Hatzis (Rockwell Automation)

Description of Talk

Traditional system integration of vendor equipment into a facility can be costly and time consuming for a pharmaceutical end user. This is because of the disparity of automation platforms offered and lack of standards adopted by their different equipment vendors. Modern technology is available to greatly facilitate system integration of new equipment into a facility, accelerating time to market for a new product through faster facility commissioning.
This presentation aims to share how to successfully adopt new technology, standards, and workflows to modernize your approach to automating a facility made of modular vendor equipment. It focuses on the adoption of Module Type Packages and Virtual Commissioning for Plug and Play equipment, reinforced through practical examples and case studies.

The audience should walk away with some practical examples of how to leverage modern workflows to accelerate system integration of modular equipment into a facility. A key component of this is what capabilities to request when procuring equipment for a modular facility build.

Speaker Biosketch

John Hatzis has been with Rockwell Automation for 12 years where he has leveraged expertise using Rockwell Automation's technology in a variety of applications in the Life Sciences industry. His responsibilities currently include engineering and consulting on digital transformation and large capital projects in cGMP biologics and regenerative medicine. He focuses on creating ecosystems to support his client's digital transformation through aligning their people and processes for the successful adoption of new technology from their key equipment vendors. John currently works with Biophorum, ISPE, and ARMI on producing industry guidance and executing proof of concepts with cutting-edge technology. John has a degree in Chemical Engineering from Worcester Polytechnic Institute.

Table 6: Connecting Digital Manufacturing to the Life Sciences Supply Chain

Speaker: Lynette Nazabal (Clarkston Consulting)

Description of Talk

Digital manufacturing is oftentimes discussed within the four walls of the plant, but its value depends on a much broader ecosystem. Manufacturing must connect seamlessly with planning, materials, logistics, quality, laboratory operations, and the enterprise systems that support them.

This roundtable will explore what it takes to build a connected digital manufacturing and supply chain ecosystem, from the processes and data that cross functional boundaries to the ERP, MES, QMS, LIMS, and other digital capabilities that enable them.

Participants will learn how to identify critical connections across manufacturing and supply chain, recognize common gaps created by siloed digital initiatives, and prioritize the capabilities needed to create a more integrated, resilient, scalable, and compliant operation. The discussion is designed for intermediate to advanced professionals across Manufacturing, Quality, Process Development, Supply Chain, and IT/Digital.

As life sciences organizations invest in automation, advanced analytics, AI, and supply chain resilience, connecting the plant to the broader enterprise is essential to realizing the value of those investments.

Speaker Biosketch

Lynette Nazabal is an Associate Partner at Clarkston and serves as the firm's pharmaceutical, biotech, and contract manufacturing and research organization lead. In her role, she provides strategic oversight and input into the firm's services and solutions relative to those industries.

Lynette has worked within the industry for over 20 years, with differentiated experience that includes quality systems, manufacturing, commercialization, laboratory operations and technology, validation, and regulatory operations and compliance. She has considerable expertise in manufacturing execution systems, with a specific focus on batch record design, master data management, business process flow, training, and project management.

In addition, Lynette has worked with Infrastructure and Information Security teams to provide innovative cloud-based solutions to support IT needs within the life sciences industry. She has also supported multiple pre-commercial companies in developing digital strategies.

Table 7: The AOC Iceberg

Speaker: Faryal Khan (CRB)

Description of Talk

Antibody-oligonucleotide conjugates (AOCs) are gaining momentum as an emerging therapeutic modality but the conjugation step itself is only the tip of the iceberg. Beneath the surface are a wide range of challenges that can influence how an AOC process is developed, scaled, and ultimately manufactured, including raw material handling, containment, facility needs, waste, operator considerations, and more.

This interactive roundtable will use an AOC iceberg map to explore which challenges are immediately visible and which may be easier to overlook until they begin affecting the process. Participants will work through different considerations together, share perspectives from their own areas of expertise, and discuss where the greatest risks and unanswered questions may lie as AOCs move toward larger-scale GMP manufacturing.

Speaker Biosketch

Faryal Khan is a lead process engineer with experience in the pharmaceutical and cell & gene therapy space, specializing in the design and optimization of manufacturing facilities ranging from $500K to $200M. She brings expertise in modular cleanroom design, single-use systems, and process automation (robotics). Faryal is passionate about bridging the gap between process development and manufacturing, and works closely with clients to streamline operations 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.

Table 8: Breaking the Batch Paradigm: Is Continuous Biomanufacturing Ready for Commercial Scale?

Speaker: Guy Rachmuth (Evotech Biologics)

Description of Talk

As biologics portfolios expand and biosimilar competition increases, manufacturers are exploring new ways to improve productivity, lower cost of goods, and strengthen supply resilience. This roundtable will discuss how continuous biomanufacturing is moving from development into commercial-scale production for biologics.

Participants will explore the opportunities and challenges of implementing integrated continuous processes, including technology transfer, operational flexibility, facility utilization, quality considerations, and regulatory readiness. The discussion will focus on practical lessons learned and the factors driving adoption.

Who should participate:
Process development, manufacturing, MSAT, CMC, quality, regulatory, and supply chain leaders.

Learning objectives:
Understand the benefits and challenges of continuous manufacturing; identify key implementation considerations; evaluate its role in commercial biologics and biosimilars.

Experience level: Intermediate to advanced.

Speaker Biosketch

Guy brings over 20 years of leadership experience in corporate strategy, business development, and commercial execution across the life sciences and healthcare technology sectors. Prior to joining Just – Evotec Biologics, he served as Vice President of Corporate Strategy – Enterprise at IQVIA, following earlier roles as Vice President of Strategy and Corporate Development at IQVIA Laboratories. His career also includes leadership positions at Quintiles, M*Modal (acquired by 3M), and Nucryst Pharmaceuticals (acquired by Smith & Nephew).

Guy is the founder of two AI-driven healthcare technology startups, where he held CEO and CTO roles. He has deep expertise in commercial market expansion, M&A and strategic partnerships.

At Just – Evotec Biologics, Guy leads strategic efforts to expand business revenue across CDMO Services, Products for Sale, Technology Out-licensing, and Continuous Manufacturing Enablement.

Guy holds an M.S. and Ph.D. in Biomedical Engineering from Harvard University, and B.S. in Biomedical Engineering from Boston University.

Table 9: Accelerating Antibody Development: Aligning CMC and Toxicology Strategies to Reach IND Faster

Speaker: Doug Lee (Nonabio)

Description of Talk

As timelines for antibody therapeutics continue to compress, development teams face increasing pressure to align CMC, analytical, manufacturing, and nonclinical safety activities while minimizing development risk. This roundtable will explore practical strategies for integrating CMC and toxicology planning from lead candidate selection through IND-enabling studies.

Discussion topics will include common development bottlenecks, material comparability considerations, selection of relevant toxicology species, timing of manufacturability assessments, regulatory expectations, and approaches to reducing delays between research and clinical development. Participants will be encouraged to share experiences and lessons learned from monoclonal antibodies, bispecific antibodies, and other emerging biologic formats.

This session is intended for scientists, project leaders, CMC professionals, toxicologists, regulatory affairs professionals, and biotech executives with intermediate to advanced experience in biologics development. The goal is to identify best practices that improve development efficiency, reduce program risk, and support successful IND submissions. Given increasing pressure to shorten development timelines while maintaining quality and regulatory compliance, this discussion is highly relevant for both emerging and established biotech organizations.

Speaker Biosketch

Douglas Lee is Director of Business Development for Biologics CMC and Toxicology services, supporting biotechnology and pharmaceutical companies advancing antibody-based therapeutics from discovery through IND submission. With extensive experience working with development teams across CMC, analytical, manufacturing, and nonclinical safety disciplines, he helps organizations design integrated development strategies that accelerate timelines while managing technical and regulatory risk. Douglas collaborates with emerging biotech companies as well as established pharmaceutical organizations developing monoclonal antibodies, bispecific antibodies, and other biologic modalities.

Table 10: Beyond the Pilot:
Where AI Delivers Real Value in Biomanufacturing and Why It Stalls Before Production

Speaker: Adrian Dobre (ManufacTek.AI)

Description of Talk

Most biopharma organizations have run AI pilots. Far fewer have AI delivering routine value inside GMP production. This roundtable addresses both sides of the gap: where AI is already creating measurable value in process development and manufacturing (with examples from real production settings), and the practical reasons promising pilots stall, such as data readiness, validation/quality hurdles, unclear ownership, and change-management friction on the floor.

Participants will leave with a simple framework for selecting high-ROI use cases and a checklist of scaling barriers to address before the next pilot. It will interest anyone in process development or manufacturing - from the development lab and production floor to MSAT, quality, maintenance and digital/IT colleagues asked to move AI from slideware into the plant. Open to all experience levels, it draws on attendees' own experiences.

Speaker Biosketch

Dr. Adrian Dobre spent nearly 20 years in pharmaceutical and chemical manufacturing, most of it at Bayer, in senior roles spanning process development, engineering, production operations and digital transformation - including Chief of Staff and Strategy Development for Manufacturing Operations. In that role he shaped strategy across a global network of 15+ production sites and advised SVP leadership responsible for 5,000+ employees and $200M+ in annual CAPEX. At Bayer he led digital transformation work and built a global community of 200+ professionals driving digitalization across production sites.

He founded ManufacTek.AI to help pharma, biotech, and chemical manufacturing leaders identify where AI creates real operational value and make it work in validated GMP environments. Today he works hands-on with AI engineers, startups, and solution providers, giving him a grounded view of what today's AI can and cannot do on the production floor and what it takes organizationally for results to stick.

Table 11: AI for Process Impurity Prediction and Experimental Validation

Speaker: Chris Thompson (BrightSpec)

Description of Talk

Bioprocessing can generate small-molecule impurities that must be identified and understood. As AI is increasingly used to predict molecular structures and properties, it may also help predict process-related impurities, including reaction byproducts and degradation products. Prediction alone, however, is not sufficient to determine what was produced. Experimental validation is needed to confirm whether predicted impurities are present, particularly when no reference standards or spectral libraries are available.

This roundtable will explore how AI-based impurity prediction can connect with emerging analytical approaches for structural validation. Participants will discuss current capabilities, potential applications in bioprocess development, and how experimentally validated structures can provide feedback to both improved bioprocessing and advanced AI models. This timely discussion is intended for bioprocess, analytical, and AI/data scientists at all experience levels interested in the emerging intersection of AI prediction and experimental validation.

Speaker Biosketch

Chris Thompson, Ph.D., is VP of Commercial Applications and Development at BrightSpec, where he works at the intersection of analytical science, customer needs, and technology adoption. He has nearly two decades of experience in analytical instrumentation, with applications spanning life science and industrial markets, from metabolomics and pharmaceutical development to petroleum analysis. His technical background spans mass spectrometry, spectroscopy, and applied analytical chemistry. His current work focuses on small-molecule identification and quantitation and on connecting experimental measurements with computational and AI-based molecular predictions.

Table 12: A Single-Use Fermenter Enables Dramatic Reductions in Fermentation Setup and Teardown Time Without Loss of Process Performance

Speaker: Joshua Ross (Distek)

Description of Talk

The primary discussion is how a single use fermentor can greatly decrease fermentation times. This is relevant for anyone running fermentation of any kind, or even running a bioreactor. The Distek single use line can be adapted to be used with most bioreactor systems on the market, but this session is best suited for professionals with a basic understanding of microbial fermentation and bioprocess development. It will focus on practical implementation considerations, operational efficiency, and process development strategy rather than introductory fermentation concepts or highly specialized process modeling. As the market expands it's capabilities, a single use offering that can be used for multiple different processes and with differing units can streamline operations at companies that have multiple sites, as well as speed up the training of new employees and keep operations running during transitions.

Speaker Biosketch

Joshua Ross is the National Sales Manager for Bioprocessing at Distek, Inc., a New Jersey-based manufacturer of laboratory instrumentation specializing in dissolution testing and benchtop bioreactor/fermentor systems. In this role, he leads national commercial strategy for Distek's benchtop bioreactor and single-use bioprocessing product lines, working across biopharma, academic, and CDMO customers. Josh joined Distek seven years ago as the Midwest Account Manager before being promoted to his current national role.

Prior to Distek, Josh spent six years at Sartorius as a bioprocess sales representative, managing the company's full upstream and downstream portfolio across the Midwest region. He began his career with three years at the U.S. Food and Drug Administration, working in post-market compliance applications within the Center for Devices and Radiological Health (CDRH).

Josh holds a Bachelor of Science in Biomedical Engineering from the Georgia Institute of Technology.

Table 13: GMP Does Not Stop at the Loading Dock: Antibody Quality Risk from Release to Patient

Speaker: Jesse Huey (Ocasa)

Description of Talk

Regulatory expectations for antibody programs now extend beyond the manufacturing site. Product released under GMP can lose quality status in storage, in transit, or at the clinical site, and a single handling failure can compromise data or halt a study. FDA and EMA inspection focus has followed that expanded scope.

This table examines where risk concentrates after material leaves the facility: temperature-controlled storage and excursion management, label integrity across jurisdictions, and audit-ready traceability. We will work through a multi-region distribution case using parallel Importer of Record structures with separate QP release in each jurisdiction, and what that implies for upstream decisions in packaging, stability protocol, and country selection.

Objectives: map GMP and GDP handoffs from release to patient; identify the distribution failure modes most likely to surface in inspection; recognize which downstream constraints belong in early program planning.

Suitable for quality, regulatory, manufacturing, MSAT, and clinical supply professionals. Intermediate level. Discussion-based, not a presentation.

Speaker Biosketch

Jesse Huey leads business development for OCASA Life Sciences in the Research Triangle, working with sponsors, CROs, CDMOs, and central laboratories on international clinical supply and biological sample logistics across LATAM, EU, and US corridors.

Two decades in business development across clinical research gave him wide exposure to the development lifecycle: EDC and clinical data capture, small and emerging biotech through full-service CRO delivery, and commercialization, market access, and claims data analytics at Symphony Health and ICON plc.

His focus now is the operational and regulatory reality of moving investigational product and samples across borders, including Importer of Record structures, QP release, and GDP handling conditions. He began his career as a US Marine Corps CBRN specialist NCO, handling controlled material under strict protocol and documentation.

Table 14: Accelerating Biologics Development with Platform Solutions

Speaker: Justin Watkins (KBI)

Description of Talk

The integration of platform technologies has become essential in streamlining biologics development, enabling rapid progression from early-stage research to first-in-human (FIH) trials. KBI Biopharma's SUREtechnology Platform , powered by Selexis®, exemplifies how platforming principles can enhance efficiency, consistency, and regulatory readiness in cell line development and biomanufacturing. This discussion will focus on practical strategies for implementing platform approaches to reduce development bottlenecks while maintaining flexibility to address molecule-specific needs. We will explore how high-throughput analytical technologies and automation can support rapid decision-making by increasing testing capacity, reducing manual effort, and enabling efficient generation of process and product understanding. Particular emphasis will be placed on the implementation challenges associated with platforming, including determining where standardization provides the greatest value, integrating high-throughput technologies into existing workflows, and balancing speed with data quality and regulatory expectations. By combining platform processes with automated, high-throughput analytical strategies, biomanufacturing organizations can create more efficient and scalable development workflows that accelerate timelines from molecule selection through FIH while maintaining robust scientific and regulatory foundations. These approaches enable CDMOs and their partners to bring innovative medicines to the clinic faster while optimizing development timelines and strengthening regulatory interactions from Phase 1 through commercialization.

Speaker Biosketch

Justin Watkins is a Project Leader/Scientist II in Analytical Development at KBI where he serves as a process development team leader, managing a team that provides rapid and robust analytical testing and assay development for early-phase pipeline biologicals targeting oncology, infectious diseases, and autoimmune disorders.

Table 15: LLM Operations in Antibody Development

Speaker: Talal Hossain (independent consultant)

Description of Talk

LLMs in Antibody Development & Manufacturing explores how AI-enabled knowledge systems may support antibody teams without replacing the inherent scientific quality or operational judgment by accelerating the process of a human reviewed assessment. The discussion is designed for professionals in process development, Tech Ops, MSAT, manufacturing, quality, validation, tech transfer, and training. The talk will examine practical use cases such as governed document retrieval, deviation support, knowledge transfer, training, and quality change processes. The objectives are to distinguish the potential for safe implementation of AI usage to act as a catalyst for decision making, identifying low-risk/high-value applications, applying QbD, QRM, and target pharmaceutical quality-system principles for traceability and human-reviewed controls. This is suitable for beginner to intermediate audiences. The topic is timely as NC biomanufacturing scene and LLM regulation expands while teams face increasing data, documentation, and knowledge-transfer demands.

Speaker Biosketch

Talal Hossain is a technical operations and validation professional with cross-functional experience in a regulated biotech manufacturing environment. He has contributed his efforts to supporting organizations such as FUJIFILM Biotechnologies, Moderna, Alnylam, Siemens Healthineers, and PerkinElmer. He has worked with several data and technical systems such as INFOR EAM, Maximo, SAP, Alteryx, SQL, and Primavera P6. Talal is a PMP-certified project professional with a growing focus on the regulatory affairs of ethical human-governed AI usage, knowledge systems, and the latest updates from governing international bodies in LLM usage within the life-science industries.

Table 16: Governing AI in a Regulated Life Sciences Environment

Speaker: Irene Birbeck (Clarkston Consulting)

Description of Talk

AI adoption is accelerating across life sciences, but in a highly regulated environment, moving from experimentation to enterprise use introduces a new set of questions. How should organizations govern AI without slowing innovation? Which use cases require greater oversight? How should existing quality, risk, and compliance frameworks evolve as AI becomes embedded in business and operational processes?

This roundtable will explore practical approaches to AI governance in life sciences, including risk-based governance, accountability and human oversight, data and model considerations, third-party AI, and the intersection with existing quality and compliance processes.

Participants will learn how to assess AI use cases based on risk and identify the foundational components of an effective governance model. The discussion is designed for intermediate to advanced professionals across Quality, Regulatory, Manufacturing, R&D, IT/Digital, Data, and business leadership.

Speaker Biosketch

Irene Birbeck is a managing partner with Clarkston Consulting. In her client work, Irene specializes in the implementation and optimization of complex, global quality systems. Her industry experience spans companies within the life sciences sector, specifically in the cell and gene therapy biotechnology, and the consumer healthcare and chemical industries. In addition to quality systems implementations, Irene has managed projects related to research and development, commercialization, and commercial manufacturing. Irene is also passionate about helping companies in business process optimization, organizational transformation, and managing global teams.

Irene received her B.A. in public policy with a concentration on science and technology policy and a B.A. in communications studies with a concentration in rhetoric from the University of North Carolina at Chapel Hill, graduating with honors.