ROUNDTABLE SUMMARY

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Lifecycle Management for CGTs: Solving Operational Challenges in an Expanding Market

Matt Britz, Chief Operating Officer, AffyImmune Therapeutics
Nimi Chhina, Head of Global R&D and Regulatory Policy, BioMarin Pharmaceutical
Tamie Joeckel, Global Business Lead, Cell and Gene Therapy Centre of Excellence, ICON
Kilian Kelly, CEO, Managing Director, Cynata Therapeutics
Greg Kunst, CEO, Aurion Biotech
Curran Simpson, Chief Operating Officer, REGENXBIO
Krishnan Viswanadhan, President, Chief Operating Officer, Be Biopharma
Moderator: Janelle Hart, Managing Editor, Citeline

KEY TAKEAWAYS

- Clinical trials for CGTs are more complex than trials for small molecules.
- Trial complexity varies based on unique considerations for different CGT product classes.
- Operationalizing CGTs is top of mind for life sciences companies.
- Regulations for CGT therapies have not been harmonized worldwide.
- A decentralized approach may be impractical for early phases of CGT clinical trials, but it could work for long-term patient monitoring.
- Patient centricity must be incorporated into clinical trials and other stages of CGT development.
- To minimize disruption, changes to CGT manufacturing processes must be made early in the development process.
- As certain targets become overcrowded, some life sciences companies are expanding to new indications.
- Sponsors partner with CROs for CGT asset development and trial management expertise.
- While challenges remain, the future of CGTs is bright.

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OVERVIEW

The development of cell and gene therapies (CGTs), such as CAR T-cells and autologous and allogeneic therapies, is gaining momentum. To deliver these cures to patients with unmet needs, life sciences companies must navigate clinical trials—a process that is more complex for CGTs than for small molecules.

CGT clinical trials often require more diverse participants and the logistics of running the trials can be very complicated. In addition, many different types of product classes fall within the CGT bucket. Each product class and subclass bring its own unique considerations and level and nature of complexity.

Gaining regulatory approval is just the start, however. Companies must also address multiple issues related to operationalizing CGTs, such as manufacturing at scale, shipping products safely, simplifying the administration process, reimbursement, and more.

At all stages of CGT development and commercialization, life sciences companies must focus on delivering a positive patient experience. To streamline the CGT lifecycle, many firms turn to contract research organizations (CROs) to assist with asset development and trial clinical management. Long-term partnerships are the key to successful product launches.

CONTEXT

In this roundtable, panelists discussed how CGT companies are solving important operational challenges related to lifecycle management in expanding markets.

KEY TAKEAWAYS

Clinical trials for CGTs are more complex than trials for small molecules.

To deliver the data that regulators require, clinical trials must include a diverse set of participants. This can be particularly challenging in areas or countries where patients live in remote areas. An important aspect of clinical trial design is identifying the right patients and the right sites to provide the desired diversity.

> "The proportion of the rural population that lives near an MD Anderson or Dana Farber is tiny. We are bringing new types of centers on board to participate in trials. We provide transportation for patients, and we also send nurses to their homes."
>
> *Kilian Kelly, CEO, Managing Director, Cynata Therapeutics*

Logistics is another concern during clinical trials. Product shipments to sites often need to conform to stringent time and temperature requirements. In addition, sites may need cryogenic cold storage for CGTs. Considerable coordination is required with sites to ensure that all goes smoothly.

ICON works with sites to address CGT-specific obstacles. For example, when ICON mapped out the end-to-end process in one of its client's programs, the team realized that the pharmacy where the IP was stored was on the opposite end of campus from where the dose would be prepped and administered. ICON figured out how to prevent temperature excursions of LN2 IP being transferred from one end to the campus to the other. The solution was finding a vendor who had a hand-carry container that maintained -180˚ temperatures for four hours.

Although most gene therapy trials don't have these IP complexities, ICON often finds that the dosing procedures are quite complex, requiring participation of multiple departments and specialists on site. Its mock run processes of matching site procedures to the protocol are just as important whether it's cell or gene therapies.

> "While courier and shipper container companies have evolved and offer better technologies and real-time GPS tracking, we've found the highest risks of temperature excursions and mishandling of the investigational product (IP) is after delivery to the sites. I call it managing the 'last 50 yards.' Whether we are managing cell therapies that require liquid nitrogen or cryostorage, or gene therapies that are -80˚, we still need to review site capabilities, equipment, and procedures. A standard best practice is mapping existing site standard operations procedures (SOPs) with protocol requirements to ensure that every site understands what's required of them. Each site does things differently and is constructed differently."
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> *Tamie Joeckel, Global Business Lead, Cell and Gene Therapy Centre of Excellence, ICON*

The complexity of CGTs can make it challenging to include CGT-naïve sites in clinical trials. If doctors are working in the community rather than in a hospital setting, that can magnify issues related to logistics and other factors. Creative approaches to product shipments may be needed and employees at trial sites may require education on product handling. CROs understand the level of experience at different sites and recognize that some locations will require white glove handholding, coordination, and training.

Competition for the most desirable sites has created the need to expand into the community site setting, especially as trials move into Phase 3. Additionally, as the therapeutic areas expand into more chronic and common diseases, working with CGT-naïve sites is becoming much more common.

> "The doctors that treat osteoarthritis are not necessarily familiar with working with cell and gene therapies. In addition, many sites in some of our trials don't have liquid nitrogen storage on site, and even if they did, the clinicians may have never been near a liquid nitrogen tank. In one of our clinical trials, we ended up making just-in-time deliveries of the product in a liquid nitrogen dry shipper. That required a lot of planning and training at the sites. We made it work but it was an additional level of challenge that wouldn't arise in a normal clinical trial."
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> *Kilian Kelly, CEO, Managing Director, Cynata Therapeutics*

Exceptions are the norm in clinical trials for CGTs. It's therefore important to partner with a CRO that proactively works with trial sites to explain how things will be handled when exceptions arise.

"Any kind of exception will ripple through the entire process. When you have six or seven stakeholders that are part of the responsible, accountable, consulted, and informed (RACI) matrix, how do you manage that? We let sites know upfront that problems will arise and that we have a communication pathway and escalation plan. Every mock training we do includes one or two exceptions that we manage with the site, so they understand that we've got this."

Tamie Joeckel, Global Business Lead, Cell and Gene Therapy Centre of Excellence, ICON

Trial complexity varies based on unique considerations for different CGT product classes.

Many different types of product classes fall within the CGT bucket, including cell therapy products, ex vivo-administered gene therapy products, in vivo-administered gene therapy products which could be systemically administered or locally administered, or targeted or de-targeted for specific organs, genome editing products, and products leveraging varying delivery methods such as viral or non-viral mechanisms. Each product class and subclass brings its own unique considerations and level and nature of complexity.

"The complexity of CGTs makes for 'following good paradigms' challenging as each product may need a tailored development pathway or manufacturing process. Considerations vary by product type and class and impact the complexity of the clinical trials. Challenges with gene therapy clinical trials typically include but are not limited to the delivery method, long-term follow-up requirements, immunogenicity, dosing, and manufacturing considerations. These factors can make clinical trial design and execution complex for gene therapies. However, the potential for life-changing benefit makes overcoming these challenges worthwhile."

Nimi Chhina, Head of Global R&D and Regulatory Policy, BioMarin Pharmaceutical

Operationalizing CGTs is top of mind for life sciences companies.

Operationalizing therapies is the key to treating diseases that are large in prevalence. Concerns exist related to automation, the infrastructure required to ship products, patient access, reimbursement, and more. As life sciences companies move into treating larger disease areas, CROs can provide considerable value around operational issues.

> "We are developing an allogeneic therapy. We can solve the scaling problem associated with manufacturing, but we also need to operationalize it. Our current technology has a 40-hour shelf life. We worry about infiltrates, cell stacks and losing the line, shelf life, and how to distribute a cryo product worldwide. Many parts of the world have huge potential, but they don't have the infrastructure to adopt some of these therapies."
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> *Greg Kunst, CEO, Aurion Biotech*

Operationalizing gene therapy (GT) requires investments in manufacturing, supply chain, clinical infrastructure, and data management. There will be pharmacovigilance and risk management requirements imposed to closely monitor safety. Manufacturing facilities must meet regulatory standards. Nimi Chhina, Head of Global R&D and Regulatory Policy at BioMarin Pharmaceutical, highlighted the importance of trained staff, appropriate facilities, and safety protocols. Diagnostic testing may be needed to identify suitable patients based on genetic markers or disease variants, so testing workflows need to be established. Since long-term monitoring is necessary for recipients of GTs, systems to track treatment history and monitor outcomes over time may be required.

Regulations for CGT therapies have not been harmonized worldwide.

As a result, it takes considerable effort to introduce a therapy to an additional region or country. The complexity of running multiple trials for cell therapies is difficult, expensive, and time consuming.

> "When it comes to allogeneic therapies, we are making large batches and trying to treat more common conditions, but we don't have the same level of harmonization. That's a real barrier. Every country you add is different. You can't satisfy the regulators in every region because their expectations are somewhat contradictory."
>
> *Kilian Kelly, CEO, Managing Director, Cynata Therapeutics*

A decentralized approach may be impractical for early phases of CGT clinical trials, but it could work for long-term patient monitoring.

Decentralized clinical trials aren't well suited to novel CGT modalities. With new therapies, the FDA has imposed stringent requirements about how often patients need to be observed. In addition, the regulatory agencies in some countries (such as France) encourage decentralized trials, while others don't.

> "We have an autologous product and patients have to go to a specific cancer center to receive the treatment and give blood samples on day one, three, seven, 14, out to day 42. It is very common in these trials to monitor CAR-T cell expansion, cytokines, and other biomarkers. Then they have to come in every other month for scans. The appointment burden for these patients and their caregivers is very high, and the industry hasn't figured out a way to decentralize it yet."
>
> *Matt Britz, Chief Operating Officer, AffyImmune Therapeutics*

Hybrid GT study designs may help incorporate certain decentralized aspects into clinical trials for GTs, and also help improve patient recruitment and retention. Further, incorporating certain aspects may help collect real-world data (RWD) on these products.

> "Decentralized clinical trial designs can facilitate some components of GT clinical trials, but some procedures will likely need to be done on-site. Hybrid GT study design models can blend remote monitoring with in-person visits for GT administration, training, and periodic physical exams. Decentralized clinical trials can improve patient recruitment, access, and retention, as well as patient convenience. Monitoring patients at home can provide real-world insights on how these products perform in the real-world and impact the quality of life."
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> *Nimi Chhina, Head of Global R&D and Regulatory Policy, BioMarin Pharmaceutical*

Patient centricity must be incorporated into clinical trials and other stages of CGT development.

Tamie Joeckel, global business lead in the Cell and Gene Therapy Centre of Excellence at ICON, noted, "Having worked on the commercial side of pharma, launching specialty biologics for over 10 years, it was common to have Risk Evaluation and Mitigation Strategy (REMS) requirements for patient hub services and registries. But when I moved into cell and gene therapy nine years ago, I realized this is patient centricity on steroids." As a result, attention to detail is critical when it comes to the patient and site experience. ICON, for example, provides concierge services for patients participating in clinical trials, as well as for their caregivers. Joeckel noted, "Managing the patient journeys doesn't just involve the patients—the caregivers are a crucial part of the team. Working in rare disease, the patients might live hours away from a site. It's important that both the patients and their caregivers understand what the process is and what to expect."

> "Administering cell therapy to the right spot in the eye is critical. We have a team of surgical trainers that goes to sites for surgeries. We image every surgery and have someone on site to supervise. That makes a big difference to the experience at the site and delivering a patient-centric approach."
>
> *Greg Kunst, CEO, Aurion Biotech*

Patient-centricity is key to informing all stages of drug development with patient input and collection of patient experience data. Some clinical trial patients must participate in long-term monitoring for as long as 15 years. Some life sciences companies believe that these interactions could be decentralized to community providers to reduce the burden on patients. To operationalize this approach, various details need to be worked out, such as ensuring that patients visit local doctors and that providers send data promptly and accurately to the study database.

To minimize disruption, changes to CGT manufacturing processes must be made early in the development process.

It's best to make changes to the manufacturing process for CGTs as early as possible in the clinical trial process—preferably in Phase I and Phase II. Every change affects the timeline.

> "Many cell and gene therapies come out of universities. Universities don't think about how to manufacture products on a large scale or consider what will be acceptable to regulators. The earlier you start working on what it will take to move the technology to product and to scale, the better."
>
> *Greg Kunst, CEO, Aurion Biotech*

At the same time, some worry that manufacturing innovations may be passed by, for fear of introducing change into production processes. If a company makes a manufacturing change and the product is not deemed comparable, there is a risk of losing all the data collected prior to the change. One potential solution is to involve regulators from the start, conduct all the right assessments, and add a bridging clinical study if needed.

> "The field is evolving fast. We need to think about ways to bring in innovation. We wouldn't want to avoid a new improved manufacturing process because we are wary of the fact that changes may be deemed not comparable to leverage pre-change data and may need to repeat studies to demonstrate safety, efficacy, both, or may prevent pooling of early and late phase data at the time of licensure."
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> *Nimi Chhina, Head of Global R&D and Regulatory Policy, BioMarin Pharmaceutical*

> "I was just reviewing a draft guidance on comparability. One of the things I noticed in it was a tendency to lump different modalities together in the way the comparability is assessed. One of the things we're concerned about and wanting to address is that you can't necessarily do that. Products are very different and have different degradation pathways and different stabilities. Applying the same comparability requirement across lentivirus versus adeno-associated virus is a bit dangerous and it may end up creating extra work that's not necessary."
>
> *Curran Simpson, Chief Operating Officer, REGENXBIO*

As certain targets become overcrowded, some life sciences companies are expanding to new indications.

This approach makes it easier to recruit sites and patients for clinical trials. The rare disease space, for example, is full of unmet needs. Approximately 7,000 rare diseases exist, and treatments are available for only five percent of those.

> "I think the fundamental challenge is we are still continuing to learn biology. There are still only a handful of targets that we understand. So, it's not surprising to see multiple companies going after the same targets like CD19, BCMA, and GPRC5D. I think that broader than just cell and gene therapy, everyone wants to make sure we have low biological risks. This enables us to focus on validating the platform and the company's engineering risk."
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> *Krishnan Viswanadhan, President, Chief Operating Officer, Be Biopharma*

> "Our lead program is in anaplastic and poorly differentiated thyroid cancers. There are several reasons that we chose this indication: one is because those cancers have high ICAM-1 (target) expression. Another is that it is an area of high unmet need. Unless the patient has a mutation that can be targeted; all of the existing treatments are either radiation or off-label. If we can prove it to be safe and effective for these types of cancers, we can become a first- or second-line therapy, and then we can expand it to other cancers that also express high levels of ICAM-1."
>
> *Matt Britz, Chief Operating Officer, AffyImmune Therapeutics*

In addition to easier clinical trial recruitment, focusing on new indications can result in CGTs that have less competition in the commercial market.

> "It's important to think about eventual commercialization in the earliest stages. You have to consider access, reimbursement, and payers. For example, if you have a 'me too' product where there are already 10 options, payers may not pick up all 10 and healthcare providers won't put all of them on their formulary. Look for ways to differentiate your therapy. A lot of emerging biotechs don't think in terms of looking ahead to commercialization. You may have the best curative therapy in the world, but if no one pays for it, it doesn't matter. The industry has certainly become creative with reimbursement models for these expensive therapies."
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> *Tamie Joeckel, Global Business Lead, Cell and Gene Therapy Centre of Excellence, ICON*

Sponsors partner with CROs for CGT asset development and trial management expertise.

Sponsors expect CRO partners to understand how to operationalize clinical trials in the most efficient and effective ways possible. This expertise is particularly valuable in the field of cell and gene therapies, since no "textbook" way exists to deliver clinical trials for these products.

> "It's the CRO's responsibility to understand and solve the nuances and challenges. Experience should be curated into best practices and foresight. We are the trusted advisor who is looking around the corners and alerting the sponsor where the potholes are."
>
> *Tamie Joeckel, Global Business Lead, Cell and Gene Therapy Centre of Excellence, ICON*

It's important for sponsors to find a CRO who will be a true, long-term partner, rather than a fee-for-service vendor. As needs change, a company must have a CRO partner with the flexibility to grow with its products, projects, and pipeline. As Matt Britz noted, "No one wants to rebid a CRO contract every time needs change."

> "A true CRO partnership in the context of a novel therapy requires both parties to work together to solve big problems. We worked with our CDMO and created a dedicated team of people who have skin in the game. Both the sponsor and the CRO must be incentivized to work together collaboratively."
>
> *Krishnan Viswanadhan, President, Chief Operating Officer, Be Biopharma*

While challenges remain, the future of CGTs is bright.

The goal of CGTs is to bring cures to people with unmet needs in a patient-centric way. To make this vision a reality, more infrastructure must be built. The good news is that a critical mass of companies is focused on addressing the challenges.

"I'm incredibly optimistic about the future of cell and gene therapy. It will require a significant amount of infrastructure—it's a bit akin to monoclonal antibodies. We need to build a core infrastructure, the ability to share learnings, improve manufacturing, and reduce costs through automation."

Krishnan Viswanadhan, President, Chief Operating Officer, Be Biopharma

"I think gene therapy is ideal for serving global markets due to its nature. It's a one-time treatment. When I started in this field six to seven years ago, most work was done in academic settings. Now, the manufacturing has modernized quite a bit and our ability to serve global markets is much broader than before."

Curran Simpson, Chief Operating Officer, REGENXBIO

ADDITIONAL INFORMATION

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BIOGRAPHIES

Matt Britz

Chief Operating Officer, AffyImmune Therapeutics

Matt Britz is the chief operating officer of AffyImmune Therapeutics, based in Natick, Massachusetts. Britz graduated with degrees in chemical engineering and biology from MIT and began his career in process development and clinical manufacturing at Merck in NJ, and later at Pfizer in St. Louis. Once he obtained a master's degree in biology and an MBA from Washington University, he started working in consulting and business development. He consulted at Equinox Group and Health Advances, and lead business development efforts at Envoy Therapeutics, including an M&A with Takeda for over 17.5 times funds raised. Prior to AffyImmune, Britz was SVP of business development at Minerva Biotechnologies, where they took a cancer specific antibody and tuned into a CAR T against breast cancers. At Minerva, Britz had significant roles in CMC, regulatory, and clinical operations, in addition to business and corporate development. Britz was originally hired at AffyImmune to be SVP of business development, and later took over operations of the entire company and the COO role.

Nimi Chhina

Head of Global R&D and Regulatory Policy, BioMarin Pharmaceutical

Nimi (Mantej) Chhina serves as executive director, head of global R&D and regulatory policy at BioMarin Pharmaceutical Inc. In addition, she currently co-chairs the US Regulatory Advisory Group of the Alliance for Regenerative Medicine (ARM). Previously, she served as vice-chair for ARM's US Regulatory Affairs Committee, and as co-chair for BIO's Regenerative Medicines Committee and

BIO's Orphan Drug and Rare Disease Committee. She co-chaired the Food and Drug Law Institute's (FDLI) 2023 Annual conference and served on the 2023 BIO global annual convention planning committee. She served on the planning committee for FDLI's 2020 regenerative medicines conference. She is well-published and has taught the community and presented on topics relevant for cell and gene therapy. For example, in 2021, she presented in APEC education series for LATAM health authorities on unique clinical and nonclinical considerations for cell and gene therapy development. Also, she spoke as a panelist on sessions on cell and gene therapy regulation at FDLI annual conferences in 2022 and 2023.

Chhina joined BioMarin in 2017 as director, leading US regulatory policy. Prior to joining BioMarin, Chhina spent seven years at the US Food and Drug Administration (FDA), where she served in multiple roles including as team lead in the Division of Medical Policy Development in the Center for Drug Evaluation and Research (CDER).

Chhina received her MS (honors school) in human genetics from Guru Nanak Dev University in India; PhD in biotechnology and functional genomics from George Mason University, VA (USA); and JD from University of the District of Columbia David A. Clarke School of Law (USA). Also, she has received the Regulatory Affairs Certification (RAC) as well as a certificate in legislative affairs from the Government Affairs Institute at the Georgetown University, DC (USA).

Chhina is based in the Washington, DC area, and is actively engaged on the R&D and regulatory policy development landscape. In her personal life, she loves traveling and spending quality time with her family.

Tamie Joeckel

Global Business Lead, Cell and Gene Therapy Group, ICON

Based in Houston, Texas, Tamie Joeckel joined ICON in 2018 with over seven years of experience in strategy and consulting for cell and gene therapy global logistics and IP management. Certified in production and inventory management, she has worked in pharma distribution for over 25 years in drug launch commercialization, commercial distribution, and clinical trial support.

As a principal in ICON's Centre for Cell and Gene Therapy, Joeckel supports ICON's CGT global portfolio with consulting expertise and distribution storage strategies to manage these cold chain, frozen chain, and cryofrozen chain therapies and source materials. She brings deep expertise in the vendor ecosystem for CGT therapies that began with some of the earliest CAR-T programs while she was the SVP of Client Services & Consulting at Cryoport.

With over 10 years' experience in specialty biologics distribution and commercialization, as Vice President of Corporate Development at AmerisourceBergen, she managed teams that launched specialty biologics requiring REMS support and patient hub services in therapies for rare disease and oncology. During this time, Joeckel also worked with patient advocacy groups & manufacturers advocating for policy & reimbursement reforms on Capitol Hill focused on hemophilia & SCID diseases.

Prior to joining the pharma industry, Joeckel was a consultant with Arthur Andersen & Co. (now Accenture) specializing in ERP, manufacturing and inventory management systems. She holds a master's degree in petroleum accounting.

Kilian Kelly
CEO, Managing Director, Cynata Therapeutics

Dr. Kilian Kelly is chief executive officer and managing director of the stem cell and regenerative medicine company, Cynata Therapeutics Limited, which is based in Melbourne, Australia. Kelly joined Cynata in 2014, initially as vice president, product development, and subsequently chief operating officer, before taking the role of CEO & MD in July 2023. Prior to Cynata, he held positions at a range of small and large companies, including Biota Pharmaceuticals, Mesoblast Limited, Kendle International, Amgen, and AstraZeneca. He holds a master's in pharmacy from Robert Gordon University, Aberdeen, and a PhD in pharmaceutical sciences from Strathclyde University, Glasgow. He is a registered pharmacist and a member of the Royal Pharmaceutical Society, the Australian Institute of Company Directors, and the International Society for Cell and Gene Therapy. He also currently serves on the Industry Interface Committee of the Centre for Commercialisation of Regenerative Medicine (CCRM) Australia.

Greg Kunst
CEO, Aurion Biotech

Greg Kunst, CEO of Aurion Biotech, has deep and varied experience in ophthalmic medical devices, drug delivery systems, diagnostics, biotechnology, and pharmaceutical products. His expertise spans global corporate development, strategy, health policy, marketing, commercialization, business development, market access, and medical affairs.

Before Aurion Biotech, Kunst spent six years at Glaukos Corporation (NYSE: GKOS) in numerous roles of increasing responsibility, most recently as vice president of global marketing, where he led the global marketing, market access, reimbursement, health economics and outcomes research, government affairs, and business development teams.

Before Glaukos, Kunst worked at Alcon, a Novartis company, as global franchise director over the Alcon glaucoma surgery and retina pharmaceutical businesses. Before joining Alcon, he worked at Kinetic Concepts, Inc. (Acelity Inc.) as the global head of market access. Kunst is a board member of Pr3vent.

Kunst received an MBA from Vanderbilt University and a BS in Economics from Brigham Young University.

Curran Simpson
Chief Operating Officer, REGENXBIO

Curran M. Simpson is the chief operating officer at REGENXBIO. Prior to joining REGENXBIO, Simpson was the head of North American supply chain and interim chief operating officer and integration lead at GlaxoSmithKline and the Human Genome Sciences division of GlaxoSmithKline. Simpson earlier served as senior vice president of operations and vice president of manufacturing operations at Human Genome Sciences.

Prior to Human Genome Sciences, Simpson was director of manufacturing sciences at Biogen and director of engineering at Covance Biotechnology Services. Earlier in his career, he served as recovery technology coordinator, worldwide and pilot plant manager of the North America Division at Novo-Nordisk Biochem; senior research engineer at Genetech; and senior chemist at Nalco Chemical Co.

Simpson has an MS in surface and colloid science from Clarkson University and a BS in chemical engineering and chemistry from the Clarkson College of Technology.

Krishnan Viswanadhan

President, Chief Operating Officer, Be Biopharma

Krishnan Viswanadhan, Pharm.D., president and chief operating officer of Be Biopharma, is a biopharmaceutical executive with over 20 years of broad cross-functional experience in advancing new medicines for patients with serious and life-threatening diseases. Viswanadhan joined Be Bio as president and COO in 2021 and is responsible in driving all operational aspects of the business to unleash the power of engineered B cell medicines as therapeutics for patients with serious diseases.

Prior to Be Bio, Viswanadhan was senior vice president, global cell therapy franchise lead at Bristol Myers Squibb (BMS) where he was responsible for overseeing the integrated cell therapy franchise strategy across the enterprise including building core capabilities including key investments to support long term growth. He oversaw the teams responsible for the development, approval and life cycle management of Breyanzi, a CD19 CAR-T, and Abecma, the first BCMA CAR T therapy.

Prior to BMS, Viswanadhan was vice president, business development and global alliances, at Celgene Corporation, where he was responsible for managing the portfolio of partnerships and equity investments. Prior to Celgene, Viswanadhan had roles in large and small companies in regulatory strategy.

Viswanadhan is a registered pharmacist and received his Pharm.D. from Rutgers University and holds an MBA degree from Cornell University. Viswanadhan currently serves the board as a non-executive director of JW Therapeutics, a leading cell therapy company in China, and as an independent director at Cargo Therapeutics.

Janelle Hart

Managing Editor, Citeline (Moderator)

Janelle Hart is managing editor of Custom Content. She previously worked in both publications and marketing/advertising in the medical communications field, with a focus on pharmaceuticals. Originally from New Jersey, she attended Miami University for her undergraduate degree and is now pursuing a master's in publishing and writing at Emerson College in Boston, Massachusetts, where she currently resides.