Orla Cloak – CEO, Minaris

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Orla Cloak, CEO of Minaris, explains how the organisation. was formed by integrating Minaris Regenerative Medicine, a dedicated cell and gene therapy (CGT) CDMO, and WuXi Advanced Therapies, which brought both CGT manufacturing and established GMP biosafety testing capabilities. Today, Minaris operates under private equity as two complementary businesses: Minaris Advanced Therapies, a global CDMO focused exclusively on CGT, and Minaris Advanced Testing, a trusted provider of GMP biosafety and analytical testing services for biologics and advanced therapies. Minaris Advanced Therapies combines 25 years of CGT expertise across the US, Europe, and Japan with a focus on deep technical capability, end-to-end sponsor partnership, and scalable, patient-centric processes to address the operational, regulatory, and commercialisation challenges of complex therapies globally.

As a recently formed organisation, could you start with providing some background on Minaris' formation and what it means to be a cell and gene therapy-focused (CGT) CDMO player?

Minaris represents the combination of two established businesses brought together under private equity ownership. At the beginning of 2025, Altaris Capital acquired Minaris Regenerative Medicine from Resonac. Minaris Regenerative Medicine traces its origins back to PCT, one of the earliest CDMOs in cell therapy, established when the field itself was still emerging. That legacy provided a strong foundation in advanced therapies across the US, Germany, and Japan.

In April, we completed the acquisition of the Advanced Therapies business from WuXi AppTec in Philadelphia. That transaction expanded our US footprint and added not only CDMO capabilities but also advanced biosafety testing through this acquisition. It also brought differentiated innovation assets, with the Oxgene site in the UK and its proprietary plasmid and vector production technologies.

Following the January and April acquisitions, we integrated both organisations into a single Minaris structure with two distinct but integrated businesses units: Minaris Advanced Therapies as a CGT CDMO, and Minaris Advanced Testing, as a GMP biosafety testing provider for biologics. As one would expect, combining two companies with distinct histories and cultures required significant effort. Establishing a unified team, operating model, and “one Minaris” philosophy was a central priority. The scale of what we’ve accomplished and the transformation we’ve driven is remarkable, bringing us closer to a one company mindset.

For me, evaluating the assets and capabilities of the company is one thing. But the most important component of any company, the fabric that makes you succeed or fail, is the culture and people. We have a strong breadth and depth of expertise within the organisation from both the WuXi and Minaris Regenerative Medicine sides, but we have also added additional talent. The question then became how do we build a company with a genuine patient-first mentality.

How does Minaris Advanced Therapies specific focus on CGT translate into value for sponsors and partners? Why take a deeply specialised approach rather than a broader CDMO model?

We want to be a partner, not just a CDMO. That is a key differentiator. With over 25 years of experience producing cell therapies, we have deep-seated expertise in the field.

Looking at the market, when CGT started originally, everybody was interested and investing. What you have really seen is consolidation in the industry. Some people are exiting the market whilst others are doubling down and further investing in the modality.

Where Minaris is uniquely positioned is in capability. It is no longer about capacity but rather breadth and depth of knowledge. Minaris is uniquely positioned not only to partner with sponsors but also to bring that deep level of technical expertise, understanding that CGT is a very complex process unlike traditional pharmaceuticals.

How does that complexity impact the needs and expectations of customers? What are the unique differences in customer needs for CGTs versus biologics?

CGTs involve highly complex, live, patient-specific products with unique analytical and technical supply chains and regulatory requirements that must be addressed at each point along the journey.

The science behind CGT is remarkable. It is highly innovative and is redefining medicine, but there is still a learning curve. The challenge now is understanding how to execute, operationalise, and commercialize these therapies effectively.

The starting material is highly variable, and in most cases, the initial manufacturing has been performed at small scale without a lot of thought for scale up or scale out. As a result, risk, variability, and cost must be carefully managed within the production process. Release presents further challenges because only limited material is available for testing, making potency and assay development critical. A risk-based, phase-appropriate analytical approach is therefore essential for CGTs.

Process optimisation then becomes a key focus. Many processes are developed by innovators and are not designed with manufacturing in mind. As is often said, R&D is not GMP. The objective is to build a robust process that reduces manual steps, enables first-time-right execution, and allows scaling either up or out depending on the therapy. Embedding that robustness into the system is fundamental.

The regulatory component is another major consideration and is not always addressed early in development. CDMOs frequently support innovators in defining an appropriate regulatory strategy alongside process and analytical development.

Minaris offers a comprehensive end-to-end service. How does that reflect in your client base? Do you primarily work with early-stage biotechs, late-stage pharma, or a mix?

It is very much a mix. We support multiple commercial products across different sites while also working closely with early innovators. Earlier engagement is particularly valuable as it allows manufacturing and regulatory strategies to be shaped from the outset rather than retrofitted later.

Our client base spans the full spectrum across early-stage innovators, sponsors entering pivotal studies, and partners preparing for technology transfer into commercial manufacturing. Whether

they are using first-generation processes or seeking further optimisation, balancing these different needs is a core part of the model.

In the current biopharma funding environment, sponsors face significant pressure to prioritise their pipelines and demonstrate tangible progress. The conversation has shifted. It is no longer solely about the clinical promise of CGT, but about execution and bringing a product to market in a way that is feasible, operationally robust, and commercially viable.

The CGT market has consolidated and evolved. Are companies losing confidence, or is the industry finding a new equilibrium?

It is difficult to describe it as a new equilibrium. Similar patterns can be seen across the broader pharmaceutical market, which tends to be cyclical. Large pharmaceutical companies invest in multiple candidates but ultimately concentrate resources on the programmes that advance most successfully through development and have market viability.

We continue to see many companies doubling down in the space. Over the past few months, we have seen certain organisations increasing their investment in CGT and acquiring technology platforms. For many companies, it is ultimately a matter of pipeline prioritisation and focus.

The industry itself has evolved considerably. Initially, cell and gene activity was concentrated primarily in oncology indications. However, the field is increasingly expanding beyond oncology into areas such as rare diseases and autoimmune indications. This shift is driving broader awareness of how CGTs, which have already demonstrated strong outcomes, may achieve wider applicability across larger patient populations.

Given the high costs and scalability challenges in CGT, what role can focused CDMOs like Minaris play in overcoming these barriers?

The central challenge in CGT is scalability, whether scaling up or scaling out, combined with the cost of goods, which remains particularly high. Across the CDMO landscape today, there is less emphasis on diversity of offering and greater emphasis on depth of expertise. This is reflected in consolidation trends and the increasing focus on specific modalities, driven by plant utilisation, execution capability, and meaningful differentiation in the market. At Minaris, we bring a long legacy and a proven track record of developing and successfully manufacturing CGTs over more

than 20 years with the operational knowledge required for execution.

Another critical component is genuine partnership with sponsors and guiding them through the development process. One approach we value in partnership with the sponsors is process optimisation workshops. Whether a sponsor is refining individual process elements or moving toward a fully closed, automated system, we have the internal expertise to support that optimization and progression at any stage of development.

A platform perspective is important, but without platform rigidity. Different technologies may be appropriate at different stages of development. Sponsors may opt for semi-automation rather than full automation, or open systems rather than closed systems, depending on their process requirements. Through close collaboration, we help sponsors determine what to optimise in order to achieve a robust commercial process that consistently delivers first-time-right results.

At the beginning of the year, the FDA issued new guidance on increasing the flexibility of CMC requirements for CGTs. How do you view this, and what implications does it have for commercialisation?

I would not describe it as entirely new, but it is more directive. It establishes a more general framework for flexibility around CMC requirements. In essence, the FDA is codifying how it intends to review CGTs, rather than relying solely on case-by-case assessments. It now clearly articulates a more principled approach and clarifies what can be accommodated within that flexibility.

This is important because it allows sponsors to advance clinical development, evolve manufacturing processes, and implement changes without jeopardising their commercial pathway. In rare diseases in particular, it has meaningful implications for the volume and type of patient data required to support commercialisation.

Overall, it is a positive step. This is a highly regulated industry and sponsors value clarity. They want a roadmap, and this guidance provides a clearer sense of direction by outlining the FDA’s general approach and how companies should align with it. It formalises the agency’s position on reviewing CGT products.

Do you see any other gaps in regulation or points of alignment that still need to be addressed?

There are a few areas, but the most significant challenge I see is global misalignment. Organisations such as the International Council for Harmonization (ICH) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) have done substantial work to align health authorities around standardisation and core expectations.

However, meaningful regional divergence remains. That creates real complexity when you are trying to globalise these therapies as it increases cost and reduces efficiency. In some instances, sponsors are required to conduct parallel studies or generate different datasets to secure approval across multiple regions. That is an area where greater alignment would materially benefit both industry and, ultimately, patients.

From a global perspective, do you see any particular regions being frontrunners in CGT? Or a significance between local and global manufacturing?

It depends on the therapy. Minaris has a truly global footprint, but our largest presence is in the US as it represents the biggest market. Strategically, our headquarters in Philadelphia sits at the heart of the US CGT ecosystem. Pennsylvania, in particular, has been at the forefront of advancing the field. Local US manufacturing is also critical given current geopolitical considerations.

The European market is still developing and will require time to mature. Having a centralised location there is important, and our Munich site is well-positioned. It offers substantial GMP manufacturing and aseptic processing expertise supported by a strong local talent pool, which is increasingly necessary in this industry.

In Japan, our facility focuses on Japan-for-Japan manufacturing. It supports local production while also acting as a strategic hub for the broader Asian market.

Ultimately, decisions around local versus global manufacturing depend on the therapy. For autologous CAR-T therapies, patient accessibility and vein-to-vein time is critical. In those cases, local manufacturing can make a meaningful difference.

China is seeing significant cell therapy investment and innovation. How do you view opportunities and challenges there for global partnerships?

China is a particularly interesting market. There is substantial investment, and significant innovation is emerging, especially in early-stage clinical data. At the same time, many Chinese

innovators are seeking partnerships with CDMOs outside of China to access global markets, navigate regulatory pathways more efficiently, and mitigate risk.

While innovation in China is strong, companies often still require partners abroad to manufacture and distribute therapies globally, depending on the product. Similarly, Western sponsors are closely observing the pace of innovation in China and the speed at which new therapies are being developed.

There also remains a degree of caution around manufacturing in China due to perceived risk. Although tariffs do not apply directly to CGT products, broader sentiment across industries still influences decision-making. We are not seeing a wholesale shift toward China. Instead, there continues to be strategic investment in the US, while early-stage innovation and clinical data from China are becoming increasingly prominent and widely discussed across the industry.

This is your first global CEO role for a very new organisation. What leadership lessons do you bring, and what kind of culture are you creating?

Culture and people are our most important assets. The right culture enables strong outcomes, whether navigating challenges or celebrating successes.

At Minaris, our culture is grounded in our PATIENT-centred values: Proactive, Accountable, Teamwork, Intentional, Empowered, Nimble, and Trust and Transparency. These principles guide how we operate as one team and we innovate to enable progress. Accountability is particularly important, ensuring individuals feel empowered, while regular feedback loops help identify what is working, what is not, and how the company can improve.

Ultimately, patients are our north star. Decisions are filtered through the lens of increasing access to innovative therapies that extend and improve lives, and that sense of purpose drives our Minaris team.

We reinforce this by bringing customers, partners, and patients into the organization to connect the work to the patient. Working on a customer’s process means recognising that these are a patient’s cells and, ultimately, a patient’s life. Creating that awareness fosters meaning and purpose across the company which is reflected in our mission and vision: enabling innovators, manufacturing therapies, and delivering hope.

As an emerging field, how do you build and develop the specialised talent needed in the CGT space?

The CGT industry has evolved rapidly, but talent development and skills training have not kept pace. There is still no formalised global training pathway, and much of the expertise is learned on the job.

There has been extensive discussion across the industry about how to support the next generation of specialists, not only innovators but also manufacturing experts. Workforce development is critical to advancing the field and ensuring its long-term success. Each process is unique, and understanding its components, building robust processes, and solving problems when they arise rely heavily on experience.

Being headquartered in Philadelphia has a distinct advantage. The city has long been a hub of innovation, and the training and expertise available here are exceptional, as is the strength of talent at the other strategic locations across our network. At Minaris, we have deep expertise across multiple cell types and viral vector production, including CAR-T, TCR-T, TIL, AAV, ,LVV and adenovirus platforms. The priority now is helping the next generation develop capability and execution, not simply capacity. Building that talent pipeline is essential to advancing the field.

Looking at 2026 and beyond, what are your key priorities, and what direction are you setting for Minaris?

As I said before, patients are our north star. Everything we do ultimately feeds into that approach.

Our first priority is achieving first-time-right results. When working with customers, we collaborate to optimise processes, reducing variability, mitigating risk, lowering cost of goods, and increasing confidence in successful commercialisation. This requires early engagement so innovators can consider commercial requirements from the outset. Historically, the CGT industry focused heavily on innovation, with less attention on building robust GMP processes or scalable manufacturing. Today, execution is equally critical, and our role as a CDMO partner is to enable that.

The second priority is innovation that enables execution. Platforms are important, but one size does not fit all. Flexibility matters more than platform rigidity, and the focus is on supporting each customer’s specific process to achieve full commercialisation. Close collaboration on process development, analytical strategies, and regulatory pathways is essential. Many early-stage innovators have limited resources or visibility into what is required to move from discovery to

delivery, and our expertise helps them avoid pitfalls and execute successfully at the point that matters most: the patient level.

Ultimately, our goal is to deliver on the promise of CGT, moving from bench to bedside, from IND to BLA, and from local to global. Early engagement with a capable CDMO partner is critical to navigating that journey. Success ultimately depends on collaboration, people, and enabling innovators to translate science into accessible therapies.

What motivates you personally, and what is your overarching message about the future of CGT?

What motivates me most is the science and impact that science has on the patient. I am a scientist by training, so I find the cell and gene field extraordinary and genuinely innovative. The key questions now are how to increase patient access, how to commercialise these therapies to enable both local and global availability, and how to continue advancing the field.

I compare the CGT field today to where monoclonal antibodies were in the 1990s. There were significant challenges at that stage in terms of cost and scalability, but they were ultimately overcome. With the right approach, I believe this field can follow a similar path.

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