# the **Medicine Maker** SPECIAL SERIES: Advanced Medicine









### IN MY VIEW

# Between Two Worlds: Doing Business as a Cell and Gene Academic

The pharmaceutical industry depends on academia, but that relationship – and its points of interchange - could be improved

By Stuart Curbishley, Head of Business and Project Development – Advanced Therapies at the University of Birmingham, in the UK

Medicine making for cell and gene therapy is a tripod; its three legs are academia, business, and the state. Pull out one leg and it falls. Without university laboratories, we would not have a single therapy for the market. And without state support through institutions such as the UK'S Cell and Gene Therapy Catapult, cell and gene companies would not perform at their best. For the foreseeable future, we can expect these things to remain true.

However, if funding worked differently, I think the academic leg could stand on its own for longer. The problem is that academics simply cannot set out to raise, say, £150 million to fund the commercialization of a therapy. This is where the private sector steps in, turning the pure science of academia into viable IP.

Conversely, I doubt that the private sector leg could ever stand entirely on its own. Although certain big pharma companies have set up cell therapy development teams, I expect that these companies are far more likely to release new iterations of existing products than truly novel therapeutics. This is where business needs academia.

I believe that we would be able to advance the field far more quickly if we could establish a way to distribute industry's financial resources to academic programs earlier. If we could lead big pharma to fund the bakery, rather than buy the bread, we would shave years off the development process.

Though I would not claim to have all the answers to what is certainly a very difficult and inflexible problem, I would insist that new and better bridges be built between pharma and academia. You don't need to take it on faith. I'm living proof.



# This is my journey...

In 1999, I launched my academic career with a Master's research degree at the University of Birmingham, UK. I stayed on to undertake a PhD on how chemokines drive inflammation and inflammatory liver disease. After completing that, I stayed on again, this time in a postdoctoral position researching monocyte myeloid cell biology with a view to developing dendritic cells as a primary liver cancer therapy.





"If we can create a network of academic centers with the right industry partnerships, the initial cost of setting up this cooperative enterprise will pay for itself down the line."

It was at this job that I first worked on a cell therapy program. It eventually led to my involvement with a cell therapy trial, treating end-stage liver cancer with a dendritic cell vaccine. That trial reached its target and closed during the COVID-19 pandemic, ultimately yielding positive results.

Across the last half-decade, I have taken over running GMP activity for the University of Birmingham as a whole. We've grown from a small, self-enclosed facility to one with a variety of academic and commercial partners. Today, we manufacture a wide range of cell types and run a wide range of GMP services for the university.

Adding commercial viability to academic centers could transform the offer to early-stage startups. This is where academic CDMOs tend to falter; they are simply not designed with commercial questions such as speed and contracting in mind. Juxtaposition with appropriate commercial partners could smoothly speed the transition of academic programs to the world of privately financed cell therapy trials.

In my university role, I am expected to make my current facility break even, but I am not being pushed to make returns to shareholders.

As a sector, academic CDMOs need to show a way out for people stuck in the rut of trying to build a therapy entirely on grant funding. After all, the moves that win you a grant are usually not the moves that will help you set up a robust, sustainable business. We need to spare these people from an imperative to regularly reinvent the wheel just to keep moving forward.

# ... and this is my bridge

In the case of my own company's transition to the market, I don't expect a massive change in our basic function – a CDMO with a strong focus on development. We will continue to work with commercial partners and focus on how they can complement our academic program. There are partial precedents for this here in the UK, where we have seen people take academic programs into our government-funded Cell and Gene Therapy Catapult and go on to raise impressive capital investments. However, in many instances, there is a lack of preparation and understanding of what is needed to commercialize. Often, the company's processes require expensive development that comes far too late, after the company has already moved into rented manufacturing space.

Sensible commercial partnerships should help ease such transitions. We need to leverage the proximity of academic CDMOs to patient treatment centers and their populations of key opinion leaders at centers of clinical excellence. Our goal should be to work closely with early-stage therapy developers to get the product and the process right first time.

Skeptics may ask: doesn't coupling with commercial partners introduce new problems, swapping the games of academia for the games of business? These are valid concerns, but all I can say in response is that, if we are careful in our establishment of key partnerships, we can still make a difference for patients. In business, of course, we have to deliver a return on investment – but the right market exists and is receptive, as we can see from the sector's ongoing acceleration. In my university role, I am expected to make my current

facility break even, but I am not being pushed to make returns to shareholders. Developing a commercial strategy would mark a change in my work, but I don't see it as a major challenge.

# Centers with no center

One of the factors we need to consider is scale. Academic CDMOs must take advantage of economies of scale to become profitable because there are huge costs involved in running a GMP facility. If we can create a network of academic centers with the right industry partnerships, the initial cost of setting up this cooperative enterprise will pay for itself down the line. For example, you can achieve a certain degree of leadership and quality oversight remotely - so these elements can be dispersed across your network, rather than replicated at every node. Therefore, the larger your network is, the more you can dilute these aspects of your running costs.

A dispersed network is also well suited to delivering autologous therapies to patients because it helps avoid the current situation. Right now, we ship materials thousands of miles to factories in the middle of nowhere only to then ship them back again. This is a bad economic practice, bad environmental practice, and adds an unnecessary high risk to your process.

# To sum up...

Companies like mine must play a significant role in providing GMP manufacturing for cell and gene therapy clinical development post-grant-funding. We want to provide a bridge in manufacturing provision for smaller institutions who wish to develop cell and gene therapies, but do not have either the resources or the need to engage a large CDMO. This will enable more cell and gene therapies from a wider group of specialist organizations to progress to the clinic and potentially reach an even wider group of patients than may currently benefit from therapies in development.









### IN MY VIEW

# Standardize for Success

High growth predictions for regenerative medicine are exciting, but what if current capacity can't keep pace?

By Mark Sawicki, President and CEO of Cryoport Systems and Chief Scientific Officer of Cryoport, cell therapies

The emergence of regenerative medicine as a viable therapy class has amplified the focus on current clinical product distribution standards and emphasized the need for enhanced requirements that parallel current manufacturing standards in the industry. The regenerative medicines market generated \$13.22 billion in revenue in 2019 but it is expected to reach a staggering \$172.17 billion by 2030 (1). According to the US Department of Health and Human Services Report, 2020: A New Vision – A Future for Regenerative Medicine, "Regenerative medicine will be the standard of care for replacing tissue/organ systems in the human body." For instance, a definitive cure for heart-valve disease in the US alone could provide annual cost savings of \$23.4 billion.

One key challenge in the regenerative medicine space is the effective collection and utilization of apheresis or leukapheresis starting materials. The stability of fresh leukapheresis starting material is usually limited to a 24- to 48-hour window because of the decrease in cell viability in nonfrozen conditions (2), so any unforeseen shipment delays can reduce manufacturing success rates. Managing manufacturing slots can also be expensive, and if the manufacturing window is missed, it can cause backlogs for future planned patients. In an effort to overcome these challenges, many companies have decided to cryopreserve the fresh leukapheresis starting material (3). Cryopreservation provides scheduling flexibility while de-risking the logistical process.

In the US, leukapheresis collection activities are governed by CFR Title 21, Part 1271. Current regulations provide significant flexibility in collection-based activities, including accreditation and characterization, typically leaving qualification to the manufacturer. Although 21 CFR Part 1271 outlines cGTP requirements associated with the manufacture of CAR-T therapies, the CFR doesn't address standardization of leukapheresis collection and processing activities. It also does not define whether leukapheresis material should be defined as a cGMP starting material with the associated cGMP regulations. And the demarcation of where cGMP requirements need to begin to be implemented in the process is unclear. On the other side of the pond, within the EU, the EMA has explicitly defined the collection and preservation of starting material as activities that occur before manufacturing. Regulation no. 1394/2007 on ATMPs, established by the EC, provides the framework for ATMPs.

Additional regulation around collection and processing activities associated with cell and gene therapy collection are anticipated as more clinical and market data on commercial therapies becomes available. In my view, regardless of regulatory status for the collection and processing of ATMP starting materials, it is critical that the industry initiates efforts to standardize the activities associated with processes.

Any standardized solution must address product consistency (regardless of geographic location), and also accommodate and provide efficiencies and scalability to the industry as a whole. I believe major areas to focus on include (but are not limited to): expanded patient and donor access into the community care setting; streamlined audit and quality system management of collection and processing activities; consistent standards and SOPs against cGTP requirements for processing across all sites; integrated data management competencies across all sites; integrated logistics management minimizing costly fresh leukapheresis material movement; truncated processing timelines to ensure product quality; scalable processes supporting significant patient volumes.

The ability to effectively optimize these key inadequacies will be a basic prerequisite for the industry to support projected volumes in the near future, while standardizing processes and optimizing cost of goods. Based on internal Cryoport data, we conservatively anticipate clinical and commercial patients' treatment cycle demand to exceed a minimum of 90,000 patients a quarter by the end of 2027. This dwarfs the current demand cycle of approximately 9,000 patients per quarter (as of Q1 2022). Moreover, based on discussion with physicians in the cell and gene therapy space, these numbers are further suppressed by the lack of accessibility to the collection and processing of blood products in community care centers – a significant latent opportunity for the market. Estimates suggest that the unaddressed opportunity in community care centers is around 80 percent of the overall patient opportunity. Consider that leukapheresis capacity is growing at a CAGR of around eight percent; this is expected to support only 13,000 patients a quarter by 2027(4).

The current high cost of therapeutic leukapheresis and cellular therapies, stringent donor recruitment criteria, and long procedural time for leukapheresis are all restraining growth. Manual coordination of operations that span across patient scheduling, apheresis procedure, cell processing and treatment and multiple touchpoints across clinical, hospitals, apheresis centers, manufacturers and delivery companies is a logistical nightmare (5).

Cellular therapies offer potential new therapeutic approaches to address a variety of unmet needs for individuals affected by serious and life-threatening conditions. Standardized collection, processing, storage, and distribution is crucial to both the availability of these therapies and continued innovation in the industry. The implementation of the considerations mentioned above – alongside new standardized regulations and requirements – will help secure and even expedite the regenerative medicine industry's growth in the safest way possible.











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### FEATURE

# Power List Perspectives: Challenges Facing Cell and Gene Therapy

Leading pharma industry experts discuss the most pertinent challenges facing cell and gene therapy

By Jamie Irvine, Associate Editor, The Medicine Maker

Cell and gene therapies are an increasingly proven therapeutic frontier – and look set to playing a pivotal role in the future of personalized and precision medicine. To date, more than 25 cell and gene therapies are licensed for use in the US alone, but – as with any evolving innovative approach – researchers and developers face multidimensional hurdles on the road to approval.

<u>The Medicine Maker Power List 2023</u> showcases inspirational individuals across the pharma industry – including those from the cell and gene arena. We asked our Power Listers about the most significant challenges standing in the way of progress in the advanced medicine space over the past two decades.



Medicine MakerPOWERLIST



# David Backer CEO, Curate Biosciences

"The use of the technology – and, more importantly, the manufacturing limitations on scale and cost – have relegated cell and gene therapies primarily to diseases that are rare, ultra-rare, or use the body's own immune cells to fight cancer. These are incredible – but fairly localized – successes, and we are still a long way from having cell and gene therapies that are a standard part of therapeutic regimens."

# Alan Boyd CEO, Boyds

"The biggest challenge affecting the field of gene therapy is the manufacturing of the product... When I begin working with a client on advanced therapy, I tell them from the start that they will have issues with their potency assay and other aspects of the product, such as purity. The client must prepare for this eventuality – and bring in the right skills to help."

# Tirtha Chakraborty

Chief Scientific Officer, Vor Biopharma

"The issue is ugly science – frequently practiced by our industry. This industry has become so much about the bottom line that we do not appreciate the culture of doing it right. The reward is for getting to the finish line, so most of the bottom line focus is understandable when it comes from the investor community. But the R&D leadership and the management of biotech companies must hold their own, and message their concerns and visions appropriately to the broader community."

# Queenie Jang CEO, International Society for Cell and Gene Therapy

"Workforce development continues to be one of the most significant challenges facing the cell and gene therapy sector. The field has seen exponential growth, which has outpaced the rate at which new professionals enter. On a positive note, we're seeing many newcomers enter the field, but we still have a long way to go to bridge the gap at mid-to-senior levels."







# Catherine Jomary ATMP Lead, IPS-Integrated Project-Services

"The biggest challenges for these new genome editing therapeutics are the specificity of delivery, control of their activity, detection of potential off-target mutations, and their inherent immunogenicity. The goal of an efficient gene editing therapy is to show perfect specificity for the target sequence without mutations introduced to any other region of the genome. Unfortunately, the existing genome editors' systems rarely achieve such a high standard."

# Sheila Mikhail Co-founder, Asklepios BioPharmaceutical (AskBio)

"Like most of the biotech industry, cell and gene therapy companies are facing an investor funding shortage and difficult stock market conditions. Gene therapy continues to work on issues pertaining to the management of the immune system, such as redosing and durability issues. The field continues to make advances to enable more streamlined and cost-efficient manufacturing solutions."

# Dirk Nagorsen Chief Medical Officer, Affini-T Therapeutics

"There are those general challenges with cell therapy approaches for conditions beyond blood cancers, notably finding ways to develop strategies that improve T-cell persistence and durability. Fortunately, we are seeing approaches that aim to address these challenges by leveraging advancements made in computational biology, cellular engineering, gene editing, synthetic biology, and more to enhance T-cell fitness and promote a durable response."

# Angela Osborne CEO, eXmoor Pharma

"It is now well recognized that the biggest challenges of the field are in CMC and in manufacturing in particular. You have to be able to make the products at scale and at a reasonable cost for the cell and gene therapy industry to become as large as the biologics industry is today."

# Victor Vinci VP, Global Product Development, Cell, Gene and Protein therapies, Catalent

"Science is moving so fast with respect to technology innovation and new applications that it creates challenges in establishing the tools to develop, manufacture, and scale up these therapies for clinical trials and potential commercial launch."









### DEPARTMENT

# Titan on the Horizon

Mammoth-resurrection company Colossal has spawned a digital pharma entity that wants to take cell and gene therapy to its next stage of evolution

A new lifeform has sprung forth from Colossal – a company using genetic science to try and resurrect the mammoth, the Tasmanian tiger, and any number of other species that mankind has driven to extinction. But this new creature is corporate, not biological. It is called Form Bio, and we spoke to its Chief Strategy Officer, Claire Aldridge, about the work it is doing in the digital side of cell and gene therapy and beyond.

# What drives you – and where has that drive taken you?

I've always loved science, but while working on my PhD in immunology and genetics, I realized that I did not want to be a bench scientist. I didn't really like being in the lab and I found it lonely. Following graduation I was fortunate enough to get involved at University of Texas Southwestern Medical Center, where I found the place I wanted to apply my scientific knowledge: the translation step.

Thus, translation is where I have stayed for the last 25 years! I've been a biotech VC too, and that was very interesting; it forces you to consider how to identify good science that has an opportunity to change something in the marketplace. I've done translation work in a number of startups, too, which is especially fun because you not only shape where you're going with the science, but shape the indications, the team, and the culture.



# Before we get to Form Bio, can you explain the basics of Colossal?

Colossal is a startup spun out of George Church's lab at Harvard University; Ben Lamm is the founding CEO. One great way to move science forward is to pair a scientist with somebody who knows how to build businesses. When Ben launched Colossal he did it with a mission in mind: to restore lost biodiversity and resurrect the wooly mammoth. These animals didn't die out because the ice age ended - plenty of their cold habitats still existed. They died out because our species hunted them to extinction. Colossal have targeted the mammoth in part because their image is so compelling – it engages the popular imagination and makes for a compelling first chapter in the company's history.

Stepping away from the mere image, Colossal's scientific project is to bring back "keystone species" that underpinned a range of natural environments and ecosystems. The wooly mammoth was key to the tundra, for example. Tasmanian Tigers are another illustrative example. European settlers in Australia drove them to extinction by 1936 – a tragedy from a biological standpoint because the species was a marsupial predator, which is a very rare kind of animal indeed. Colossal intends to use tools, such as genome analysis and CRISPR, to bring such species back.

# Form Bio isn't trying to bring back the mammoth; what's the mission?

The leaders of Colossal knew early on that they couldn't conjure the wooly mammoth from thin air. They needed – among other things – the right software. The right platform would make the entire project run faster, allow for smoother collaborations between the company and the academic labs it partnered with (in Harvard, the University of Melbourne, and the University of Connecticut), and bring in the latest and greatest bioinformatics algorithms.

In biology and molecular biology, we have some amazing tools, but we haven't yet brought in the sophistication of advanced software.

Targeted advertising software, for example, could provide a massive boost for individualized precision medicine. Colossal could find no software company in the marketplace able to meet their needs, so the company built its own software platform. While they were building it, they realized that the platform would have applications across the entire field of molecular biology - not just de-extinction. Any lab and any company doing anything with vast quantities of data and next generation tools like CRISPR needs validated ways to analyze its data. Across the field, we all generate more data than we can handle. Therefore, until we have the right tools we won't be able to bask in the full benefits that all of that data can offer.

At Form, we have pulled that software platform out and are working on further developing and selling it – while still supporting our parent company. Colossal is our biggest customer now, but they won't be forever.

# Cell and gene therapy is going places, but facing serious challenges too. How can digital tools offer material change?

In cell and gene therapy, the product comes straight from the academic lab. Once it has gone through animal testing, it gets licensed to the company who will move it forward. Consideration from the manufacturing perspective comes into the process rather late. Contrast this with small molecule medicine, in which you begin with a small molecule that you fully understand and need to figure out how to make lots of it. For the sake of producing more drugs, cheaper drugs, and safer drugs, we need to bring the same capability into the cell and gene field. There are ways that process improvements, such as boosting purification and cell lines, can help – but they won't be enough to give us the level-up that we need. What the field needs is a construct that will replicate efficiently.

Machine learning will be crucial to this endeavor. With one of our own machine learning tools, we were analyzing truncations – errors that occur when machinery replicating DNA "gets stuck" because of a secondary or tertiary structure. In our in silico modeling, we

found that it only takes a few changes to the nucleotides to reduce truncations by 70 percent. We're currently in the process of validating these findings in the wet lab. There is a huge potential here for safer, more efficient production – all made possible by digital tools.

# What is the greatest possible outcome of the cell and gene therapy field? Anything as bombastic as a real live mammoth?

Its potential is to revolutionize the way we treat disease. Paying \$3.5 million to correct a single hemophilia mutation may seem a very large upfront cost, but it is still a far lower than a lifetime of payments for conventional treatment. If we can bring that cost down so that it is more scalable, we could fundamentally make medicine more precise and more personalized. One day, a cancer diagnosis could be immediately followed by a cell therapy specific for your type of cancer.

In gene therapy, there is the potential to turn disease management into disease modification, or chronic care into a cure. For example, recent work demonstrated that edits in the liver can reduce cholesterol formation. Cardiovascular disease is one of the largest killers right now, so herein lies the potential to change the health longevity of entire populations.

I am passionate about making all therapies like these more "off-theshelf" and accessible. Making these therapies easier to manufacture and easier to place on a freezer shelf is one way that we can make them more available to the poor, the marginal, and the underserved.

# In 2022, Colossal received funding from CIA's venture capital firm. Are you expecting such high-level support at Form?

We're keeping all our options open. We just raised a round that will give us well over two years of runway, but we still love having conversations with potential investors and getting them excited about the work that we're doing. I think the breadth of the investors that we might be able to engage with is incredibly large, so we shall see where that takes us.





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### SITTING DOWN WITH

# Time for (CAR) T

Sitting Down With... Carl June, Richard W. Vague Professor in Immunotherapy in the Department of Pathology and Laboratory Medicine; Director of the Center for Cellular Immunotherapies at the Perelman School of Medicine; Director of the Parker Institute for Cancer Immunotherapy, at the University of Pennsylvania – and 2018 TIME 100 honoree!

# How did you feel when you were recently honored at Advanced Therapies Week with the Lifetime Achievement Award?

It is a huge honor – and really it's down to the team. In some cases, I've been working with people for 25 years who have been involved with this. It's great to have the recognition, particularly at such an exciting time for the field since it's the 10-year anniversary of when we started CAR T therapy in humans.

# How far back in time do the roots of CAR T reach?

The first successful cell therapies in humans were bone marrow transplants in the 1980s. In this type of transplant, a donor's T cells are given to a patient with cancer, but the cells are not genetically modified. Around 1989, Zelig Eshhar at the Weizmann Institute of Science made something called "T bodies." He made the first T cell that worked with antibodies binding the target cells instead of a T cell receptor – and this is really at the heart of what a CAR is. With this work in place, it was acknowledged that T cells could be very potent for bone marrow transplants and could work with an antibody redirection – a chimeric form of a cell between a B and a T cell. However, it took until 2017 to get FDA approval for a CAR T.

# How did you get involved with this field?

I'm a medical oncologist and immunologist. After completing medical school, I trained in bone marrow transplantation and became interested in how T cells could activate and kill with "graft versus host disease". In the case of a bone marrow transplant, donor T cells can go out of control and cause severe damage. T cells are highly potent and research in this area has led to breakthroughs in CAR T therapy – but it's taken 25 years to get to this point.

# Looking back to what first got you interested in the field, do you think the success of CAR T could have been predicted?

No one could have predicted what has happened in CAR T – for many reasons! For one thing, it actually worked a lot better in our initial trials in humans than it had worked in mice. That's a very unusual situation; over the years, many mice have been cured of cancer but there are still only very few new therapies for humans. Also, back in the 1990s, there were only about five labs working on CAR T cells. There was no pharmaceutical industry involvement back then, and for the academics (including my own lab) that were working on the topic, it was more of an academic thought experiment: Could you redirect a T cell and use it to treat cancer? We weren't necessarily thinking it would or could ever be commercialized, but it worked. Back then, there was no cell therapy industry – but now there is. And the statistics are amazing.

# You were in the movie Of Medicines and Miracles; how did that come about?

Ross Kauffman is an accomplished documentary filmmaker who has won Academy Awards. When he saw the first report in The New York Times about our CAR T cell therapies, he thought it would be an interesting story.





"The effect of that first CAR T trial has led us to become a center with broad experience and expertise."

He got permission to make a three-minute documentary called Fire With Fire about Emily Whitehead's treatment, severe cytokine storm, and then recovery. That three-minute video went viral with about 25 million views, and it also served a really important purpose because it allowed people to see that cell and gene therapy had promise. It also helped increase research funding – which at the time had been difficult to obtain.

Ross Kaufman then decided to make a full-length documentary, which was released in 2022 at the Tribeca Film Festival. It's been an exciting time and I never thought in my career that I would end up in a film! I'm really glad that he has made Of Medicines and Miracles because it highlights the true benefits of these new therapies, and can help educate the public about the long-term need for funding basic science research.

# How has CAR T success affected the University of Pennsylvania?

Usually, new findings in academia at the bench get licensed and go into industry so there is a clear handover. Since there is a handoff, the academics don't really benefit from the growth or participate in new directions of the research. In the case of the CAR T cells, we worked with those first patients, and that caught the attention of Novartis, who then licensed the CAR molecule; we had a very vibrant research partnership with them. The effect of that first CAR T trial has led us to become a center with broad experience and expertise. And that has led to new faculty, attracted very talented postdocs and graduate students, and led to huge growth and innovation at the university. But the real reason it happened is strategic planning. In the early 1990s, Penn made a strategic plan to bring in cell and gene therapy, which is how I got recruited to the university in 1999 to establish human immune therapy. Today, there is a large and diverse research portfolio at the university.

# Are you emotionally affected by your work?

Personalized therapy is a unique experience because the therapy is made from the patient's own cells. When a pharmaceutical company usually makes a batch of drugs, the people who make that product never actually see the patients. But with cell therapy, it is hard baked into what we do. We get the blood from the patient and then a few weeks later the patient gets their treatment. The people in our group get to know our patients and it is hugely rewarding. We've seen cases where people are deathly ill but then they come back to our center and they are healthy: true Lazarus cases. When you are so involved with the patient, this experience is hard to put into words.

# You are well known in these circles for being named one of the 100 most influential people in the world in 2018. But could you share a little known fact about yourself?

I've had a lifelong interest in athletics. During the COVID-19 pandemic, I suffered a little from cabin fever because I could not go outside and do the races that I usually do, so I took part in something called the Everesting Challenge, which is where you go up the equivalent height of Mount Everest (29,000 feet) in one bike ride. About 12,000 people – and only seven of my age – have done the challenge. I did it in Haleakala with my wife and daughter. And it took 19 hours!

# Priorities for the Cell and Gene Field

Three experts give their views on the state of play in cell and gene manufacturing, and the challenges that lie ahead

Cell and gene therapy is arguably one of the most exciting sectors of the drug development industry right now. In this roundtable, we invite three experts to discuss the turning points for the field so far, the manufacturing challenges, and what can be done to lower the costs of these medicines.

# Featuring:

Komal Hatti, Director, Process Architect, IPS-Integrated Project Services Tim Lannan, Senior Director, Rare Disease New Product Leader – Launch Excellence, Pfizer Global Supply Alan Boyd, CEO of Boyds



