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SPOTLIGHT

EXPERT ROUNDTABLE ARTICLE

Autologous versus allogeneic: the future of manufacturing and standardization in cell therapies

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RUPA PIKE, PhD is the Senior Director of Technical Affairs for Advanced Therapies, Pharma Services Group at Thermo Fisher Scientific. The Office of Technical Affairs comprises scientific experts that serve as a strategic, innovational and educational leaders in the area of cell-based therapies, plasmids and mRNA therapeutics. In her prior role as the Director of Enterprise Science and Innovation Partnerships, she developed and managed strategic partnerships with global BioPharma, Biotech and Healthcare customers in the area of Cell and Gene Therapy. Prior to this, she was the Head of Technical Operations (Patheon/Thermo Fisher Scientific) where she worked closely with customers to conduct technology transfer and process optimization activities related to GMP manufacturing of cell-based therapies. She has over 15 years of expertise in GMP manufacturing and has successfully led GMP operations, Process Development and MSAT activities, infrastructure buildout, customer relations and business development.

DELARA MOTLAGH, PhD the General Manager of Cell Therapy Technologies at Terumo Blood and Cell Technologies, headquartered in Lakewood, Colorado. She is passionate about the cell & gene therapy market and the potential these innovative therapies hold to improve the lives of patients.She brings more than 18 years of experience in biotechnology and healthcare in various therapeutic areas including oncology, cardiology, orthopedics, hematology, and nephrology. Prior to joining Terumo Blood and Cell Therapies in 2017, Delara served in diverse leadership roles at Baxter Healthcare in marketing, research & development, and operations.

Her cross-functional background provides a unique perspective and deep understanding of development, cell manufacturing, and commercialization elements in the industry. Delara received a PhD in Physiology and Biophysics from the University of Illinois, fellowship in Vascular Tissue Engineering at Northwestern University, and Executive MBA from Kellogg School of Management.

PATRICK HANLEY, PhD is the Chief and Director of the Cellular Therapy Program and an associate professor of pediatrics at Children's National Hospital and the George Washington University, respectively. He oversees processing for standard of care stem cell transplantation as well as the development, manufacture, quality, and testing of novel cellular therapies and is responsible for seeking partnerships and commercialization of promising cell and gene therapies. Trained as an Immunologist, Dr Hanley has an extensive background and interest in cellular therapy and is passionate about improving regulations for cellular therapy, training the next generation of cell therapists, and facilitating the translation of new therapeutics. Over the past 15 years he has helped to translate more than 300 products on over 25 cell therapy protocols – ranging from mesenchymal stromal cells to cord blood virus-specific T cells and tumor-associated antigen specific T cells – into the clinic.

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Q Where is the market going? More specifically, where do you see the future of autologous versus allogeneic cell therapies heading?

RP: To set the stage, we do not believe that it is autologous 'versus' allogeneic cell therapies. We believe that both are important, and both will positively impact the cell therapy space for patients who have stopped responding to traditional treatments.

Autologous therapies, specifically chimeric antigen receptor T cell (CAR-T) therapies, have charged ahead with six commercial products now on the market. Some of these products are even pushing towards usage as a second-line treatment. The chemistry, manufacturing, and controls (CMC) requirements and the regulatory journey for autologous CAR-Ts is clear and well documented because of this progress. Autologous therapies have demonstrated an excellent safety profile, and a significant durability of response, as we have seen from the real-world data that has been published by multiple companies. The strong efforts of many companies are evidenced in the number of clinical trials in Phases 1, 2 and 3.

Since 2020, when the first clinical study was published on off-the-shelf CARs, there has been a huge investment and effort in developing off-the-shelf approaches. Many major pharma companies as well as small start-ups are putting large efforts into this field.

However, safety, efficacy, and durability for gene-modified allogeneic cell therapies is yet to be proven, as there are no commercial products on the market. Immune rejection is a concern. Haploidentical matching and other human leukocyte antigen-related concerns need to be addressed. Understanding and managing the risks associated with chromosomal aberrations and off-target effects is still a concern, too. As more therapies come to market, we will learn based on how patients respond. But ultimately, off-the-shelf allogeneic cell therapies will be the only way to democratize the cost and make these therapies available to patients in the remotest parts of the world.

"Both allogeneic and autologous products will continue to play a big role in the lives of patients who are in the refractory or relapsed cancer settings."
- Rupa Pike

Both allogeneic and autologous products will continue to play a big role in the lives of patients who are in the refractory or relapsed cancer settings.

DM: The science continues to outpace technology. Unlocking some of those scientific challenges will help us to advance the field.

PH: There has to be a need for using allogeneic therapies. It is not enough to just want to continue the traditional model of pharma in having off-the-shelf medicines. When going after the hardest-to-reach tumors, it does not make sense to start with an allogeneic approach. For example, hopefully, we will see the approval of tumor-infiltrating lymphocytes from Iovance Biotherapeutics, who are submitting their Biologics License Application (BLA) soon. Right now, it does not make sense to use this as an allogeneic therapy.

There are plenty of examples where it does make sense to use an allogeneic model, though. Zooming out, virus-specific T cells is a great area where there is demonstrated efficacy, need, and logic behind using an allogeneic approach. Hopefully, with Atara Biotherapeutics or AlloVir, we will start to see some licensed products coming soon in that space.

RP: Quality of cells also comes to mind. The starting material is very important, and for autologous therapies, sometimes the patient has gone through multiple rounds of chemotherapy and the cells can be fragile. Anecdotally, clinicians are often more inclined to go to autologous therapies first. In the case of a patient from whom it is not possible to obtain high-quality cells, would looking to allogeneic therapies first be beneficial?

PH: The manufacturing success rate of licensed CAR T cells is approaching 95%, so it is only a very small subset of patients who will lack cells of a high enough quality. However, in these cases, it could be beneficial to try allogeneic therapy.

In 2017, there was no infrastructure to deliver CAR T cells. Five years later, there are now 300+ centers across the world that can treat patients with CAR T therapies. In the last 6 months, 3000 patients have been treated with commercial CAR T cells. The curve is

growing exponentially. It would be foolish of us to neglect the infrastructure we have created that seems to be working. This is not to say there is not a need for allogeneic, but it should not be at the expense of autologous.

DM: It is important to note that the infrastructure for the care continuum is getting strained, though. As we treat more and more patients, the ecosystem we currently have will eventually fall apart. We need to build the plane as we are flying it, bearing in mind that the logistical aspects of allogeneic approaches will likely be less cumbersome and more conducive to treating a higher volume of patients. There is a lot of science and thinking that has gone into allogeneic therapies, and they are here to stay.

PH: There are also infrastructure constraints from the manufacturer. Companies have built large facilities to accommodate this. From the hospital perspective, apheresis collection is a massive bottleneck. Then, getting that product back, storing it, and scheduling the infusion is a more difficult process than chemotherapy. Thawing the product is logistically more difficult than giving a pill.

At the end of the day, we did not train 700 people on Risk Evaluation and Mitigation Strategy (REMS) to give only a handful of CAR T cells a year. We saw that this was the next generation of cancer treatment and built that infrastructure for all these different therapies.

Q What are the best practices for successful manufacturing in both autologous and allogeneic cell therapy spaces?

RP: Many of the best practices are going to apply to both autologous and allogeneic approaches, though there are some differences.

An important factor to consider is ensuring the availability of critical raw materials. No one was prepared for the COVID-19 pandemic, and we saw an acute shortage of raw materials. We learned a lot of lessons as a result of that experience, including the importance of choosing your vendors carefully. It is important to understand the benefits of established vendors versus younger, less experienced vendors, including the possibility of exit strategies that they may have in place.

At Thermo Fisher Scientific, we perform extensive vendor qualification, and for critical raw materials, we practice dual vendor sourcing, wheever possible. We are establishing more robust supply agreements and have put in place measures to allow us to monitor lead times and inventory levels in real-time. Interestingly, in a recent publication by McKinsey & Company, the idea of creating a digital twin was proposed. This means creating a simulation of your circular supply chain to have more control and understanding of chain of custody and chain of identity events.

Secondly, de-risking the manufacturing process is critical for success in both autologous and allogeneic therapies. This involves closing the open steps and reducing human touchpoints, which can be done using closed and automated instruments and/or platforms. Digitalization can also streamline good manufacturing practice (GMP) record keeping. Master

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batch records are critical, and process and quality oversight functions can be simplified by digitalization.

Another important aspect is having a meaningful in-process analytical assay portfolio. We focus on final release testing, which is if course absolutely critical, but having robust and meaningful in-line, in-process assays is also important. This allows us to track the phenotype and behavior of cells as they transition from one unit operation to another to give us the confidence that they are conforming to the critical quality attributes (CQAs) of the final product.

Lastly, establishing excellent training programs is important, not only for GMP operators, but also for process development scientists, quality control (QC) scientists, quality assurance (QA) staff, and warehousing staff.

So, regardless of whether a cell therapy product is autologous or allogeneic, ensuring the availability of raw materials, de-risking the process through various aspects, and having a highly trained workforce are all best practices for manufacturing.

DM: If we zoom out and think about raw materials in a broader context, whether you are producing an allogeneic or autologous product, you benefit from more consistent starting materials. To be able to define a raw material, it is important to firstly characterize the process. Understanding the process and the things that are impacting it will help to define what an ideal raw material looks like, whether it is a starting material for a cell product or reagents used in the process.

Given that we are manufacturing living therapies, person-to-person variability is always going to exist. That will be amplified in sicker patient populations where autologous therapies have comorbidities. With allogeneic therapies, you can at least define an ideal donor with eligibility and screening requirements.

Q From a manufacturing standpoint, what aspects and logistics are distinct for autologous and allogeneic cell therapies respectively?

DM: When moving into manufacturing, the most critical unit operation is the modification and expansion of these cells. Automated and closed systems will help to control and manage the process. As you look to treat more and more patients, that process must be scaled.

For autologous therapies, you need to scale the process out with multiple platforms and workstations, each making a single drug product for one patient. Whereas for allogeneic therapies, your lot size can be much larger. You are treating hundreds of patients. This is scaling up, to produce larger quantities that can be aliquoted into doses to treat many patients.

The manufacturing timeframe is also different. For autologous therapies, we are all envisioning a patient waiting for their therapy. Time-to-manufacture is important because there is a life waiting at the other end. Faster manufacturing allows you to treat more patients. With allogeneic therapies, there is less of a time constraint, because you produce a large batch in advance so treatment can be more readily available.

PH: It is important to firstly note that the manufacturing differences have an impact from the patient's perspective. For autologous therapies, patients may have to wait a while. This means maintenance or consolidation therapies are important to make sure they can receive those cells. The time between evaluating whether the patient is eligible, and the infusion can be months. That changes when looking at an allogeneic therapy, where you can infuse the patient in three days.

How do we do a conditioning regimen for an allogeneic therapy? For example, do we give patients one large dose of an allogeneic therapy with a conditioning regimen, then give smaller follow-up doses? Do the patients need an additional boosting regimen, or will one dose allow endogenous immune response? I do not think we are going to see long-term persistence of these cells, so we may need additional treatments.

DM: This does impact manufacturing. It is important to think of the clinic as both the starting point and the end destination, regardless of the therapy. I get excited when I see faster manufacturing, but I also wonder how it is going to play out in real-time. It is one thing to make a product in one to three days, but it is another thing to complete the release testing so the treatment can be infused.

PH: Right now, we have a 10–17-day manufacturing process. The new T-Charge next-generation CAR-T platform from Novartis, which offers 24–72-h manufacturing, could make a big difference. If you can get to a final cell therapy product in 4–5 days, that is close to the allogeneic therapy timeline. The logistics and supply chain will be different, but it will be similar in terms of delivery time. Currently, we do not have much data on this, though.

RP: Everyone is excited about the possibility of shorter expansion time outside the body. This is where a very small population of pristine naïve T cells – for example, in CAR-T therapies, they – will be infused and then expand inside of the body. We want the patient to be the bioreactor. It will be interesting to find out what the regulatory agencies are going to say about release testing in this setting, which is going to take longer than the manufacturing process. Many people are bringing most of this testing in-house, such as quantitative PCR assays for mycoplasma. I want to wait and see how that piece is going to come together with this short manufacturing process and expedition of the release testing. Will in-house release testing become standard practice? This will save time, but it will not involve the traditional 14- and 28-day assays.

PH: One of the inherent challenges of this field is that we need differently qualified people – Delara, Rupa and I may all need a differently trained technologist for example. It is an interesting conundrum we face in the field.

It is great to have the full force of big pharma behind us. I am confident that they can validate an assay that will allow rapid-release – for example, endotoxin testing that we can do in-house in three hours. There will also be assays to reliably detect mycoplasma within 24 h.

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Sterility testing may be more difficult. I have heard of companies that have seven-day tests validated with US food and drug administration (FDA) approval – but I think it needs to be shorter than this. The frequency of endotoxin and mycoplasma contamination is incredibly low, and we have systems to detect them. It will take some flexibility from the regulatory agencies to demonstrate that this can be done safely.

"Allogeneic therapies will have more flexibility than autologous both in terms of timing and sample volumes required."
- Delara Motlagh

Q The regulatory landscape is somewhat different for autologous and allogeneic cell therapies. but are the chemistry, manufacturing, and controls (CMC) requirements the same for the two different product types?

DM: Overall, CMC packages are probably one the biggest pain points for the industry right now. If you want to see a developer stricken with fear, talk about a CMC package! Half of all approval delays are related to CMC package difficulties. It is not a copy-paste exercise: you cannot copy and paste an autologous package for an allogeneic product, much as you cannot copy-paste from the traditional drug manufacturing of small molecules and biologics into cell and gene therapy. These are living therapies. There are going to be different cell characteristics, and the processes will vary.

The good news is that associations like Alliance for Regenerative Medicine (ARM) and National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) have recently partnered to publish A-Cell – a case study designed to assist developers as they are planning their CMC packages.

The process analytics are key to support a robust package. Depending on the modifications made to the cells for autologous and allogeneic products, there are different types of cell-based testing needed. This is a motivated industry, though, and we will be able to get these analytical tools faster and have them validated. Process testing in addition to release testing defines your process, and both require refinement over time. CQAs will also all be product-specific and need to be defined.

For an autologous process, the innate variability from patient to patient will lead to wider specifications. This is justified by looking at the data and being able to demonstrate comparability to support your manufacturing.

In product release testing, there is both timing and volume to consider. Every sample volume that you take, you are taking away from the precious final drug product. There is a desire and a need to maximize the cells for therapy versus using them for testing.

Allogeneic therapies will have more flexibility than autologous both in terms of timing and sample volumes required. However, these are still areas where developers need to lean in

early and understand their process, to be able to make those modifications as time goes on. This will allow more robust CMC packages for both autologous and allogeneic cell products.

RP: There are a lot of excited people in the field, and a lot of incentives to develop new things. One thing that has already helped the industry is the premise of non-invasive, non-destructive sampling for in-process testing. There are many companies coming out with instruments that can sit in the GMP setting, where cells can pass through these instruments and certain measurements can be made. The cells can then be returned to the process and are still useful to us. Investments in artificial intelligence will help with this effort.

There is always a friction between QC scientists who want more cells to do the assays, and GMP operators who do not want to give out those cells as they need to ensure they achieve the clinical dose.

PH: One key distinction between autologous and allogeneic is the criticality of the starting material. In the autologous setting, the material you have is the only material you are going to get. It can be unethical in some instances to not deliver that final drug product to the patient, as long as it can be done safely. There might be technical deviations, but for the most part, you want to try to deliver that product to the patient.

In the allogeneic space, it is the opposite. We might have to wait weeks to collect from the healthy donors a second time, but we can. There is less flexibility in terms of deviations because you have the ability to go back to the donor and do it again or choose a different donor. Those deviations happen in every product – that is why there are processes for deviations and an audit system; but with autologous it is more critical that we get it right.

Q Rupa, from a contract development manufacturing organization (CDMO) perspective, what preparations are needed to allow the manufacturing of allogeneic cell therapies?

RP: Everyone is thinking about this right now because it is only a matter of time before allogeneic therapies become as prevalent as autologous therapies. It is important for any CDMO that does manufacturing for multiple customers to understand the differences in the manufacturing processes and logistics. They then need to decide which of the existing facilities and infrastructure will work for both autologous and allogeneic cell products and make changes accordingly to accommodate partners and customers who want to scale manufacturing. It is possible that larger GMP suites will be needed for allogeneic therapies, because it is a scale-up process rather than scale-out process.

Allogeneic therapies are more similar in some ways to traditional bioprocessing with upstream and downstream processes. They use multiple-step bioreactors as they keep expanding the cells, they may have seed trains, and they may be manufacturing multiple GMP cell banks and working banks at a time. It therefore becomes important to have a suite that is reconfigurable, modular, and can accommodate large pieces of equipment that can be wheeled in and out as necessary.

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Staff training is also going to be different, as understanding and characterizing starting material for allogeneic products is going to be different. It is important to have the right training of QA and QC staff, and to have the right assays in place. It can also be good idea to have a dedicated suite available for cell banking.

Another factor is cryopreservation. Cryopreservation of large numbers of doses requires specialized equipment – the decision of whether this happens in the same suite, or an adjacent suite needs to be made.

Allogeneic therapies require a large storage capacity because there is a need for thousands of doses rather than a single dose per patient. For truly off-the-shelf therapies, your goal is for them to reach the global regions where is it currently difficult or impossible for autologous therapies to make an impact. We are putting all the best practices in place and making changes so we are ready to manufacture allogeneic to the same standard as we can manufacture autologous.

DM: With allogeneic cell therapies, you are storing much more in the way of samples, including starting material from the donors, the final drug product, and everything in between, including master cell banks. Carefully managing that to make sure that these products are viable and well taken care of is important.

Given that these are all different products that are being manufactured, there is a lot of innovation in the types of platforms that will process these cell materials. Having flexibility in these manufacturing environments to be able to accommodate different kinds of platforms depending on the process is also going to be key. Being modular supports a nimbler process and workflow, which will be important for success, especially given the variability of cell types and applications.

PH: Mesenchymal stromal cells have been used in an allogeneic way for 20–30 years. We need to build on that work and develop better systems with better expansion capabilities, as we want to be able to treat as many patients as possible to drive down cost.

A lot of these therapies could be derived from induced pluripotent stem cells; in which case we could make an infinite number of doses. We all hope to get there someday, but it seems far away right now.

Q How can standardization help for both types of therapies?

PH: It is important to frame standardization because everyone has a different take on it. Some people want to throw everything in the same piece of equipment, which I think is a bad idea. We want innovation in this field. We do not want every CAR T cell therapy to cost US$500,000.

The three key areas where we can perform standardization are:

1. The upstream collection of the apheresis product
2. The delivery of the cell therapy
3. Patient monitoring

In the upstream patient or donor collection, we could standardize the criteria for the selection, the collection volumes, and the desired total nucleated cell count. We should agree on the type of collection on the apheresis machine. Some people use different additives. That makes it hard for the collection centers because every company must have their own specific collection protocol. It means everyone must be trained for each individual product, and every time they mess it up there is a deviation. We should try to standardize that.

Let's also standardize the required testing. For autologous products, the FDA does not have criteria for donor eligibility, as they are exempt. For safety purposes, almost everyone still wants to do that same infectious disease testing. Because there are no guidelines, some people treat it as a stem cell product which is required 30 days prior to collection or 7 days after, and some people treat it as a GMP therapeutic product, required seven days before or after. If we could standardize that it would greatly help the collection centers.

Fast forward to the delivery – generally, people use the same vials and bags, but the cassettes can differ as can the liquid nitrogen storage. Other considerations include the expiration date and REMS training. These are other areas where we can standardize.

With allogeneic therapies, we can standardize to a greater degree, because we know certain outcomes such as dosages.

DM: As we look at standardization with the starting material, there is much variability in how we do the collection for apheresis, for example. Over 70% of cell therapy products manufactured today start with an apheresis product. It is a natural place to start.

When we look at autologous therapies, people consider standardization to be a tight, specific thing that takes away some of the flexibility. We need to be purposeful and intentional in how we define what a standardized product looks like. We must consider the variability of these patients. We want to prevent any bottlenecks in collections and ensure that the products meet the standards necessary to go into manufacturing.

The other piece is cell viability, which is such a basic thing, but everyone defines it a bit differently and uses different assays to do so. There can be huge variation. For example, Trypan blue is not the most robust viability measure. This is a place where the industry could come together and define a standard.

There is also a lot of intellectual property (IP) associated with the process. There is sometimes a reluctance, particularly for the biotech pharma companies, to share details of their process. However, it is important to remember that in the end, the opportunity to collaborate and have more standardization benefits everyone and need not compromise some of the concerns people have around IP.

In the hospital setting, there are bottlenecks in collection but also in the infusions, as there are so many different protocols. The major academic institutions are robust and have fantastic capabilities. It's also incumbent on us to determine how we can make this work in more rural centers, in order to truly expand access. Having guidelines and standards that can be rolled out globally is a way in which we can do this.

RP: There is already talk of commercial products being made available in different parts of the world. Regulatory agencies in the US, EU, and the UK have some

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similarities, but the Asia-Pacific region can be different. There are a few things that can be standardized, though, even when treatments are given in different countries – for example, labeling for chain of identity and chain of custody. There is FDA-approved software currently available and validated to do this. Even if you are manufacturing in one country and sending it to another, it can become easy to carefully monitor the chain of identity and chain of custody by creating unique donor identification numbers. The testing of the incoming material could also be standardized.

There are conversations happening between regulatory agencies, grassroots organizations, patient advocacy groups, and non-profit organizations. From a payer perspective, there will be relief when we have proof of better chain of custody and chain of identity.

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- Patrick J Hanley

Q Finally, what is your brief call to action for our industry?

DM: Firstly, as a piece of advice to the cell and gene therapy industry, it is important to have the end in mind. The end is not just getting a product out the door – it is treating a patient.

My call to action is, regardless of the role you play in the ecosystem, consider how you can enable the treatment of more patients, whether it is through logistics, manufacturing, or hospital management. These patients are counting on each and every one of us.

PH: Keep an open mind with an eye to the future. I would also encourage us to think differently about how we deliver these cell and gene therapy products. Perhaps they can be delivered in a decentralized way, even if we cannot do that right now. And I'll give you one very good reason why we should try to do what seems impossible: The patients. We might need to work with the agencies to create the regulatory framework in a safe and ethical way, but it would drive down costs and increase patient access.

RP: My call to action, or what CDMOs and everyone in this field should strive to do, is to always have the patient in mind. What was not possible in the blood transfusion and bone marrow transplant industry in the past is the standard of care now. We should all work together on solutions where experimental therapies can become the standard of care. I am excited – I think it is possible, but it may take a long time. We are already at the second line of treatment, though, and working towards these therapies becoming first-line treatments.

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AUTHORSHIP & CONFLICT OF INTEREST

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