CELL & GENE THERAPY INSIGHTS

CELL THERAPY MATERIALS &
UPSTREAM PROCESSING/ANALYTICS

SPOTLIGHT

INTERVIEW

Ensuring success in working with apheresis centers

David McCall, Commissioning Editor, BioInsights,
talks to **Suzanne Kamps,** Associate Director,
Apheresis Operations, Adaptimmune

SUZANNE KAMPS, BSN RN, currently serves as the Associate Director of Apheresis Operations at Adaptimmune Therapeutics. Suzanne provides expert oversight guiding the procurement of starting material for Adaptimmune's clinical trials. In her previous role at the Children's Hospital of Philadelphia, she was a Safety Quality Specialist for Apheresis, responsible for onboarding clinical and commercial cell therapies at their Apheresis Center. In addition, she maintained compliance with regulatory standards to ensure uninterrupted accreditation of the Apheresis Center. She is a Registered Nurse with over 10 years of experience treating Oncology and Apheresis patients.

Cell & Gene Therapy Insights 2023; 9(2), 141–146

DOI: 10.18609/cgti.2023.019

Q What are you working on right now?

SK: I am building on and expanding apheresis operations at Adaptimmune, a T cell therapy company focused on solid tumors. This includes developing standards

for apheresis and maintaining our apheresis manuals (and expanding upon them, where appropriate). I am also engaged with the training at clinical sites during our site onboarding process, and I am working on a project to try to characterize our starting material with our scientific departments. Last but certainly not least, I am involved in a rolling Biologics License Application (BLA) submission, which we are conducting this year. For this, I am utilizing my experience and expertise to assist writing of the starting material-related component of the BLA submission document. This work is running alongside preparations for building out what will be our commercial infrastructure.

Q You are in a great position to be able to refine Adaptimmune's approach to working with apheresis centers, given your previous experience on the other side of the fence at the Children's Hospital of Pennsylvania (CHOP). Can you firstly reflect on the concerns, considerations, and frustrations you experienced when working in the hospital setting with apheresis for cell-based therapies?

SK: The strain on apheresis centers has been increasing due to the growing number and variety of cell-based therapies. This expansion in the field is great for patients but leads to many other considerations and requirements for apheresis centers, and the variability that occurs across the cell-based therapy industry can be time-consuming to navigate. Participating in the audits and onboarding for each different product drains time and resources for the apheresis centers, and at the end of the day, that ultimately affects their ability to care for patients and perform the quality assurance (QA) necessary to provide high-quality starting material. At CHOP, I had the privilege of working with a very experienced cell therapy team who did all they could to ease those burdens for the apheresis center. However, the center was still required to dedicate time for review of, and training on, all of the varying apheresis manuals. This is something that I hope will change in the coming years, with standardization across industry becoming more and more of a priority. For me, any chances I get to advocate for apheresis centers are opportunities I want to take. I want to ask, 'what can we do as industry to lessen that strain on apheresis centers?'.

Q Now you are on the industry side, what are some of the key challenges you face there? What were your related main priorities when you took the role at Adaptimmune?

SK: To be honest, the main challenge I initially faced was navigating a matrixed biotech environment, as it varies so greatly from the hospital setting. In doing so, I became aware of all the work that is being done during the patient journey as a whole, from

DOI: 10.18609/cgti.2023.019

"Standardization is key to reducing the burden on hospitals and thus allowing more patients to receive treatment: the more time that hospitals have to collect cells, the higher the potential for patients to be treated."

apheresis collection through to infusion. The hospital setting sees the apheresis collection and the infusion stages, but from a hospital perspective, what goes on in between can be unclear for roles outside of the prescribing physicians. Being able to see the work, the research and dedication, that occur between those two stages has been eye-opening for me.

When I started, my main priority was the starting material and its impact on various different departments within the company. I've focused on education of variabilities in starting material, quality measures that are done at a hospital, and all the regulations that apheresis centers must follow, so that our teams at Adaptimmune can better understand how we can – and also where we cannot – engender positive change in the collection of starting material for our specific products.

Q The need for standardization is an overriding theme in this particular area – what should be some of the specific priorities in this regard?

SK: Standardization is key to reducing the burden on hospitals and thus allowing more patients to receive treatment: the more time that hospitals have to collect cells, the higher the potential for patients to be treated. Having read many apheresis manuals in my previous role, I believe that the standardization priorities should be documentation, auditing, and the requirements for collection.

In terms of the auditing of apheresis centers by industry, I strongly believe that we should capitalize on widely recognized standards to determine the quality of an apheresis center. There are different standards and accreditations, but I would specifically highlight FACT (Foundation for the Accreditation of Cellular Therapy) accreditation. Apheresis centers work diligently to obtain and maintain FACT accreditation, and the FACT standards are heavily focused on the quality of the starting material. Therefore, if you are working with an apheresis center that is FACT-accredited, you should feel confident that the apheresis center has achieved a high level of quality – that they can collect a quality product. You should adjust your auditing to remove any redundancies between what your audit covers and what is already addressed in the FACT standards. Focus instead on your company's specific requirements.

There are a number of additional forums being developed with key industry leaders right now for standardization. Some cover auditing while others cover the apheresis collection and

documentation. Again, those three key areas stand out to me as the most important in the effort to reduce the burden on apheresis centers, particularly in terms of addressing the variability challenge. After all, the more variability you have, the greater the likelihood of error.

Q With Adaptimmune building towards a potentially landmark approval for the field with afami-cel, can you identify some ways in which your role has changed and is changing as preparations for commercialization intensify?

SK: I have been heavily involved in creating and building out the infrastructure that we are going to need for a successful commercial launch. More specifically, I am currently working on developing our auditing and onboarding process for apheresis centers, keeping in mind everything I just previously said. Other aspects I anticipate being involved in include assisting in the drafting of quality agreements, creating our commercial apheresis manual, and then onboarding a team to go into the field to support our sites.

Q What are some of the important 'take-homes' from this experience for earlier stage developers? What should be done early on to address issues that will arise later?

SK: I may sound biased here, but I would suggest that when a company is building their team for any type of cell-based therapy, they should consider hiring or consulting professionals who have direct experience in caring for patients in the cell and gene therapy space. The background knowledge and understanding that these individuals bring are incredible attributes that fill the knowledge gap between what industry believes and what actually goes on with direct patient care at the apheresis and infusion stages. Hiring people that have that experience at an early stage can definitely boost your company's relationship with the clinical sites you will utilize and rely upon to be successful later.

Q Can you distil for us your key words of advice regarding how to approach development of an apheresis manual?

SK: Overall, I would say there is no need to complicate operations required on the side of the apheresis sites, as this can impede their participation with these products. You want to try to be as flexible as possible and rely on the site's expertise. This

DOI: 10.18609/cgti.2023.019

includes being as flexible as you can be with your manufacturing, particularly in terms of patient scheduling. These patients are going through multiple treatments and being flexible on when you can collect and deliver the treatments to these patients is beneficial. Furthermore, offering an option to collect apheresis earlier in the patient's cancer journey, when their cells are healthier, increases the chance of manufacturing success.

"...offering an option to collect apheresis earlier in the patient's cancer journey, when their cells are healthier, increases the chance of manufacturing success."

Involving the apheresis center early in development means you can get a lot of those conversations out of the way early, leading to a much smoother onboarding process down the line. Also, do not get too specific unless you have solid data to back up what you are putting in your manual. Guidance in the manual is great because some apheresis centers might not be as experienced with these types of products as others, but think about what you require an apheresis center to do, and weigh carefully that balance of control over the starting material with the actual practical feasibility from the apheresis center's perspective. Failure to do this may cost you the participation of an apheresis center in your clinical trial and ultimately, your commercialization activities.

Q Finally, can you sum up some important priorities and goals that you have for your work over the foreseeable future?

SK: As we are moving closer to the completion of our rolling BLA submission, my focus is to ensure we are comprehensive in everything that we are doing from an apheresis perspective. Furthermore, clearly communicating our message about our specific treatment and allowing apheresis centers the autonomy to excel in collecting a quality starting material are real priorities for me. I want to continue to advocate for apheresis centers, and to reduce the wait-time for their participation with cell-based therapies.

AFFILIATION

Suzanne Kamps
Associate Director, Apheresis Operations,
Adaptimmune

AUTHORSHIP & CONFLICT OF INTEREST

Contributions: The named author takes responsibility for the integrity of the work as a whole, and has given his approval for this version to be published.

Acknowledgements: None.

Disclosure and potential conflicts of interest: Kamps S discloses she is an employee of Adaptimmue and has stocks/stock options from Adaptimmue.

Funding declaration: Kamps S received financial support for the research, authorship and/or publication of this article from Adaptimmune.

ARTICLE & COPYRIGHT INFORMATION

Article source: This article is based on an interview with Suzanne Kamps carried out on Jan 18 2023.

Interview held: Jan 18 2023; **Revised manuscript received:** Feb 20 2023; **Publication date:** Feb 2 2023

DOI: 10.18609/cgti.2023.019