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SPOTLIGHT

INNOVATOR INSIGHT

Current issues & future trends in cryopreservation for advanced therapies

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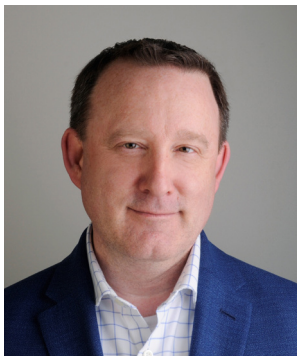
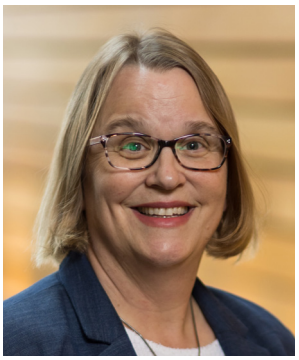
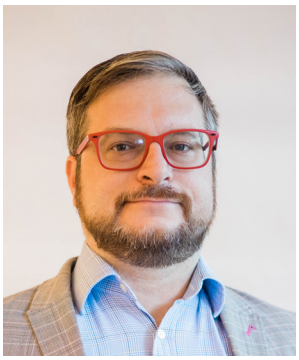
(pictured from left to right)







Three industry experts discuss lessons learned in the cryopreservation sector over the last decade, as well as potential innovative solutions to current challenges within the space. The authors also explore the question of how industry and academia can come together to create these solutions.

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Q Can you summarize your past and current work in the area of advanced therapy cryopreservation?

JA: I am a Professor in Laboratory Medicine and Pathology at the University of Alberta. In that capacity, I lead a cryobiology research group that investigates basic freezing response of natural systems and their response to environmental stress as a prelude to understanding how to develop ways to mitigate issues in natural and engineered systems. I also consult with the industry to help ensure that the principles of cryobiology are properly translated.

AH: I am a faculty member in mechanical engineering at the University of Minnesota. My work has always involved the preservation of cells. In terms of contributions to the field, I have worked on the development of low-temperature Raman spectroscopy as a tool to understand freezing damage. I have also worked on the development of dimethyl sulfoxide (DMSO)-free methods of preserving cells—that technology is being commercialized and used in the cell and gene therapy space.

SW: I am not a cryobiologist by training—my background is in cell and cancer biology. However, since 2015, I have been working on the commercialization of cryopreservation vials and systems. I work with BioLife Solutions, and we have a range of products involved in the storage and processing of cell therapies for cryopreservation and cryostorage.

Q How are the cold chain logistics tools and services sectors continuing to evolve post-COVID-19, and what does this mean for the cell and gene therapy sector?

SW: A couple of key things have changed in the last few years. Pre-COVID-19, people used cold chain logistics, but the pandemic opened everyone's eyes to what was missing in terms of being able to store and globally ship vaccines at an ultracold temperature and at a really large scale. How do you ship that many vials around the world all at once? Post-pandemic, people are starting to look at what else is needed. We developed large repositories and companies evolved and developed methods to do storage at ultracold temperatures. Prior to the pandemic, these types of facilities really were not available at the scale they are now.

This progress has set the stage for us to be able to translate into accomplishing this at cryogenic temperatures. There are many challenges in that task. For example, it takes nine different cryogenic shipments around the world to complete a manufacturing line for an autologous therapy. However, there are now systems to make this process easier and allow us to use, for example, commercial airlines to carry these products whereas before that might not have been a possibility.

There are some logistical and storage facility solutions that are evolving, such as being able to store raw materials close to the cellular starting material collection point or the manufacturing facility, instead of always having to move things around on a just-in-time basis. There is a lot of work to do, but we are on the way.

AH: It is helpful to take a step back and say, "Why are we even talking about cold chain?" That is because the supply chain for cell and gene therapy is far more complicated

than for other types of medical therapies. We must keep cells viable and functional all the way along that supply chain. This realization has led to the development of some of the technology that Sean talked about.

JA: To build on Allison's comments, throughout the COVID-19 pandemic, we learned about the fragility of supply chains, which introduced variability that exacerbated a lot of the injury that was occurring in cryopreserved products. As a result, we were running into situations where products were not able to move through the supply chain successfully.

In some ways, the fact that we did get an interrupted supply chain during COVID-19 helped reinforce the importance of the supply chain phase when talking about an allogeneic or an autologous cell therapy product. This was an important and beneficial lesson from a very unfortunate situation that we all had to go through.

Q What have been some of the key issues around cryopreservation in the space over the past decade, and what have been some of the key related learnings for industry?

JA: Over the last decade, the industry has become a lot more aware of the basic cryobiology science that was done half a century or more, which focused on understanding the foundational elements of how to preserve, and then ultimately store a stable biological product. The problems that the cell therapy sector is facing today are problems that were recognized a while ago with respect to cryoprotectant toxicity: how do we add, remove, and select those cryoprotectants to mitigate that toxicity? How do we control ice, and how do we mitigate the amount of ice and the damage caused as a result of it? How do we understand the cell specificity for every one of our products with respect to what those optimal parameters are, so that we can maximize recovery? Each one of these elements factors into the process that ultimately becomes the cryopreservation methodology that a company would use, so this increased awareness of that long-established basic science has been helpful.

These learnings have been really well appreciated at the industry level because they are either dealing with a problem they cannot understand due to a lack of knowledge of the fundamentals, or they have encountered a problem that with well mapped out fundamentals can be resolved.

There is still a reliance on a standard 10% DMSO, 1 °C/min freezing rate approach in the commercial space, which was developed and validated for certain types of cells. But as we are starting to see much more sophisticated cell products being engineered with very specific properties, that approach is not going to work. You have to go back and rely on the science. That is where, again, the learnings from history are starting to be re-discovered. There has been some interesting dialogue within the industry around building scientific capacity in this field within a company or organization in order to bring more products through the design, development, and manufacturing stages.

AH: Another layer that has entered the space is the discovery of things like induced pluripotent stem cells (iPSCs), which are used as a source of starting material for cell therapies and regenerative medicine products. We are now taking a stem cell or a pluripotent cell and differentiating it into another cell type, creating completely different cells from those we can harvest from a patient's tissue or their peripheral blood.

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We are expanding the potential for those cells to be used therapeutically, but it is not at all clear if, for example, an iPSC-derived natural killer (NK) cell is going to respond in the same way as a primary NK cell to current cryopreservation methods. So, we are creating more need for this fundamental cryopreservation knowledge because we are creating cell types that have different biology and different cryobiology. The field is getting to the point where it really needs our fundamental knowledge to move forward.

SW: One of the most important elements of a successful drug product is that you can demonstrate comparability: that you are making the same thing every time with the same ability to meet the quality specifications. For a cell therapy product, those specifications are sometimes less robust than we might like them to be. We are still trying to understand what the critical quality attributes of cell therapy products really are.

In the absence of being able to identify and test for all the attributes that are important, we have to be able to control the variability. Two of the really important steps in the overall cell manufacturing process where there can be a lot of variability are the cryopreservation process and then the thaw process on the clinical side. For us to be able to have really well developed, robust optimization of the cryopreservation process and the thawing process, the interim storage process must be well established. This is one of the ways that we can avoid running into problems with the therapy after the fact. In fact, we might not even know of the problems unless we go through the effort of optimizing those processes.

JA: One of the things we are realizing is a lot of the methods that were developed from a cryopreservation perspective, like the 10% DMSO, 1 °C/min freezing rate protocol, were developed for single autologous cell products where you only have to produce one dose. In that setting, you can have much greater control over the conditions under which that product is cryopreserved.

However, when you start to scale and move from one dose per batch to perhaps tens of thousands of doses per batch, the principles of cryopreservation become even more important because any problematic issues are scaled up, too. For example, the impact of cryoprotectant toxicity can be minimized when exposing one bag of a product. But if you have to expose 10,000 bags, by the time you have gone through the fill-finish and labelling process, that becomes a lot more significant.

As a result, we are seeing that those standard preservation processes that have been historically used well in autologous products are not translating well to the allogeneic world. Most in the cryobiology community would say, "That's obvious, but now how do we solve the problem?" That is where the industry is now working with cryobiologists who have some historical context and can help come up with innovative ways to try to address these problems.

Q What is the current state-of-the-art in cell and gene therapy cryopreservation and associated transportation and storage technology—for instance, as used with the commercialized CAR-T cell therapy products and their cellular starting materials?

JA: The industry has evolved in the sense that the materials used for the containers are a little more robust. They are chemically defined, qualified materials now, so we have better materials that we are using in the cryopreservation process. However, the cryotechnology that is used, unfortunately, still falls into that 10% DMSO, 1 °C/min standard way of approaching the cryopreservation process.

For a CAR-T product or indeed, any T cell product, that standard approach works adequately well—again, there are nuances around the cryobiology of T cells that would suggest that you could use other methods that would be even more effective. However, when you start to look at other products like an NK cell or a heavily engineered CAR-T or CAR-NK cell, that approach is not going to work. We are seeing the cracks now in the state of the art of the cryopreservation process because it is just not allowing the industry to scale. It is not giving the post-thaw recovery or the stability throughout the supply chain that the industry is asking for.

It is necessary to go back and look at the fundamental approach from a process design standpoint, and look at those areas from the cryopreservation process itself in order to further refine, optimize, or completely redevelop using different approaches that have been known in the industry for decades, and which will allow us to overcome some of those challenges. Many of the conversations that are currently going on are about taking the next generation of ideas and moving them into the industrial context.

Unfortunately, recognizing the challenges that many companies are facing with respect to cryopreservation is generally the last step in the process. As a result, the cryobiologists are inheriting a whole bunch of process decisions that are very difficult to change, which makes implementing something different even more problematic.

AH: Let's say that we are wickedly successful—that there are dozens of cell therapies for dozens of diseases that have been approved by the regulatory agencies around the world, and that are now being used in the clinic. Then we go to the cell therapy ward where these patients are being infused, and we have nurses or cell therapy technicians thawing different bags to go to different patients for different diseases.

The result of this success would be a mess because, according to interviews with nurses, each of these different cell therapy companies has a different method of thawing, infusing, documentation, and shelf-life. One of the technologies that needs to be developed is one that handles those products once they leave the hands of the cell therapy developer and go to the clinical site.

The other layer of this is that people need to be communicating with each other and with cryobiologists so that we can develop best practices for thawing and post-thaw handling of cell therapy products that make it implementable in a clinical context, especially if we are talking about a dozen different patients with a dozen different cell therapies for different disorders all happening simultaneously. That is something that people are really just becoming aware of that could be an emerging area of importance down the road.

SW: I believe we are already at that mess, to be honest. A few well-known hospitals have talked about this as being one of the big problems they are facing. You have got to have unique, dedicated pieces of equipment and unique, dedicated processes for each therapy. The clinical study is one thing where you have the data to report, but then once you move on from the clinical study, you have to trust that your clinicians, nurses or practitioners are going to be following those processes and procedures.

There is already a great deal of difficulty in simply trying to maintain things as they are currently. We have largely moved on from the concept that we cannot freeze or adjust these cells. Using fresh cells does not really work from a logistics perspective. You would have to move your products around the world in three days, which clearly was never going to work. Cryopreservation has given us the opportunity to take into account things like the messiness of scheduling a patient to come in for a visit. We now do not have to throw out a US$500,000 product because it sat out overnight before a patient could get to the point of care. Cryopreservation allows us to address that issue, but now we have to figure out how we do this at a global scale.

Q What are some of the key historical and ongoing issues and challenges with the containers utilized for advanced therapy cryostorage and transportation?

AH: There are some tensions when we talk about containers for cryopreservation. The first tension is heat transfer. To freeze something, you have to remove heat, so the container must enable efficient heat transfer. That is one of the reasons why bags in presses have been a common paradigm for freezing large volumes. The other tension is the question of using the container in an automated setting, now that we are moving to the scale-up paradigm. The third layer of tension has to do with materials because we must have materials that are usable at cryogenic temperatures. The container issue has been a source of tension due to the need to balance these three specific considerations.

JA: To lend a little historical context, some of the first cell products that were cryopreserved were red blood cells and stem cells. Red blood cells always need to be stored at –80 °C. The blood bag technology was used because it can maintain container closure at –65 to –80 °C temperatures. Bag breakage was a problem, though, early in the history of red blood cell cryopreservation, until we learned how to pack them and get them into the right protective box so that they do not get juggled and broken as part of the shipping process. That process was never going to work for lower temperatures. The early blood bags that were used for cord blood or stem cells, for example, were actually those same container systems. There were significant challenges in storing those at liquid nitrogen temperatures until, as Allison mentioned, newer plastic configurations became available.

There has been some evolution, but the challenges are still very much present, particularly now that we are adding the complexities of having to maintain container closure in a system that is scalable and automated, and needing to withstand the extreme ranges of temperature during freezing and thawing processes at a specific volume for the specific cell therapy application. There are no standards yet for the kinds of containers that we need. As a result, there is a lot of confusion in the market about what to adopt because your container drives your freezer configuration—the racking systems that you use in your storage container, as well as

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your controlled-rate freezer and your thawing device. Then ultimately, the container controls how the product is manipulated by the end-user in terms of being able to infuse, transplant, or transfuse it. A lot of design constraints are now being placed on the containers themselves, which is causing some tension as Allison mentioned.

SW: We are talking about bags here in the main, but for small volumes, bags are not necessarily the ideal format. They have some issues with recovery and all kinds of different challenges with smaller volumes. What a lot of people have used instead are screwcap vials. In fact, there are a few commercially approved products out there that use these vials as their final drug container, but those also have real issues. For one thing, there is serious concern with leakage in the screwcap-type vial—both in terms of contaminants getting in, and cross-contamination throughout your storage systems. There is documented evidence of this having happened in the past. Also, if you have a leak and get vapor nitrogen in that vial, when you take it out, the pressure will change and could cause explosions and some dangerous situations.

Another challenge with vials is that if you think about a standard rubber or elastomeric stopper on a vial, those closures are a lot less secure in cryogenic temperatures. You have to do some pretty significant engineering to make sure that you are not getting leakage with those types of stoppers.

So, we need to start looking at what has been developed over the last 10–15 years. There are some options for sterile ready-to-use vials that have specifically been designed for this type of storage.

AH: To circle back on what Sean said, in cell therapy, there can be very, very small volumes of cells that are administered to the eye or the brain, or any other specific organ. There is really a dearth of solutions available to manipulate and to cryopreserve that small cell number.

SW: Yes. As an example of that, we talked to a lot of people in the dendritic cell vaccine space where they are talking about less than 0.5 mL for the final product volume.

Q Can you go deeper on the key challenges with bags and larger volume vials?

SW: There are a couple of things that we have already touched on. One of them is that when we have a soft material, a bag material can fracture. Over the last 10 years, there have

been some significant and important advancements in materials. Processing the bags correctly is not necessarily the issue anymore. However, I will say that biostorage facilities often see more breaks in the bags that come in than people might be aware of.

When you are handling thousands of units through cryopreservation, a 5% or even a 1% fracture rate is still quite significant. At US$500,000 or more for one therapy, it is a big loss for the company. More importantly, that is a therapy that may not be recoverable for the patient. We think that that low fracture rate is still important to consider.

The other thing is that as you go into larger volumes, you must consider the freezing profile and the geometry of the material within that bag. If you want to have a consistent freezing profile, you have to control the geometry. You cannot say, "We are going to scale up in volume and we are going to do a freezing process of a 5 mL vial. Now we are going to put 100 mL in a vial-shaped container and freeze that." You must have a very different freezing profile at the center of that. Bags resolve this issue, but you have to keep the same geometry in order to do that.

One of the big things alluded to earlier concerns scale. When you take a bag and you want to fill that with 1,000 units in a short period of time, or if you are considering some of these large incidence indications with many thousands of patient treatments, that is difficult to do with our current soft bags. You cannot hook those up to a fill system very easily to get that going. There are some challenges in the current configurations, so more rigid, automation-friendly types of containers would be really useful.

Q On that note, what soon-to-arrive innovations can we look forward to that will improve the situation?

AH: You can think of the newly arriving innovations in different categories: in equipment, in reagents, and in techniques.

There has been a steady development of new preservation technology, such as thawing technology, that allows us to record the temperature of the thawing unit as a function of time to go into the batch production record, which is very important. In terms of other technologies, I would love to have the ability to control nucleation in every sample in a controlled-rate freezer. That would help the field considerably.

In terms of other equipment, there are companies working on the bedside process. After the dry shipper comes from the developer and is at the clinical site, how do we create an infrastructure at the clinical site in terms of equipment that really facilitates the proper thawing and dispensation of the product? As for reagents, I have a personal bias here—the reagent that we are most invested in allows the DMSO-free preservation of cells.

We also need techniques to improve processing and to improve proficiency. Those are the things that I see as emerging areas in this field.

JA: Picking up on Allison's wish list, there are certainly exciting new products coming out in the near future. I share Allison's wish to be able to control ice, whether it is nucleation or growth, in ways that allow us to think about the freezing and thawing differently. Those technologies are soon to come to market, which will help to reduce our dependence on the traditional cryoprotectants that are used and introduce other ones that would be more favorable.

We are probably going to see a shift away from the reliance on equilibrium freezing, where you are cooling very slowly, to more kinetic-based freezing methods that are faster. While

they may not necessarily result in ice-free freezing or vitrification, they do result in conditions that are still highly favorable for cell recovery. To make those methods really practical, we are going to need the cooling and thawing technologies to support large-scale production. That will come in the near future, as more advances in cryopreservation sciences are made.

One of the things I am seeing in the industry is an attention to the cryopreservation process from the pre-cryopreservation analytical side right through to the thawing side, and understanding how decisions at each of those stages build on each other. As Allison mentioned, developing the data sets to support that process from a supply chain perspective will be really important. We are starting to see freezer companies, for example, that have built-in automation or tracking either by radio frequency identification or 3D barcode. They are able to track the thermal profile of a sample throughout its lifespan by indirectly monitoring time-out-of-temperature or time-in-environment. That is incredibly valuable data to understand because the thermal profile of these products will predict the outcome.

In the very near future, I expect to see transient warming excursions being taken a lot more seriously by regulatory agencies. Having that kind of data is going to be absolutely essential to knowing how many times your freezer was opened, and as a result, the exposure conditions for every sample that you have in that inventory. Without the technology to support that innovation, it will be unachievable to implement. Again, there are a lot of small innovations happening that are going to collectively help the field.

SW: To pick up on that last comment about smaller innovations, it is interesting if you look at the independent products that are available out there. A lot of the capability now exists to do these things that you were describing, Jason, and the things that we think we need in the industry for success. We do not have to develop and do anything brand new. We just need to put together these innovations in the way that the people need it to function. It is all already there.

One of the things that we on the tool provider side require is an understanding of exactly what is needed by industry so that we do not bring through something that does not make a lot of sense. We are close to being able to provide tools that allow you to do things like at-scale cryopreservation, reproducible volume, and novel containers for larger volumes. The more we hear from the end users what they need, the better we will be at hitting that target correctly.

Q What are the most pressing priorities when it comes to standardization in this field?

AH: Standardization would be fantastic, but I do not know if the field is ready for it. I have been a part of developing standards over many decades, none of which were actually used by people! The field must be elevated before standardization can take place. People need to understand the scientific principles behind preservation, and they need to understand how those scientific principles get translated into a protocol that is used for preservation. Then, that end outcome can be done consistently and reproducibly.

From what I have seen, the level of proficiency of people who are in the field actually doing preservation, is very, very low. Standardization will not be adopted and used until that proficiency is improved.

JA: In terms of the standardization, I would share that sentiment. We have to be cautious about what we are standardizing and why we are standardizing it. There has been a push to standardize some elements of the cryopreservation protocol that would work for a specific cell type or specific cell product, but are not necessarily what is going to be needed long-term. What the industry needs to focus on is standardizing elements like tube size, rack systems, and shipping container configurations. We have been focusing too much on standardizing the variables driven by the cell product themselves—the actual cryobiological requirements of that cell therapy. We need to get out of standardizing these variables because we are walking ourselves down pathways with our bioprocessing that are not going to be the best paths forward for cell types and cell products that we know are coming down the track.

The desire would be for us to standardize those steps where control and reproducibility are important. Again, I am hesitant to jump to standardization quite yet because there is some evolution that has to occur within the system first. There are certain needs holding up advances in a few areas. Tools like containers and freezing equipment could be standardized right now, but that does not mean locking down processes. That is a conversation that has to occur with the tool developers and the cryobiologists.

SW: When people raise a question about standardizing something, you have to ask if standards are even the right solution to the problem. Are people asking for standards because there is too much confusion in the process, or is it because standards would make their day easier since they would not have to think about how to solve a particular problem? Having said that, standardization of containers in terms of specific geometry and performance requirements makes sense because it allows you to automate systems. You could buy an automated system that will work with any vial, for instance. There are elements along those lines that you can develop at any time.

The other area of standardization that would really help has to do with the questions that developers need to ask about cryopreservation. I do not necessarily think that everybody is getting the same questions back from their regulatory authorities. For example, we need to know the standard method of qualifying your dry shipper so that you do not have to go through a year of validation just to show that one dry shipper that maintains temperature is going to work just as well as another dry shipper that maintains temperature. These are the kinds of things that we can come up with in standard protocols and standard requirements that would really help therapy developers address supply chain and logistics challenges.

Q Looking to the future, what will be some other key next steps to continue bridging the cold chain knowledge gap between cryobiologists, cell and gene therapy developers, and clinicians?

SW: The first thing that comes to mind is the future students coming into the field. What is great about this industry is that people who have studied cryobiology are getting roles with important companies that are putting cryobiologists on these programs to develop therapies. The answer is to just keep doing that. These are the people who are going to be able to tell their process development and research development scientists, "Hey, don't forget about these elements of this process, if you are going through it, because we cannot change things after you have come a certain distance."

"In terms of other [preservation] technologies, I would love to have the ability to control nucleation in every sample in a controlled-rate freezer. That would help the field considerably."

AH: The most important thing we can do is talk to each other. I will give you a specific context. We host a monthly meeting called CryoChats where we bring in experts to talk on a panel. We bring in everybody from cryobiologists to industry representatives. The point of it is to talk about the challenges people are facing so they can hopefully get help. That kind of community building is important, and can help us bridge the gap between academia and people who are in the trenches using this technology as part of their day-to-day work.

JA: I would echo both Sean and Allison's comments with respect to needing more highly-qualified individuals who have the skills to work with industry in developing the technology. We need to get the academics to be more engaged with the community. It is also really important to recognize that there is a role for the scientific societies and organizations that are bringing people together to make sure that there are applicable and easily accessible content and materials for each of the communities to engage with.

Oftentimes, we see the industry folks talking in their own spheres about the problems that they are facing, and the cryobiologists talking and publishing and presenting material in theirs, but there is not a lot that is crossing between these groups in terms of materials and knowledge. Even this panel is a good example of where we can bring together communities that would normally not necessarily mesh. It is important to find opportunities for collisions, bringing problems forward in an academically interesting way, while still being practical.

That is sometimes the challenge on the academic side. We look at the problem and say, "That's easy to solve," but we do not understand the complexity of the regulatory side, the quality system, the scale, or any of those other elements that are missing. There is a requirement for there to be joint sharing of that information in forums and vehicles that allow for that information to be translated.

The regulatory authorities and the government have a role here as well to engage more broadly. I am seeing that in various forums where the regulatory agencies realize the field is coming into problems and, in an effort to solve those problems, they are trying to bring together the industry and academics through funding vehicles and grant programs. Money can sometimes unlock innovation. If we have additional funding in various forms in both industry and academia, these communities could come together and allow for innovation to proceed much more quickly, as opposed to having to occur more naturally.

The final step is to recognize that cryopreservation does require some tweaking. It is not a standard process. We are trying to standardize a lot of things in advanced therapy manufacturing. There are a couple of ways of transfecting cells in order to actually express a vector, for instance. Cell expansion technologies are becoming a little bit more standard as different manufacturing companies jockey for position in the market, too. But the cryobiology process itself is still fairly open and there is a lot of opportunity for innovation within that. How do we provide encouragement early in process development to allow that innovation to continue, and to be evaluated before processes begin and it becomes more difficult to do?

Looking to the future, opportunities to get those innovative ideas into companies and into academic programs early would really be helpful.

Q Do you have any parting comments?

SW: We are all very lucky to be involved in this really innovative part of the healthcare industry. The promise of cell therapies is one of the most interesting things that has happened in my lifetime. However, we have got to keep communicating because the promise is so big. If we just let it fall down, we will be missing so many opportunities.

JA: We are trying to solve a really hard problem by putting something biologically alive into a state where it is not biologically alive and store it for an extended period of time. The kinds of cells that we are preserving do not do that naturally. The science to make this happen in itself is pretty amazing. Then, to do it at an industrial scale is quite the accomplishment. Now, we have to look at translating what we are doing with cells into more complex biological therapies, like organoids, tissues, and ultimately, human organs.

The same kind of technology path is taking us down that stream. As an industry, how do we start to think about getting ready for this future where biological material that is stored in low temperatures for periods of time becomes the new medicines? We are seeing it now, but the future is so much brighter, and it is going to be enabled by the ability to cryopreserve and store these products.

AH: We have just scratched the surface here today. There are a lot of opportunities to learn more and become more involved in the field of preservation. The Society for Cryobiology will be meeting in Washington, DC in July 2024. People can come, meet cryobiologists, learn some of the science that is there, and really become more immersed in the field. I strongly encourage people to attend that meeting and learn what they can, so that they can continue down the path to wisdom and greater knowledge in the field.

BIOGRAPHIES

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SEAN WERNER is the Chief Technology Officer of Cell Processing at BioLife Solutions, a leading provider of bioproduction tools and services to the cell and gene therapy and broader biopharma markets. BioLife acquired Sexton Biotechnologies in 2021 where Sean was President of the company known for providing processing and handling solutions for the cell and gene therapy industry. Sean received his PhD from Purdue University in Biology followed by post-doctoral positions at the Indiana University School of Medicine and Eli Lilly and Company. Sean has previous experience filling various roles in the scientific, global regulatory, and general management functions supporting medical devices, autologous cell therapy, and single use disposable development programs. In his 23 years working in the life science industry, he has guided regenerative medicine research programs, pre-clinical, and clinical testing and submission strategies leading to global commercialization of medical devices and bioprocessing tools and successful initiation of multi-national cell therapy clinical studies.

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AUTHORSHIP & CONFLICT OF INTEREST

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You can also watch the recorded roundtable here

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