

Mayo Clinic Q & A - Dr. Julie Allickson

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SPEAKERS

Dr. Halena Gazelka, Dr. Julie Allickson, Narrator

N Narrator 00:01
Coming up on Mayo Clinic Q&A,

D Dr. Halena Gazelka 00:04
Biologics are very complex, much more so than what you'd normally receive from a pharmacy. Many times, we have to do a lot of testing to understand how to identify it and how to characterize these cells. Because it's a living source. The important thing is that there's an opportunity to use these types of therapies to cure rather than just treat patients.

N Narrator 00:27
Biotherapeutics and biomanufacturing are moving discoveries from the lab to clinical trial and into commercially available therapies. To move technologies forward, partnerships are key.

D Dr. Julie Allickson 00:38
Collaboration in this field of regenerative biotherapeutics is so important for us to keep our pulse on the end goal. And the end goal is really to treat the patient. Thank you, Dr. Gazelka. I'm excited to be here today.

D Dr. Halena Gazelka 00:49
Welcome, everyone to Mayo Clinic Q&A. I'm your host, Dr. Halena Gazelka. People are living longer, which is good news. But as people live longer, they are also more likely to acquire chronic diseases or develop age-related illnesses. Through research, clinical trials and

biomanufacturing, Mayo Clinic's Center for Regenerative Biotherapeutics is working to develop new types of medicines derived from the human body to treat chronic and age-related diseases. That's a mouthful. And here to help us understand this better and to explain biologics and biomanufacturing is Dr. Julie Allickson. She's the director of Mayo Clinic's Center for Regenerative Biotherapeutics. Welcome, Julie. Well, I'm absolutely excited to have you here because I learned so much every time that I talked to someone about regenerative medicine and biologics, and I'm wondering if you could just explain for our listeners, what is meant by biologics?

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Dr. Julie Allickson 01:54

Yes, so, biologics is a living source of medication. You could think of it as a vaccine, or a blood product or cell and gene therapy, or a tissue that might be implanted. So it's composed of sugar or proteins or cells or tissues. And it's isolated from a natural source, so human and animal, or a microorganism.

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Dr. Halena Gazelka 02:20

Interesting. So, Julie, how does that differ from therapeutics that we would get saved from our pharmacy medications?

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Dr. Julie Allickson 02:28

Yeah, so that's a great question. Biologics are very complex, much more so than what you'd normally receive from a pharmacy. And so in contrast to those drugs that are chemically synthesized or produced, and the structure is known, it's the same every time, a biologic is very complex. And many times, we have to do a lot of testing to understand how to identify it and how to characterize these cells because it's a living source. So they tend to be more sensitive to temperature as a living drug. But the important thing is that there's an opportunity to use these type of therapies to cure rather than just treat patients, as we move forward looking at different ways of being able to use these products.

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Dr. Halena Gazelka 03:18

Julie, I and probably many of our listeners are familiar with the idea that some of the very common medications that we use, such as aspirin, such as some antibiotics are derived from either plants or fungus even. And is that different than what you're talking about with biologics?

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Dr. Julie Allickson 03:43

No, those would be considered a biologic as well, because it's from it's from a living organism. So that would be the same. And I think the thing that's on the top of everybody's mind might be that the cells are much different than what you would think of than a Tylenol that's chemically synthesized.

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Dr. Halena Gazelka 03:59

Certainly, that makes sense. So what type of chronic diseases or age-related conditions can be treated with biologics? Julie, could you explain what is meant by gene therapy and cell therapy?

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Dr. Julie Allickson 04:07

I think the one thing that everybody could relate to would be cancer. That would be, you know, there's a lot of cell therapies that have been used for a very long time, blood cells such as cord blood, and now we're looking at a lot of different applications for cancer, rheumatoid arthritis, and inflammatory diseases. We look at cells that might decrease that inflammatory response. So stem cells used, I would say, for cancers, genetic diseases, and now most recently immunotherapies that specifically kill certain cancer cells. So there's a wide variety that treats chronic diseases currently, or we're investigating through clinical trials to determine if it's effective. Yes, cell and gene therapy are sometimes thought to be interchangeable terms, but they're really much more unique in medicine. And cells are really placing a new cell into your body. It might be your cell, or it might be another cell from somebody else that's highly tested to treat a certain condition. So I mentioned cord blood, that's one that's been used for, you know, several decades, for hematological, or blood diseases. So if there's a part of the body that's damaged or missing cells, we can inject those into the body. If you compare that to gene therapy, you can alter a specific part of a genetic makeup, so you're treating a genetic disease or an inherited disease. So, for example, there's gene therapy, currently, that's being used for a disease called MSA, multiple spinal atrophy. And that's a viral, a virus that carries the gene to those cells to replace it. So it's much more specific, the cells don't really affect the genes. And then also gene editing as part of gene therapy. So where you're actually editing a gene, so you can be editing out a gene, or editing in a gene, usually for inherited diseases. So that's also a part of the gene therapy. And sickle cell would be one of the diseases that we would look at being able to edit the gene to be able to cure.

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Dr. Halena Gazelka 06:39

That is just fascinating. And I imagine that for some, it's we're talking about infecting someone with a virus, aren't we always trying to avoid viruses?

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Dr. Julie Allickson 06:48

Yes, there are a lot of safety parameters. FDA goes through many, many steps before they can approve anything to be able to move forward. So there's a lot of safety testing that that takes place, and that we understand that it would just go to where it needs to go in the body. And then it's no longer there. So you're right, that does take a lot of effort to be able to use that in a patient.

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Dr. Halena Gazelka 07:14

Julie, tell us about biomanufacturing. And do we do this at Mayo Clinic?

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Dr. Julie Allickson 07:19

Yes, we do. We've actually been manufacturing products probably over the last decade. We manufacture products across the enterprise. So we have manufacturing facilities in Rochester, Minnesota, in Jacksonville, Florida, and in Phoenix, Arizona. And this manufacturing then uses those biological systems that we talked about, to be able to produce products. We can also include synthetic materials. So if we were looking at tissue engineering, we would incorporate a synthetic material as well as the biologics. One example of the biomanufacturing that has been used here for a long time at Mayo Clinic is harvesting fat tissue and taking those adult stem cells from the tissue. So we digest that tissue, we take the stem cells, and then they can be used to treat diseases. So we're in early phase clinical trials, looking at things such as osteoarthritis of the knee, where we might be able to decrease the pain and modulate or change the immune system in that area that's going to help to repair the area.

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Dr. Halena Gazelka 08:40

That's very interesting. Tell us a little bit about 3D printing and biomanufacturing and how they intersect.

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Dr. Julie Allickson 08:49

Yeah, so exciting. There's so much potential in 3D printing, and it's been around for a long time. I think some of the first discoveries just looked at using an inkjet printer and took out where you'd put in the ink and put in cells and what we call you know, biocompatible material, where they could actually print something. But it allows us to customize or produce a biocompatible product that's three dimensional. So the 3D printing, without the bio, is basically printing a scaffold, and we are right now, in the process of doing that in Arizona at the Mayo Clinic. Dr. Lott, has a 3D printing setup in the cleanroom. And he is currently using that to heal larynx or your voice box if you have cancer or a traumatic injury. So he's really pioneering those 3D bioimplants and tissue engineering to regenerate the larynx. So I do feel we're ahead of the curve. The 3D bioprinting which incorporates then the biologics or cells. We don't see, there's nothing that's gone to clinic yet, but we're certainly working on that piece of it. And that gives us a lot more potential to look at producing organs and tissues once we put the cells together, but there's just a lot of potential to customize what we need in a patient. So we can scan an organ or tissue and then we can produce it.

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Dr. Halena Gazelka 10:22

That's just fascinating. The way that I've been familiar with that before, we've actually done a Q&A on it, is the use of 3D printing to make, we were making a lot of little COVID viruses at the beginning of COVID. But also replicas of organs based on people's CT scans, et cetera, so that surgeons can determine how to do the case in the operating room. It's really amazing.

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Dr. Julie Allickson 10:46

Yeah, it's amazing how its advanced surgery. So there's just a lot of applications for the 3D printing.

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Dr. Halena Gazelka 10:53

Wonderful. Tell us about collaborations in the biomanufacturing space, I can imagine that there are a lot of people working on a lot of different areas, and that bringing them together is important. How does that work for your teams?

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Dr. Julie Allickson 11:06

Yeah, definitely collaboration in this field of regenerative biotech therapeutics is so important for us to keep our pulse on the end goal. And the end goal is really to treat the patient. And without being able to commercialize these technologies, we wouldn't be able to treat all the patients that need it. So we recently signed an agreement with National Resilience. They're a technology focused biomanufacturing company that are dedicated to bringing these medicines to the patient, then they look at end to end solutions. How do we manufacture these products safely and at scale? And they are going to be working side by side with us on process and analytical development. What does that mean? That's kind of the first couple steps before we get into manufacturing. So they will help to facilitate the acceleration of those therapies to move them into clinic into the manufacturing process. And they're going to be right within our health care corridor, or the Destination Medical Center, in the newly built Two Discovery Square. So they're building a new space there. And we're really excited because our new process development space will be built right next to that. So that's one relationship that we have. And the second was a bit of a news that came out about a week ago, where Mayo Clinic is teaming up with Hibiscus BioVentures and Innoforce to produce and launch Mayflower BioVentures, which is a cell and gene therapy accelerator where we identify critical therapies. And that's in discovery. And we want to be able to advance those quickly into startup companies. So looking at all of the preclinical studies that get done in the early phase clinical trials. And we think that this collaboration is really going to bridge the gap between industry and the innovative work we here have here at the Mayo Clinic, and enabling startups to move forward. It was interesting to me, because I started a year ago. And when I saw this list of 100 discovery projects, I was thoroughly impressed. I think that we have a lot of hard working clinical investigators and scientists that work heads down. And sometimes we don't always get to hear about everything. That's amazing that's going on at the Mayo Clinic. But I was super impressed. And we do have a long line of industry and pharma that want to understand what we're doing here at the Mayo Clinic. And these relationships are key to be able to move things forward. As we're building bio manufacturing. The important piece for us is really to look at the early phase clinical trials, de-risk the technology and then allow someone else to license or take those to a startup. So this really facilitates all of that.

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Dr. Halena Gazelka 12:28

That's amazing. It's so wonderful to hear what's going on. It's one of the reasons I love doing this podcast, I learned so much myself and get to share it with listeners. Tell us Julie, what should we be looking for in the short-term and long-term in biotherapeutics, do you think?

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Dr. Julie Allickson 14:22

Yeah, I love that question. I mean, the near term, if you look at 2022, we already have several cell and gene therapies, that are called CAR-T therapies, six that have been approved. And that's a lot for the FDA because there's a total of 20 plus projects, under cell and gene therapy, that have been approved over the last, you know, decade. So there's really a significant uptick in these therapies. And CAR-T is for blood cancers and we're looking at those potentially, in the future, to be able to use them for solid tumor. So I think that's one of the near terms. The other thing is that we've been working on CRISPR or gene editing for a decade. And we do believe that probably in less than a year, we will see CRISPR therapy for sickle cell anemia. It's in a phase three right now. And there are really good results. It's on a fast track with FDA called RMAT. And that means they have more face time with FDA. And if they see highly stunning results in efficacy and safety, they're able to move them a little bit faster. I think in the mid term, or seeing induced pluripotent stem cells. That's where they take a small biopsy of skin. And they're able to add factors that can put push it back to an early state where we can differentiate those cells into several different cells. And just recently, the NIH came out with the first clinical trial using these cells, that's demonstrated that it prevented blindness in animals. So we're super excited to see that. And when I think about long term, I think about the 3D bioprinted organs, and there's a lot of excitement around that. The opportunity to really eradicate the transplant waiting lists. If you think about it, you know, it's more than a lot of people think, you know, it's like the science, sci fi movies, but really, it's, you know, has the potential to transform healthcare, the way we see it today. There's, um, you know, communications of companies. One example, I would say, United Therapeutics and 3D Systems that had just recently released a lung scaffold that they've been working on and talked about this at a conference in San Diego, and said that, you know, they really planned to see these manufactured, hopefully, within the next five years, and that would be using the patient cells, so there'd be no rejection. So that would be you know, such an incredible difference. For health care, you know, for the quality of life, these patients, for all the patients waiting in line, and then it would also significantly affect healthcare economics, the way we see it today. So there's just so much potential in the field. It's, it's quite exciting.

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Dr. Halena Gazelka 17:18

Really exciting is so fascinating. So it sounds like, more and more, our physicians will be able to treat us with biologics as time goes on.

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Dr. Julie Allickson 17:27

I hope so. Fingers crossed, but it's definitely a bright future. There's a lot of investment in the field. And Mayo Clinic is certainly prioritizing this across the enterprise, to allow the patients here to have treatments focused on rare and complex diseases, Not always for the rare diseases are there opportunities to bring some of these therapies forward, and here at Mayo Clinic, we want to make sure that that happens.

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Dr. Halena Gazelka 17:54

What an incredible example and examples today that you've brought forward of not only innovation, but keeping the needs of the patient first. It's just inspiring.

innovation, but keeping the needs of the patient first. It's just inspiring.

D Dr. Julie Allickson 18:04

Thank you. Thank you so much. Inspiring to be here at the Mayo Clinic.

D Dr. Halena Gazelka 18:09

It is. Challenged every day to learn more. Thank you for being here today, Julie.

D Dr. Julie Allickson 18:15

Thank you for your time. I appreciate it.

D Dr. Halena Gazelka 18:18

Our thanks to Dr. Julie Allickson, the director of Mayo Clinic center for Regenerative Biotherapeutics, for being with us today to explain to us what biologics and biotherapeutics are. I hope that you learned something, I know that I did. We wish each of you a wonderful day.

N Narrator 18:35

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