

ISCT Featured Member: Doug Padley

Join Up Early, Enjoy the Ride



Doug Padley

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Our Featured ISCT Member is Mr. Doug Padley of ReGen Theranostics, Inc. (Rochester, Minnesota). Doug attended The University of Iowa, where he earned his Bachelor of Science degree and completed the Medical Technology Program (equivalent to a Clinical Laboratory Science program today). From there, Doug went on to work at the forefront of developments within cellular therapy, from initial scale-up of bone marrow processing to the advent of advanced regenerative therapies. His career is a testament to the roller coaster that may come with working in cellular and gene therapy, but also how rewarding it can be to take chances and hang on for the ride.

How long have you been an ISCT member?

A long time, I don't remember exactly. It was called ISHAGE then, and it was probably within a few years of when the society was founded. I attended a meeting in San Diego in the early 90's called Bone Marrow Processing and Purging, and ISHAGE came out of those early purging meetings.

What was your first job in cell & gene therapy?

After 3 years of blood banking on the overnight shift, which is a type of cell therapy, I helped set up the bone marrow processing laboratory at the University of Iowa. Iowa's program was one of the early leaders of unrelated bone marrow transplants. Autologous peripheral blood stem cell transplants were just taking off at that time, so the role of the lab increased. And then Iowa began pediatric bone marrow transplant using T cell depleted bone marrow. I spent 13 years at Iowa in Transfusion Medicine/Stem Cell Processing then 19 years at Mayo Clinic in Rochester doing similar things in an ever expanding role and laboratory. I think I was the fourth

employee hired by Dr. Dennis Gastineau in the newly-formed Cryobiology unit, the precursor to the Human Cell Therapy Lab. Mayo is one of the leading academic cell therapy centers, and I enjoyed playing a part in helping that program grow to what it has become.

Are there any career transitions that were challenging and/or exciting for you looking back?

Starting a laboratory from nothing, only a few years out of school, offered plenty of opportunities to make mistakes and learn from them. Being involved in this field from before the time it was recognized as such to what it is now has been interesting, to say the least. I'm grateful that I got a chance to do a little of everything: processes development, regulatory, clinical trials, conference planning and presenting, standards setting, training, mentoring and more. The transition from an employer with 50,000+ employees to a start-up company with <15 employees has been quite a transition. It has been fun starting over from scratch. I think I was the tenth or eleventh employee in a group that didn't know a lot about GMP - I was that expert.

ReGen came out of the Todd and Karen Wanek Family Program for Hypoplastic Left Heart Syndrome (HLHS). ReGen's goal is to treat HLHS with cellular therapies. We support an actively enrolling phase 2 trial of autologous umbilical cord blood mononuclear cells delivered into the right ventricle, during a standard of care cardiac surgery. We are also developing an autologous iPSC derived cardiac lineage cell product that is currently in pre-clinical development.

Do you see any differences between healthcare in academia and industry?

My career has come full circle. Early in my time at Mayo, we worked with the company (that later became Dendreon) on their early phase clinical trials of dendritic cells for prostate cancer, which later became the first FDA licensed cell therapy for treating cancer. Now 20+ years later I'm the one at the startup company working with partners at academic centers, helping get our product licensed. I do sometimes miss the variety of studies and interactions that the IMPACT lab at Mayo Clinic offered me, and it is harder to stay engaged in the broader field when focused on one disease. But that is where it helps to keep up with my connections in the field to stay informed and open to fresh ideas.

Do you have thoughts on the roles of formal versus informal education in our field?

Since I started before this was recognized as a field, there wasn't much of a choice. It was on-the-job training and learning through interaction with colleagues. I think it is important to get hands-on experience, time in the lab and in lab-related activities, see a variety of things. First generation lab directors are retiring and the next wave will be bringing a combination of background knowledge and real-life experience. I'd also note that collaboration is key to learn about the entire field and how your colleagues do things. Lab inspections also teach you a lot.

What is your outlook on mentoring in the field?

I enjoy mentoring, bringing people up to speed and making the place run without me. There is a lot of mentoring at ReGen that is very similar to mentoring in academia. We have a young group with different perspectives and work styles. In the early days, we were a startup where everyone, myself included, cleaned, took out the garbage and wrote protocols. Everyone is still wearing a lot of different hats. Mentoring is the key because we are still building a culture there, institutionalizing things like “if you didn’t write it down, then it didn’t happen.”

Any advice you would give an early stage professional now?

Get involved in the field however you can. The relationships you develop will last throughout your career. Early in my University of Iowa bone marrow transplant laboratory days, we participated in a multi-center clinical trial of a novel T cell depletion method that required numerous face-to-face meetings. Literally decades have passed since then and I’m amazed how many of those people are still working in this field, and how many I still have regular contact with. Most importantly, they and others I’ve gotten to know...have become not just collaborators, but friends. The field is still small enough so that you still have people who want to help each other. And ask a lot of questions. Probably to a fault I ask too many questions.