Academia: Krishnendu Roy, Robert A. Milton Chair—Parker H. Petit Institute for Bioengineering and Biosciences, Georgia Tech

Yes, hi, I'm Krish Roy. I'm a professor here in biomedical engineering at Georgia Tech, and I direct two national centers in cell therapy manufacturing—the NSF-funded Engineering Research Center for Cell Manufacturing Technologies, called CMaT, and a philanthropically funded center called the Marcus Center for Therapeutic Cell Characterization and Manufacturing. I'm also part of the executive Board of the Standards Coordinating Body and have been part of that since the beginning/inception of the SCB.

How could the use of standards benefit regenerative medicine research?

Yeah, this is a great question. You know, I remember when we first started talking about standards with NIST at our consortium meetings, and the first thing they say, you know, is that the field is far from standards. You all don't even agree how to count cells, which is one of the most fundamental activities that everyone does every day in the cell therapy/cell manufacturing space. And that was very true at that point, so some of the early standards that NIST worked on was this guidance document for cell counting.

Audio	Visual
And this is sort of where the field still is, and there are lots of activities on the standards development side that are there.	ISO 20391, Biotechnology – Cell Counting Part 1: General guidance on cell counting methods Part 2: Experimental design and statistical analysis to quantify counting method performance

Several standards have been implemented already, so the field is moving very quickly. But I feel that bringing standards—not just in industry—but into the academic research labs and training graduate students and undergraduate students from early on in following standardized assays and analytical tools and methods and protocols really creates better reproducibility, really from the R&D data all the way to the manufacturing products, and also creates the ability for comparability between one lab's work with another lab's work and makes translation that much easier than what it is currently. So, standards absolutely have to play a vital role from the academic side, obviously from the regulators' side, from the clinical manufacturers' side—standards are the key tool to make sure we have reproducibility, comparability, and in ease of translation. But bringing [them] back to the research domain from very early R&D to me is absolutely critical.

What standards advancement projects have you been involved with?

Yeah, so one of the ones we have been pretty deeply involved with is the rapid microbial detection—RMTM project that SCB undertook pretty early on in collaboration with NIST, and I think that was extremely critical, because, as you know, there is very little consensus on what are the best assays for

microbial detection, and how do we do that faster, and cheaper, and more accurately. So, that's one that we worked on, you know—I'm a co-author of the *Cytotherapy* publication that came out of the SCB on that topic. We have also been part of the Flow Cytometry Consortium with NIST; we and others have taken part in the cell manufacturing equipment standards thing as well, so there are a number of projects that we have been involved through the SCB and the ISO over the years, and I think more and more are coming down the pipe.

What motivates you to remain involved in standards development?

Yeah, I think standards are really the fundamental workhorse for any industry, especially any manufacturing industry, and I give this example—that when, you know, the reason my cell phone when I go to another network or I go out of the country and I switch it off and it seamlessly starts working is because of standards in the wireless industry—precompetitive standards that every carrier has agreed to despite their competitiveness and other aspects of that industry. And that crosstalk between one equipment to other equipment, that portability of the data, the ability to trust the data, the ability to reproduce the data and think about comparable analysis of one product at multiple different centers and institutes is the fundamental basis of progress in the industries. So, standards is incredibly important for us to grow this industry, to make reliable products, reproducible products, cheap products—and so, which is one of my primary motivations to be sitting and be part of the Standards Coordinating Body. But I also think this bringing the standards into the academic domain is an absolutely critical process for the progress of the field. So, that sort of is my motivation in being able to stay in connection with the latest in the standards development of the field.

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