

Industry: Claudia Zylberberg, Founder and Executive Chair, Akron Biotech

I'm Claudia Zylberberg, co-chair and co-founder of Akron Biotech, a company that has been involved in ancillary material manufacturing since the very beginning, 18 years ago.

I became part of the SCB since the very beginning, understanding that the industry maturity was coming to a point where common language was needed among stakeholders, manufacturers of cell therapies, and providers of services and products for that industry. Since cell therapies are not manufactured in the same manner as biologics, new standards may be needed to create an opportunity for these products to be manufactured in a compliant and consistent manner.

What are some ways the use of standards has benefited Akron Biotech?

The use of standards gave us the opportunity to see the gaps and opportunities to improve our products to fulfill our customers' needs, and therefore their regulators and their pipelines.

What are some standards advancement projects that you have been involved with?

Akron was involved since the very beginning in ancillary materials. Ancillary materials are critical for the manufacturing of these products. Cell and gene therapies are not manufactured in the same way as regular biologics like monoclonals and others, so a new set of standards were much needed. The product is not being sterilized at the end, so definitely the ancillary materials were critical. And then after that, we became very much involved in bioprocessing, scaffolds, and cryopreservation media. Those are the four standards that we were very actively involved since the very beginning.

How will standards development benefit the community?

I think that as the industry matures, common language and having an understanding among all the stakeholders is very critical, so standardization becomes key to make sure that the expectations on the products and the processes are aligned with the regulatory standards.

So, I think that, basically, having all the stakeholders in the industry—customers, providers, service providers, and bioprocessing equipment providers—all at the table creates a conversation that makes everybody understand where everybody is and where the gaps are, and moves the industry forward and upwards.

Why is it important for others to become involved in standards development?

I think that the industry only will grow as standardization occurs, and I believe that having an early opinion at the table is critical. Once the standards are done, it's a set of rules that everybody will follow. But to create those rules together in a conversational manner and a discussion manner seems the appropriate way to do it. And, of course, afterwards create the outreach and educate the community.

I believe that this is a long-term project and very dear to me and I believe that this is the way that the industry is going to grow, and the patients will benefit a lot from it. So, definitely, my commitment is not



only to create those standards, but I think that sitting at the table with different stakeholders and giving them the opportunity to understand the importance of it, and then eventually outreach and educate the community about them.

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