Advances in AAV process development

"Overall, we have been very pleased with the regulatory agencies and how they are approaching gene therapy. It's a very rapidly evolving space, and they're trying to learn and work with manufacturers to make these therapies work better.
If your organization is trying to pursue an accelerated pathway [...] you need to pull in some later-stage activities earlier in the development than you normally would. Organizations need to be ready for this – if you think you're going to be trying to register on Phase I data, you need to prepare to do a lot of these BLA-enabling activities at your IND stage."

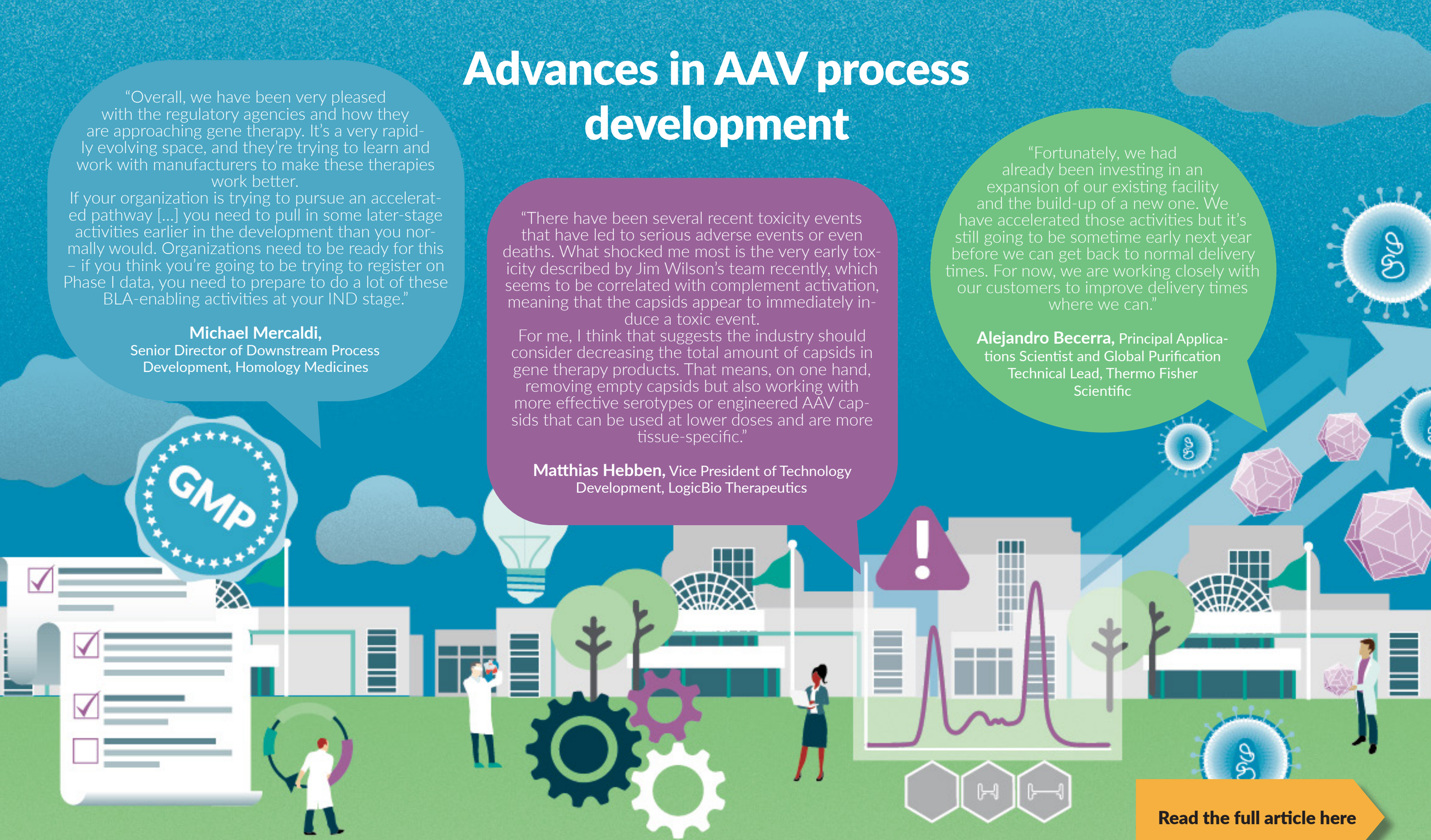
Michael Mercaldi,
Senior Director of Downstream Process Development, Homology Medicines

"There have been several recent toxicity events that have led to serious adverse events or even deaths. What shocked me most is the very early toxicity described by Jim Wilson's team recently, which seems to be correlated with complement activation, meaning that the capsids appear to immediately induce a toxic event.
For me, I think that suggests the industry should consider decreasing the total amount of capsids in gene therapy products. That means, on one hand, removing empty capsids but also working with more effective serotypes or engineered AAV capsids that can be used at lower doses and are more tissue-specific."

Matthias Hebben, Vice President of Technology Development, LogicBio Therapeutics

"Fortunately, we had already been investing in an expansion of our existing facility and the build-up of a new one. We have accelerated those activities but it's still going to be sometime early next year before we can get back to normal delivery times. For now, we are working closely with our customers to improve delivery times where we can."

Alejandro Becerra, Principal Applications Scientist and Global Purification Technical Lead, Thermo Fisher Scientific



Read the full article here

Cell & Gene Therapy Insights **and Thermo Fisher Scientific brought together a panel of experts to discuss how viral vector manufacture has evolved over the past 2 years, the challenges created by the pandemic, and what we can expect in the future.**

Cell & Gene Therapy Insights 2022; 8(1), 59; DOI: 10.18609/cgti.2022.030

CELL & GENE THERAPY INSIGHTS

In partnership with:

ThermoFisher SCIENTIFIC