the business of Bio & Health Sciences
BioSpectrum
ASIA EDITION

Building the Digital Backbone of Cell and Gene Therapy: Why Data, Not Science, May Determine the Industry's Future

June 22, 2026 | Influencers | By Ankit Kankar | ankit.kankar@mmactiv.com

Alexander Seyf, CEO and Co-founder of Autolomous and Founder of Act for Hope, discusses data interoperability, AI-enabled manufacturing, regulatory convergence, and the infrastructure needed to scale advanced therapies globally.

Cell and gene therapies have transformed the treatment landscape for complex diseases, yet scaling these innovations beyond individual successes remains one of the industry's greatest challenges. **During BIO International Convention 2026 in San Diego, BioSpectrum Asia spoke with Alexander Seyf, CEO and Co-founder of Autolomous and Founder of Act for Hope, about the critical role of digital infrastructure in enabling the next phase of CGT growth.** From data interoperability and AI-powered manufacturing to knowledge sharing and regulatory harmonisation, Seyf argues that the future of advanced therapies will depend as much on information flow and operational intelligence as on scientific breakthroughs.

Data interoperability remains a challenge across the CGT ecosystem. What practical steps are needed to improve data sharing without compromising compliance and patient privacy?

We've been talking about data interoperability for years, and the needle hasn't moved much. That's because the conversation keeps landing on whether companies should share more, when the real question is how you build a framework where sharing is structured, bounded, and safe enough that it actually happens - federated models, common ontologies, consortia that let organisations put anonymised process and outcomes data into a shared pool without surrendering IP or exposing patient identifiers.

What's missing isn't the technology; this exists. What's missing is the governance layer. Regulators, CDMOs, developers, and platforms like ours need to agree on a common data architecture so that when information moves between a sponsor, a CDMO, and a testing lab, it doesn't need to be translated three times and validated from scratch at each handoff. GxP compliance should enable that kind of data integrity, not create a reason to keep everything siloed.

Patient data protection and competitive data protection are different arguments. They get used interchangeably, and they shouldn't. The frameworks for responsible sharing - de-identification, consent, governed access - are mature enough. What hasn't shifted is the commercial calculus around contributing data to a shared pool rather than holding it.

How can the industry better leverage lessons from failed or discontinued programmes to accelerate future development?

This is one I feel strongly about, and I've said it before - sharing unsuccessful outcomes needs to be treated as seriously as publishing breakthroughs. The scientific community has an almost cultural aversion to discussing what didn't work, but in CGT, that reluctance has real costs. When a programme is discontinued, the manufacturing learnings, the process deviations, the patient selection data - all of that disappears into a filing cabinet or a confidential data room.

That's a structural problem. Act for Hope was co-founded specifically because we believe the knowledge infrastructure around CGT development is as important as the therapeutic pipeline itself. If we're asking health systems and payers to fund these therapies, we have a responsibility to demonstrate that the industry is learning efficiently. Repeated failures in similar areas, caused by the same unaddressed process variables, are not acceptable when the tools to address them exist.

Practically, this means creating a channel - whether through consortia, regulatory repositories, or peer publication - where discontinued programmes can contribute process and safety data to the field. It doesn't require commercial disclosure. It requires intent.

What role will digital infrastructure and AI play in reducing operational uncertainty in advanced therapy manufacturing?

Operational uncertainty in CGT manufacturing comes from a very specific source: you're working with living, variable biological starting material, often a single patient's cells, under time pressure, through a complex multi-step process involving multiple sites and stakeholders. Every manual touchpoint is a potential source of deviation, and every paper-based record is a delayed signal.

Digital infrastructure fundamentally changes the signal latency. When you have real-time data capture across the full chain of custody - from apheresis through to final product release - you're not reviewing what happened, you're responding to what's happening. That's a different operational posture entirely.

The AI conversation in this industry tends to skip a step. The capability exists - pattern recognition, yield forecasting, anomaly detection across batches. What often doesn't exist is the data foundation underneath it. Process data spread across disconnected systems, batch records on paper - that's not an input you can do anything with, regardless of how sophisticated the tooling is.

That's where we focus. autoloMATE is designed to create that structured, GxP-compliant data environment so that AI tools - whether embedded in the platform or brought in by the customer - have something coherent to work with.

How is Autolomous helping developers create a more connected CGT value chain?

The CGT value chain is genuinely complex. You have therapy developers, CDMOs, logistics providers, testing labs, clinical sites, and regulators all needing to exchange information about a single patient's treatment journey. Historically, those handoffs have been managed through a combination of paper, email, and disconnected systems - which works at low volume but falls apart completely as you try to scale.

The coordination overhead in CGT manufacturing is enormous - and most of it is just people chasing information that exists somewhere but isn't accessible to the person who needs it. autoloMATE puts process data, batch records, chain of custody and deviation management in one place, with the right access controls. A sponsor gets manufacturing oversight without a site visit. A clinical team tracks a patient's product without the email chain.

Our set of over 25 integrations is a good example of how this extends into physical automation - integrating digital orchestration with instruments and robotic processing platforms so that the data and the process are genuinely unified, not bolted together after the fact. The goal is always the same: remove the friction from information flow without removing the controls.

Looking ahead, what ecosystem change would have the greatest impact on CGT scalability?

Regulatory convergence. It's not the most exciting answer, but it's the right one.

Right now, a therapy approved in one jurisdiction requires a substantially different submission in another, often requiring additional clinical data, different manufacturing standards, or separate GMP inspections. For a small developer or an academic spin-out, that's not a manageable overhead. It's a reason to deprioritise markets or delay access. For patients, it means geography continues to determine whether a therapy is available to them.

The tools exist at the development stage; the gap is at the commercial scale, where GxP expectations still diverge, manufacturing standards aren't aligned, and an inspection in one market doesn't travel to another. That's not a scientific problem, and it directly affects which patients can access these therapies and when.

Digital manufacturing platforms can support that convergence by providing the kind of auditable, structured process data that regulators need to have confidence in a product without requiring redundant oversight. That's part of what we're building toward - not just compliance with current frameworks, but an infrastructure that makes regulatory confidence portable.