

HPE 
GreenLake

Andelyn Biosciences: accelerating gene therapy through The Digital CDMO

Born from a pediatric hospital that pioneered gene therapy, Andelyn Biosciences became a commercial entity that uses groundbreaking research to turn hope into reality for more patients. The startup leverages data throughout the product lifecycle to accelerate the development of investigational new drugs, delivering greater value for its biopharmaceutical clients. With a scalable edge-to-cloud platform, it's ready to define the future of gene therapy.

A legacy of hope

A spinoff created from the Nationwide Children's Hospital in Columbus, Ohio—where the first FDA-approved systemic gene therapy was discovered—Andelyn Biosciences is now a contract development and manufacturing organization (CDMO)—helping customers in the biopharmaceutical industry develop and commercialize gene therapy products.

The company leverages the expertise developed by researchers at its parent hospital, now taking it to commercial scale. The Andelyn team has been responsible for over 450 current good manufacturing practices (cGMP) clinical batches and over 75 investigational new drug (IND) approvals. It provides services to pharmaceutical clients spanning every stage of investigational new drug applications, starting at proof of concept, through to clinical testing, human trials, and entering the marketplace.

“We save and transform lives,” relates Bryan Holmes, Vice President of Digital and Technology Solutions at Andelyn Biosciences. “Our mission statement revolves around the acceleration of development and manufacturing, to bring more treatments to more patients, and turn hope into reality.”



Industry: Healthcare

Region: United States

Vision

Digitalize operations to accelerate the development and manufacturing of gene therapy products

Strategy

Build a data-first environment that can scale to serve new customers and create more treatments

Outcomes

- Delivers a platform for growth without a huge upfront investment
- Protects intellectual property by keeping critical workloads secure
- Empowers staff to focus on science with a simplified, fully managed environment

The data foundation for digital manufacturing

Andelyn Biosciences harnesses data throughout the entire product lifecycle, starting at process development and pre-clinical manufacturing, then manufacturing and commercialization. “We brand ourselves as the digital CDMO,” Holmes states.

“Data is the modern currency. It’s key to determine the efficacy and safety profile of the product. Data indicates whether a product should advance to the next stage,” he explains. “We provide both the product and the data back to our customers. This is a critical component for them. The faster we can turn data around, the faster we can change direction and focus resources.”

Sharing insight from every stage of the development process is a key differentiator from the competition. Andelyn Biosciences deployed a custom-fit solution to collect and protect this valuable data.

Building a greenfield environment

The company was officially launched in September 2020, giving Holmes and his

team the rare opportunity to define a digital strategy from scratch. “We don’t know what the next three to five years are going to look like, so having a solution that would grow with us was critical,” he says. “We didn’t want to overbuy or oversize our environment and HPE GreenLake fit perfectly.”

The HPE GreenLake edge-to-cloud platform is a hybrid cloud solution that delivers IT resources with built-in flexibility and scalability. “We have a greenfield setup. We chose HPE GreenLake because it helped us simplify our environment. It’s easy to manage, easy to implement, and helped us get a good head start,” Holmes explains.

To increase the scale and reach of gene therapy products, Andelyn Biosciences is building a 200,000-square-foot manufacturing facility in Columbus, Ohio, in addition to a 50,000-square-foot development center in Dublin, Ohio. The company uses HPE SimpliVity in its platform to run critical workloads, like building management systems or data collection from connected devices, for both facilities.

A road map for growth

Holmes worked with Advizex, a long-time technology provider at parent Nationwide

Children’s Hospital, to set Andelyn Biosciences up for growth. “We really felt comfortable working with Advizex. They had our best interest in mind and brought the best solutions to the table,” he recalls. “HPE GreenLake is a one-stop shop, consumption-based solution. This is great for a startup like us. We didn’t have this exorbitant cash outlay upfront and were able to focus resources elsewhere.” Advizex was instrumental in the recommendation to go with HPE GreenLake, the sizing of the environment, and delivers managed services for all the compute resources at Andelyn.

“I’m proud of the team that we’ve assembled to jointly define a go-forward strategy. We put together a set of guiding principles to anchor our decisions,” Holmes shares. These principles were to design with security in mind, be born in the cloud, have organizational balance, position data as an asset, and deliver a total experience for both internal and external customers.

Securing data from edge to cloud

Data security is crucial for Andelyn Biosciences, which handles not only its proprietary data, but also that of



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external customers. “The biggest concern is around protecting intellectual property,” explains Holmes. “Other companies come to us with their recipes and ideas to make a scalable product. They want to work with someone they can trust, where data security is at the forefront of the operation.”

Keeping critical workloads secure with redundancy built in is one of the strategies to strengthen data security. “HPE GreenLake is a game-changing solution for our environment. We can leverage that cloud mentality, bringing it back to the site where we need the compute resources,” he says.

The organization uses multiple cloud solutions, like TetraScience, which it leverages to ingest and analyze scientific data, as well as Microsoft 365 and several others. “HPE GreenLake works great with other systems. We’re putting a puzzle together, and we’re ecstatic about how every piece fits,” Holmes continues.

“We have an edge-to-cloud collection mechanism for our connected plant strategy. We’re using HPE GreenLake to gather and standardize data from

instrumentation devices on-premises, and then populate that data into our scientific cloud.”

A focus on transforming lives

Pharma companies are finding value in Andelyn Bioscience’s vision to become a digital CDMO and prioritize data as an asset. Holmes and his team are already receiving positive feedback, both from external and internal customers. “One potential customer said they’ve seen others in the industry think about this, but that we’re far ahead on that journey,” he recounts.

Scientists at Andelyn Biosciences now have more flexibility to analyze data whether they are at the lab or their home office. “This really expands their potential,” Holmes continues. “We can also share data from multiple experiments without redoing all the work. This takes data wrangling out of researchers’ day-to-day efforts, allowing them to focus on the science and transform lives.”

Because HPE GreenLake delivers simplified IT and Advizex fully manages

and automates the environment, Holmes and his staff are free to work more closely with strategic teams in the company. For example, by bringing in the Connected Plant team, which focuses on instrumentation and automation engineering.

Pushing gene therapy forward

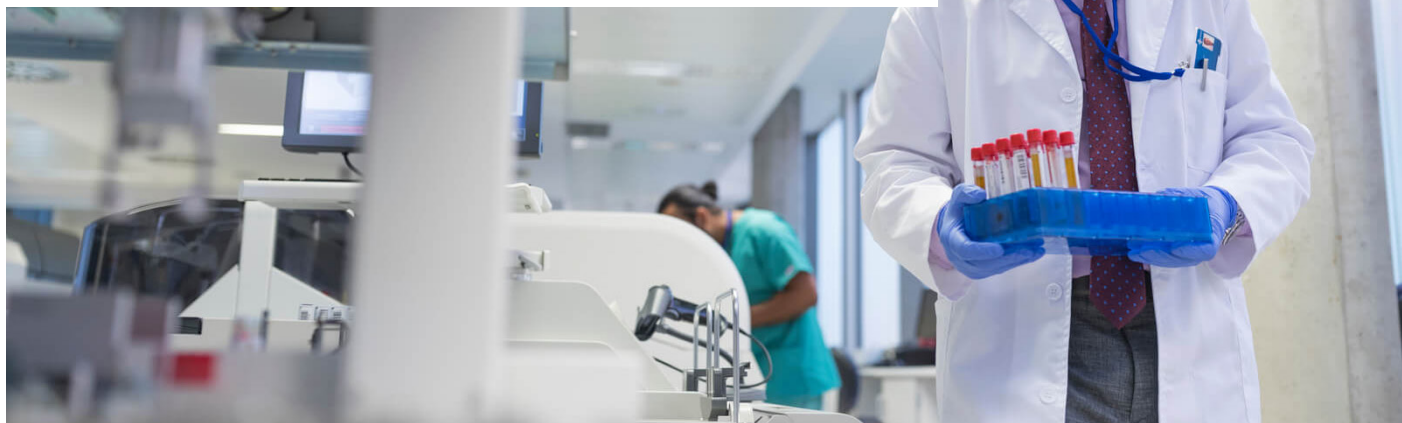
“This has been the most rewarding job of my career,” Holmes recounts. “We were able to start this from scratch and see the impact of the work we’re doing. The company believes in it, and customers believe in it. That really is a motivating factor, knowing we are making a change.”

Andelyn Biosciences has a vision to keep driving value from data, with real-time processing and predictive analytics as the next frontier. “HPE GreenLake allows the environment to grow as we grow as a company, as new solutions and opportunities come to us,” he continues. “We’ll be able to use advanced technologies, like AI and ML, to keep transforming the gene therapy industry.”



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