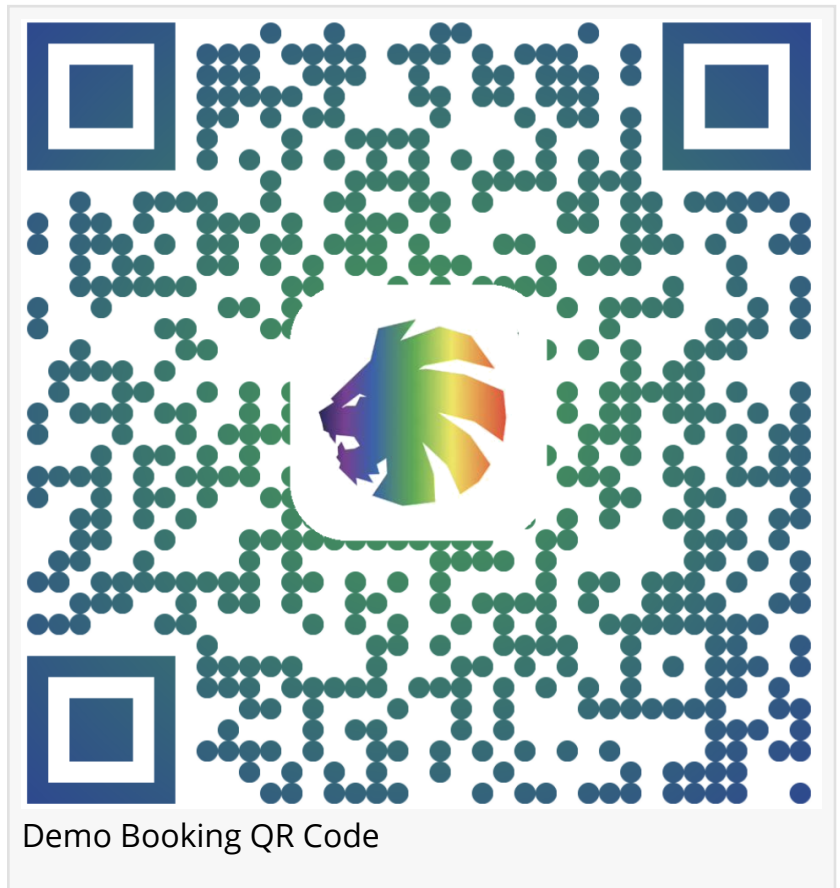


Global Cell and Gene Therapy CDMO Selects Valkit.ai

Multi-site CDMO with 8,000+ GMP batches and multiple FDA-approved products adopts AI-native digital validation for C&Q, CSV, and CSA across global operations

INDIANAPOLIS, IN, UNITED STATES, September 21, 2026 / EINPresswire.com/ -- Valkit.ai, the leader in AI-powered digital validation for the life sciences industry, is pleased to announce that a global cell and gene therapy contract development and manufacturing organization ("the Company") has selected the Valkit.ai platform, replacing a first-generation digital validation tool as its validation system of record across its worldwide operations.



The Company is a pure-play cell and gene therapy CDMO and multimodal biosafety testing organization with more than 25 years of advanced therapy development and manufacturing expertise and more than 40 years in biosafety testing. Operating five GMP sites across the United States, Europe, and Asia, the Company supports therapy developers from IND-enabling studies through commercial supply, has manufactured more than 8,000 GMP batches, and manufactures multiple commercial cell and gene therapy products, including FDA-approved autologous therapies.

“

First-generation platforms digitized the paper. Valkit.ai was built to accelerate the work.”

Hugh Devine

Having previously invested in one of the industry's leading first-generation digital validation tools, the Company

undertook a formal re-evaluation of its validation technology as it scaled commercial manufacturing across a multi-site, multi-modality footprint spanning CAR-T, TIL, iPSC, AAV, and

lentiviral programs. That evaluation concluded that a document-centric, workflow-first platform could not deliver the throughput, flexibility, or AI-driven rigor required by a global CDMO managing continuous tech transfers, sponsor audits, and regulatory inspections in parallel. Valkit.ai was selected as the Company's Gen 2 replacement.



Valkit.ai will be deployed as the Company's global digital validation platform, supporting Commissioning & Qualification (C&Q) of manufacturing and testing infrastructure, full Computer System Validation (CSV) lifecycle management from User Requirements Specification through Validation Summary Report, and Computer Software Assurance (CSA) for its expanding portfolio of regulated systems. Capabilities include AI-assisted validation documentation, native 21 CFR Part 11/EU Annex 11 controls, automated risk-based traceability across every requirement and test, and sponsor-level data isolation ensuring no client data is ever exposed to third-party large language models.

"When an organization that has already lived with a first-generation digital validation tool chooses to move on, it tells you something about where the industry is heading," said Hugh Devine, CEO of Valkit.ai. "Cell and gene therapy CDMOs operate under some of the most demanding validation loads in life sciences: every new sponsor program brings new equipment, new systems, and a new audit. First-generation platforms digitized the paper. Valkit.ai was built to eliminate the work. We are honored to be selected as the Company's platform of record and to support its mission of getting more therapies to more patients worldwide."

The selection continues Valkit.ai's rapid expansion within the CRO and CDMO segment and adds to a growing number of customers who have migrated from first-generation validation platforms to Valkit.ai's AI-native architecture.

About Valkit.ai

Valkit.ai provides leading companies in the life sciences industry with AI-powered digital validation that dramatically accelerates compliance processes. As a global SaaS provider headquartered in Indianapolis, IN, Valkit.ai serves pharmaceutical, biotechnology, and healthcare organizations with solutions spanning Commissioning & Qualification (C&Q), Computer System Validation (CSV), Computer Software Assurance (CSA), and AI-Powered Risk Assessment. Valkit.ai is a pre-validated, commercial off-the-shelf platform that is ISO 27001:2022 certified and 21 CFR Part 11/EU Annex 11 compliant. Independent customer studies have shown Valkit.ai to reduce validation cycle times by up to 85%, cut validation setup time from weeks to hours, improve documentation accuracy to 99.9%, and reclaim thousands of resource hours annually. For more information visit www.valkit.ai.

Lisa Silva

Valkit.ai LLC

+1 888-912-0190

[email us here](#)

Visit us on social media:

[LinkedIn](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/943652764>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2026 Newsmatics Inc. All Right Reserved.