Peer-Reviewed: MarinBio's Novel Cell-Based Potency Assay for Gene Therapy

MarinBio publishes validated GMP/GLP cell-based potency assay for AAV-delivered anti-CD3-anti-CD19 diabody (GP101) in Journal of Immunological Methods.

NOVATO, CA, UNITED STATES, November 21, 2025 /EINPresswire.com/ -- Marin Biologic Laboratories ("MarinBio") today announced the publication of a breakthrough research article in the peer-reviewed journal Journal of Immunological Methods (published online) detailing the development and validation of a robust cell-based potency assay for a diabody-based gene therapy construct. The peer-reviewed study details the development and validation of a novel cell-based potency assay for GP101, an anti-CD3-anti-CD19 diabody designed for gene therapy applications in treating B-cell malignancies. The article demonstrates how MarinBio's assay platform can reliably measure the bioactivity of a diabody expressed via AAV mediated gene delivery, supporting lot release, manufacturing consistency and regulatory compliance.

> This publication is a milestone for the cell & gene therapy field, delivering a validated, robust cell-based potency assay for diabody gene therapy that meets stringent regulatory requirements."
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> *Tania Weiss, Ph.D., CEO, Marin Biologic Laboratories*

"This publication represents a significant milestone in supporting the development of next-generation gene therapies for cancer treatment," said Tania Weiss, Ph.D., CEO of MarinBio. "Our team has developed a GMP/GLP-compliant potency assay that meets stringent FDA requirements while providing the sensitivity and reproducibility essential for advancing novel biologics through clinical development."

Key Highlights of the Research

- The assay employs a physiologically relevant cell system to reflect the mechanism of action of the diabody gene therapy agent (a bispecific diabody engaging a T cell target and a surrogate cancer cell).
- The design allows quantification of functional cytotoxic potency (or cell‑mediated effect) in vitro, thereby facilitating lot‑to‑lot comparability and stability testing.
- The method has been qualified under GMP/GLP–guidelines and shown to have reproducible performance, thus supporting downstream regulatory dossiers (IND, BLA) or commercialization.

• The assay format is readily adaptable to other cell- and gene-therapy constructs (viral vector, plasmid, transduced cell) and can serve as a model for future potency assay development across the advanced-therapy space.
• The publication reinforces MarinBio's 30 + year legacy in potency assay development for small molecules, biologics, cell therapies and gene therapies.

Meeting Critical Regulatory Requirements
The assay meets GMP (Good Manufacturing Practice) and GLP (Good Laboratory Practice) compliance standards, providing quantifiable and reproducible measures of efficacy essential for regulatory submissions. These characteristics address FDA requirements for potency testing of gene therapy products and bispecific T-cell engagers.

"For over 30 years, MarinBio has specialized in developing sophisticated cell-based assays that bridge the gap between early research and clinical application," noted Dr. Weiss. "This publication marks an important milestone, not only for our team's capabilities, but for the broader cell and gene therapy industry. By delivering a validated, robust cell-based potency assay for a diabody gene therapy, we are helping to de-risk the CMC (chemistry, manufacturing and controls) path for these next-generation treatments. We look forward to partnering with developers to implement this assay paradigm and accelerate translational timelines from bench to bedside."

About Marin Biologic Laboratories Inc.
Marin Biologic Laboratories (MarinBio) is a woman-owned contract research organization (CRO) with over 30 years of experience supporting the pharmaceutical and biotech sectors. Specializing in custom cell-based assays, GMP(https://www.marinbio.com/services/cgmp-services-ind-nda-bla-commercialization/) /GLP (https://www.marinbio.com/services/cgmp-services-ind-nda-bla-commercialization/) compliance, and regulatory strategy, MarinBio partners with clients to advance therapeutics from discovery to commercialization. With a team of senior PhD scientists and a flawless regulatory audit history, MarinBio provides the scientific expertise and quality systems necessary to meet global compliance standards.
MarinBio is recognized for its scientific agility, rigorous quality systems, and deep understanding of FDA regulatory expectations. The company is known for working collaboratively with clients, ensuring each assay is customized to meet specific regulatory, technical, and commercial goals. Operating from a GMP-compliant facility in Novato, CA, MarinBio supports US and international clients ranging from venture-backed startups to top-tier global biopharma firms.

For More Information
To read the full article, visit: [Link to the article on ScienceDirect]
(https://www.sciencedirect.com/science/article/pii/S0022175925002042)

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