Marin Biologic Laboratories Releases FDA-Ready Bioanalytical Cell-Based Assays White Paper

New Publication Sets Standard for Phase-Appropriate Assay Qualification, Offering Clear Path from IND to Commercialization

NOVATO, CA, UNITED STATES, June 27, 2025 /EINPresswire.com/ -- Marin Biologic Laboratories Inc. (MarinBio), a leading bioanalytical testing and regulatory compliance contract research organization (CRO) based in Northern California, announces the release of a new white paper, "Selecting Bioanalytical Assays for FDA Approved Clinical Trials and Commercialization." https://www.marinbio.com/company/selecting-bioanalytical-assays-fda-clinical-trials-commercialization/

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> *Tania Weiss, Ph.D., CEO, Marin Biologic Laboratories*

This in-depth publication offers the biopharmaceutical industry a clear, scientifically grounded roadmap for selecting regulatory-ready assays that meet FDA requirements. The white paper walks readers through the full continuum of assay development—from early-stage, fit-for-purpose qualified assays to fully validated, GMP-compliant platforms ready for BLA and NDA submission, and commercialization.

"Whether you're preparing for your first IND or scaling up for commercial release, assay integrity is non-negotiable," said Tania Weiss, Ph.D., CEO of Marin Biologic Laboratories. "This white paper reflects our commitment to excellence—scientific, operational, and regulatory—and our desire to enable clients to meet FDA expectations without unnecessary delays or cost overruns. Our goal has always been to act as a true scientific partner to our clients, including those pioneering the next generation of therapeutics. This white paper is a natural extension of that mission. We are codifying three decades of experience to provide the entire industry with a clear, actionable framework for navigating the immense complexities of modern drug development. We believe that sharing our expertise in regulatory strategy and advanced bioanalysis will help accelerate innovation across the board."

The white paper content leverages MarinBio's 30 years of scientific leadership and impeccable

regulatory track record to enable companies on their journey from preclinical projects to commercialization. The publication draws upon MarinBio's deep expertise in GMP/GLP-compliant assay development and its recent successes in passing both FDA, with no 483s, and EU regulatory audits.

Key insights from the white paper include:

- Phase 1: Research-Level Assay Development – Streamlined approaches for initial technology transfer or de novo assay design that deliver reliable, fit-for-purpose data for preclinical and early clinical studies.

- Phase 2: Assay Qualification – Criteria for building a qualified assay for Phase 2 FDA submissions including intermediate precision, accuracy, linearity, and specificity to support IND-enabling studies with confidence.

- Phase 3 & Commercial: GMP Assay Validation – A guideline for validating, and documenting robust assays in full compliance with GLP/GMP and FDA standards—ready for commercial deployment.

The white paper also offers real-world advice for biotech and pharma clients navigating pre-IND/IND readiness and BLA/NDA submissions and commercialization phase —making it an essential read for development teams, regulatory leads, and scientific executives.

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/GLP 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.

Marin Biologic Laboratories 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. The company's service portfolio includes:

- Potency Assays for Lot Release
- Stability Testing

- PK/PD & Immunogenicity Studies (ADA)
- ELISA, Flow Cytometry
- Cell-Based Assays (https://www.marinbio.com/services/cell-based-assays/)
- Molecular Biology
- qPCR
- GMP / GLP Compliant Validation and Regulatory Reporting

For the complete white paper or to discuss your bioanalytical assay development needs, please visit the MarinBio website at https://www.marinbio.com/

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