RRPV Member Spotlight

Q: Provide some insight into your company's history, core business areas, focuses, or key ideas that you wish to describe.

A: Curi Bio is a Seattle-based biotechnology company founded in 2016 specializing in human-relevant engineered tissue platforms and biosystems that accelerate drug discovery and development. The company integrates human cell models, hardware instrumentation, and advanced software analytics to deliver clinically relevant functional data for cardiac, musculoskeletal, and neuromuscular applications. Curi Bio's platforms have been widely adopted by major pharma, biotech startups, and academic institutions worldwide. The company operates BSL2 laboratories for cell and media manufacturing, contract research, and model development, with manufacturing and prototyping facilities supporting consumable and hardware production.

Q: What specific capabilities or strengths does your company offer?

A:

- Mantarray Platform: Magnet-tracking hardware for real-time functional measurements of engineered tissues with addressable electrical and blue light stimulation, parallel 24-well readout, and automated Pulse 3D analysis.
- Neuromuscular Junction (NMJ) Model: iPSC-derived neuromuscular junction with motor neurons and engineered muscle tissues, enabling assessment of both NMJ function and muscle contractility.
- Botulinum Neurotoxin (BoNT) Potency & Medical Countermeasures (MCM) Assessment: Multiple serotype sensitivity (A, B, E tested so far) with reproducible, label-free, non-destructive measurements. Supporting Consumables: Engineered muscle tissue kits, cell products, specialized media, and microplates designed for scalable manufacturing.
- Complete end-to-end solutions: hardware systems, consumables, cell products, media, and software (Pulse 3D) for functional tissue readouts. FDA-funded development with demonstrated regulatory pathway via ISTAND. Strategic

partnerships with **Battelle** for GLP support and select agent work. Proven serotype sensitivity and reproducibility metrics suitable for lot release and potency testing. Commercial availability and scalable manufacturing for high-volume production.

Q: Are there any specific partnership opportunities you're seeking with other members in the industry? What kinds of expertise or resources would be beneficial for your company to explore through partnerships?

A:

- Partner with BoNT pharmaceutical manufacturers and MCM developers for assay validation and regulatory submissions.
- Collaborate with regulatory agencies and CROs on ISTAND and IND pathways.
- Engage with biodefense/public health agencies advancing non-animal testing for MCM development and long-term potency assay support.
- Support from GLP-certified contract research organizations for regulatory-grade testing.

Q: What trends or innovations do you foresee shaping the future of the industry, and how is your company preparing for those changes?

A: The future of MCM development hinges on transitioning from animal-based potency testing to validated human-relevant in vitro platforms—and importantly doing so at scale and with cost savings. We foresee growing global regulatory acceptance of such platforms through FDA programs like ISTAND, driven by the need for faster development timelines, reduced costs, and alignment with 3Rs principles (replacement, reduction, refinement).

Curi Bio is advancing this transition by positioning the NMJ platform as a scalable, validated replacement to animal models while building regulatory pathways that enable MCM manufacturers and pharma companies to confidently adopt this technology for lot release and potency assessment.

Q: How can we contact you?

Greg Luerman, Vice President of Research & Partnerships
greg@curibio.com

Project Spotlight: NMJ Platform for Botulinum Toxin and Medical Countermeasure Potency Assessment

Q: Brief Description of the Project, Achievement, or Success Story.

A: Curi Bio has developed a functionally mature, human iPSC-derived NMJ platform capable of detecting BoNT potency across multiple serotypes (A, B, E so far) and assessing MCM with reproducible, label-free functional muscle measurements. Built on the widely adopted Mantarray hardware system, the NMJ platform provides real-time functional readouts without animal models and can do so at scale. The assay was FDA-funded through an NIH SBIR award (U44TR004795) and is being advanced through the FDA's ISTAND qualification pathway.

Through a strategic partnership with Battelle—an institution with GLP expertise and select agent accreditation—Curi Bio is positioning the assay for regulatory use in pharmaceutical lot release and MCM potency testing. All consumables, cell products, and media are commercially available and designed for scalable manufacturing and ease of use in standard laboratory settings.

Q: Key Outcome or Impact.

A: The NMJ platform delivers <3% variance in BoNT EC50 estimates across independent experiments, users, and time periods, positioning it as a reliable and scalable replacement to traditional animal-based potency methods. For MCM developers and manufacturers, this creates a validated, scalable platform for potency assessment that meets regulatory standards while reducing dependency on animal testing—critical for advancing the next generation of MCM.

Q: Collaborators or Partners for this Project.

A: Battelle (Strategic Partnership for GLP, Select Agent Work, and Regulatory Applications)