RRPV Member Spotlight

VISMEDERI america

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

A: VisMederi is a CRO based in USA (Cleveland, OH) and Europe (Italy), specializing in clinical research, laboratory testing, and immunological studies. Founded in 2009, the company supports pharmaceutical, biotechnology, and public health organizations through high-quality laboratory services, vaccine and infectious disease research, and clinical and pre-clinical trial support.

VisMederi operates in compliance with European quality standards and continuously validates its methods according to EMA, FDA, and PMDA guidelines, ensuring the reliability, robustness, and scientific integrity of its testing platforms. Working within BSL-2, BSL-2+, and BSL-3 laboratories, VisMederi develops, validates, and standardizes bioanalytical, serological, virological, microbiological, and molecular assays for vaccine development, epidemiological studies, and infectious disease research.

The company has extensive expertise in the study of influenza viruses, emerging and re-emerging pathogens, and bacterial microorganisms, providing services including immunogenicity assessments, serology, virus neutralization assays, pseudovirus-based assays, molecular diagnostics, and biomarker analysis. Through innovative and validated testing solutions, VisMederi supports clinical research programs and advances public health initiatives worldwide.

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

A:

- Assay development, validation, qualification and standardization
- Clinical and pre-clinical laboratory testing; Immunology and vaccine immunogenicity assessments
- Serology and virus neutralization assays

- Pseudovirus-based testing platforms
- Cell-Mediated immunity testing (ELISpot, ICS, CYTOF)
- Molecular diagnostics and biomarker analysis
- Virology and microbiology testing
- Emerging infectious disease research
- Multiparametric platform
- Clinical trial laboratory support
- BSL-2, BSL-2+, and BSL-3 facilities
- Design and Manufacturing of sample collection Kits for clinical and research use
- Long term storage and central hub for clinical samples
- Global shipping and distribution

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: VisMederi America is seeking vaccine and therapeutic developers that may benefit from our comprehensive analytical and testing capabilities and services.

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 biopharmaceutical and, more specifically the vaccine industry, is increasingly moving toward faster, more flexible, and more predictive technologies for assessing immune responses and vaccine efficacy. Key trends include the adoption of high-throughput functional assays, the growing use of pseudovirus-based neutralization platforms, the identification of correlates of protection, and the integration of advanced data analytics to support clinical development and regulatory decision-making.

At VisMederi, we are actively preparing for these changes by continuously expanding our portfolio of innovative immunological, virological and bacterial assays. A major focus has been the development of next-generation neutralization platforms, including both VSV- and lentiviral-based pseudovirus technologies, which provide robust, scalable, and biosafety-friendly alternatives to live-virus testing. These platforms enable rapid adaptation to emerging pathogens and variants, supporting vaccine developers in an increasingly dynamic environment.

We are also investing in assay standardization, automation, and validation according to international regulatory expectations, ensuring that our methods generate high-quality, reproducible data suitable for global clinical programs.

By combining scientific innovation, regulatory readiness, and a strong focus on emerging infectious diseases, VisMederi is well positioned to support the future needs of vaccine, therapeutics, and immunology research worldwide.

Q: How can we contact you?

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Project Spotlight: Development of a New Bundibugyo Ebolavirus Neutralization Assay based on VSV and Lentivirus Technologies

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

A: During 2026, outbreaks in the Democratic Republic of the Congo and Uganda have resulted in more than 1,100 reported cases and around 300 deaths, underscoring the continuing risk posed by Ebola in regions where health systems face significant challenges. The absence of approved vaccines or treatments specifically targeting the Bundibugyo strain further highlights the need for continued research and vaccine development.

To support these efforts, VisMederi has developed a new neutralization assay based on VSV pseudovirus technology. The assay enables the evaluation of vaccine-induced neutralizing antibodies without requiring Biosafety Level 3 laboratories, making it more accessible for research and development activities.

Recognized as the gold standard for assessing the immunogenicity of vaccine candidates, this assay is currently available at VisMederi and is designed to support researchers, vaccine developers, and the global scientific community in advancing new countermeasures against Bundibugyo ebolavirus.

Q: Key Outcome or Impact.

A: VisMederi successfully developed an in-house pseudovirus neutralization assay platform to support the evaluation of Ebola virus-neutralizing antibodies. The project focused on the development and optimization of two complementary pseudoviral systems: a VSV-based platform and a lentiviral-based platform. Following particle production, the pseudoviruses were characterized and titrated before being evaluated in neutralization assays using the Ebola International Standard provided by the National Institute for Biological Standards and Control (NIBSC).

Both platforms demonstrated excellent performance, generating highly satisfactory and reproducible results. This achievement represents a significant milestone, as it establishes robust and scalable alternatives to live-virus neutralization assays, enabling high-quality immunogenicity assessment under lower biosafety requirements. Based on

these promising outcomes, VisMederi is now preparing a full assay validation program in accordance with ICH guidelines, with the objective of supporting future research, vaccine development, and clinical studies.

Recognized as the gold standard for assessing the immunogenicity of vaccine candidates, this assay is already available at VisMederi and is designed to support researchers, vaccine developers, and the global scientific community in advancing new countermeasures against Bundibugyo ebolavirus.