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Viralgen receives cGMP certification from EMA

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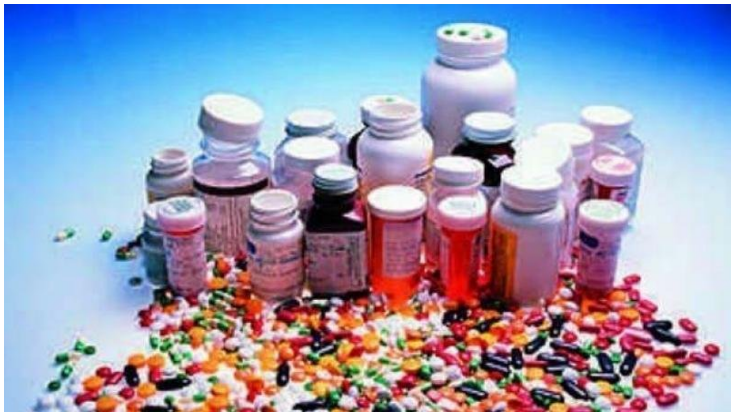
Certification confirms Viralgen's commitment to high operational standards with the world's most flexible and robust AAV manufacturing capability



Viralgen and AskBio announced that Viralgen has received Current Good Manufacturing Practices (cGMP) compliance accreditation and Pharmaceutical Laboratory authorization by the AEMPS (Spanish Agency for Medicines and Health Products) and certification from the European Medicines Agency (EMA). Viralgen is a leading contract development and manufacturing organization (CDMO) that specializes in developing, validating and manufacturing adeno-associated virus (AAV) gene therapies.

"We have gone from a bare concrete floor to a fully certified, world-class facility in less than two years," said Javier García, Viralgen's CEO. "The quality of our facility, scaled-up manufacturing processes, and this certification underscore our commitment to helping our clients develop safer and more effective therapies for genetic disease. We have an amazing facility and a highly skilled team focused on delivering technology that produces higher yields of rAAV vectors, ultimately contributing to lowering the cost of potentially life-saving therapeutics for patients in need."

Adherence to the cGMP regulations guides the proper quality, monitoring, safety, efficacy and information accuracy of medicines and health products for manufacturing processes and facilities in the interest of protecting and promoting people's health.

A key benefit of Viralgen's technology is the cGMP production of high-quality rAAV in large batches through a unique and robust manufacturing platform. AskBio, which owns 50 percent of Viralgen, has developed the world's foremost clinical stage gene therapy platform that includes an industry-leading proprietary cell line manufacturing process known as Pro10™.

This allows Viralgen to scale cGMP manufacturing of rAAV vectors at levels that exceed what other CMOs can produce and enables flexible, scalable clinical manufacturing faster than current industry standards.

According to Mr. García, Viralgen's current cGMP capacity is comprised of:

Three independent, state-of-the-art cGMP production suites (>1800m2), providing the capability to continuously and simultaneously manufacture three different products

- 50L scale to supply toxicology/biodistribution studies with full support for research, toxicology and GMP production in parallel
- 50L, 250L and 500L single-use stirred-tank bioreactors for culture of suspension cells with a total capacity of 1,250 liters of dedicated AAV production
- In-house quality control labs for critical release assays

Mr. García also noted that Viralgen plans to expand its current footprint with support for up to 2000L scale for commercial use by the end of 2021. This will enable full life cycle support and maximized flexibility to serve a wide range of AAV capsids for manufacturing potentially curative therapeutics