

Symbiosis Successfully Completes Gene Therapy Focussed FDA Regulatory Inspection

Global contract manufacturing organisation (CMO) Symbiosis Pharmaceutical Services has successfully completed its latest inspection by the US Food and Drug Administration (FDA) of its facilities in Scotland.

Headquartered in Stirling, UK, and specialising in the sterile manufacture of pharmaceuticals and biopharmaceuticals for clinical trials and the supply of commercial markets, Symbiosis recorded zero GMP observations from the FDA during the inspection in January 2025. This represents another significant positive milestone for Symbiosis which endorses the company's global reputation as a trusted partner in global biologics sterile manufacturing, (which is also referred to as "fill/finish"). This achievement highlights Symbiosis' embedded regulatory excellence, and its commitment to quality-driven manufacturing, and industry-leading compliance standards.

The FDA inspection was conducted over a seven-day period, and focussed on the ongoing fill/finish of ongoing commercial supplies of an AAV (Adino-Associated Virus) viral vector biologics product of a for a long-standing US big pharma client, The inspection outcome validated Symbiosis' robust quality management systems, ensures continued adherence to FDA regulations, and reinforces the capability of Symbiosis to deliver high-quality biopharmaceutical sterile manufacturing solutions globally.

Since previous FDA inspections, and with a focus on maintaining regulatory excellence and continuous improvement, the company continues to expand its quality function with the ongoing recruitment of experienced quality professionals while enhancing process controls and risk management frameworks in order to maintain a state of regulatory readiness.

Colin MacKay, CEO of Symbiosis, said: "Achieving this successful FDA inspection outcome is a reflection of our team's expertise and on-going commitment to quality excellence. In a rapidly evolving biopharmaceutical landscape, regulatory rigor and GMP operational performance are enduring priorities for the company and a fundamental part of our business and cultural ethos. We are proud to provide our clients with unparalleled confidence in our quality capabilities and how that diligence translates into product excellence."

The latest successful inspection of the existing Symbiosis quality system platform underpins the latest inflexion point in the Symbiosis' growth strategy.

The company continues its physical and operational expansion with the commissioning of its new state-of-the-art automated sterile GMP manufacturing facility, close to its existing facilities in Stirling, UK. This will increase the company's commercial scale sterile

manufacturing capabilities, enabling it to support a growing number of clients globally through the clinical and commercial injectable drug product lifecycle challenges.

“Symbiosis continues to thrive as a specialist fill/finish global CMO leader, fuelled by a sustained increase in demand for its services which align with broader industry trends such as the number of biologics and injectable drugs in development and an increasing appetite for outsourced sterile GMP fill/finish services, adds MacKay.

“Maintaining our prevailing high standards of both customer service and quality compliance is part of our long-standing strategy to drive the continued organic growth of our core sterile manufacturing service offering principally to the US and European markets.”