Press Release

March 11th, 2025

White Raven, a new Belgian CDMO, obtains GMP certification for its aseptic fill & finish facility with a robotic gloveless workcell for small-batch manufacturing.

- White Raven has successfully obtained **GMP certification** for its state-of-the-art aseptic fill & finish facility.
- The facility features **Cytiva's SA25** aseptic filling workcell, a fully automated system enhancing sterility assurance and minimizing contamination risks, making it Europe's first GMP-certified facility using this cutting-edge technology.
- Compliance achieved under the **newly updated EUDRALEX Annex 1 guidelines** for sterile medicinal product manufacturing.
- Delivered in **just 18 months from project kick-off to GMP certification**, this achievement highlights White Raven's agile execution, innovative principles, and determination to redefine industry standards in pharmaceutical manufacturing.

Liège, Belgium – March 11th, 2025 – White Raven, a newly established CDMO specializing in GMP formulation and aseptic fill & finish services for clinical and orphan drugs, announces its successful Good Manufacturing Practice (GMP) certification. This major milestone emphasizes White Raven's commitment to delivering safe, flexible, and accelerated manufacturing solutions for life-saving medicines.

> *"Thanks to this exceptional achievement of our team, White Raven is now fully prepared to fulfil its mission: to support the biopharma companies developing life-saving therapies through fast, reliable and flexible fill & finish services."*

Dimitri Woronoff • CEO & Co-Founder, White Raven.

Europe's first GMP-certified facility featuring Cytiva SA25

White Raven joins a growing list of Cytiva SA25 users which have achieved GMP certification or received commercial manufacturing approvals from a variety of health authorities, including the FDA (United States), NMPA (China), Health Canada, HSA (Singapore), and now for the first time European Medicines Agency (EMA) success. By eliminating human interaction, it manages to remove contamination risks, offering enhanced sterility assurance, higher product quality, and a reduced risk of contamination.

New EUDRALEX Annex-1 compliance

White Raven's GMP certification has been processed under the new **EUDRALEX Annex-1 guidelines** that were enforced in 2023, demonstrating alignment with the latest, and most stringent, requirements for sterile medicinal product manufacturing. This sets a precedent for best-in-class aseptic operations, validating the company's strategic investments and rigorous approach to quality.

18-Month Timeline

- **September 2023:** Project kickoff, conceptual and basic design begins.
- **October 2023:** SA25 purchase.
- **March 2024:** Cleanroom construction begins at White Raven's LégiaPark site in Belgium.
- **June 2024:** Cleanroom construction completed, all equipment installed.
- **October 2024:** Cleanrooms and equipment qualified.
- **November 2024:** First successful APS - Aseptic Process Simulation, also known as Mediafill.
- **February 2025:** GMP certification granted.

This rapid timeline proves White Raven's dedication to streamlining production cycles for clients. White Raven can now release GMP batches in as little as four months, driving faster patient access to critical and novel therapies.

Belgium, heart of Europe's pharmaceutical industry

Belgium is a leading hub for pharmaceutical innovation and manufacturing excellence, known for its advanced infrastructure, top-tier research facilities and skilled workforce. The strategic establishment of White Raven's GMP-certified robotic aseptic fill & finish facility at LégiaPark, Liège enhances White Raven's operational capabilities and aligns with Belgium and Europe's commitment to supporting innovative pharmaceutical companies and biotechs.

About White Raven

White Raven is a **CDMO** specializing in **GMP formulation and aseptic fill & finish services** for small batches. Established with a vision to speed up the availability of life-saving medicines, White Raven leverages advanced technologies and agile processes to release GMP batches in four months, helping ensure that vital treatments reach patients faster and more safely.

Media Contacts

White Raven
Adam Soufi
Email: adam@whiteraven.bio

Learn More

whiteraven.bio/contactus