

# Lyell leverages Werum PAS-X MES as a Service for clinical phase production to support GMP and data-driven operations

The US-based cell therapy biotech Lyell Immunopharma has successfully taken Werum PAS-X MES as a Service into operation at their GMP production site in Bothell, WA to produce autologous T cell cancer therapies. Lyell is a leading clinical-stage T cell reprogramming company dedicated to developing curative cell therapies for patients with solid tumors.



## Need to scale out on a digital foundation

The company had taken the next step in scaling out its production to deliver multiple autologous cell therapy platforms with an ambitious timeline. Instead of using paper, clinical processes and GMP manufacturing started on a digital foundation as they work through clinical development to increase speed, efficiency and compliance.

**“Together with Körber, we are achieving our ambitious GMP technology roadmap that enables our teams to focus on the core business – the production of therapies for people with cancer.”**

Joe Maguire  
Head of GMP Automation and Data, Lyell

“Rome was not built in a day, nor is one’s digital footprint. It is imperative now, more than ever, with the evolution of the FDA’s guidance on data integrity to start the digital journey from the beginning to avoid compliance gaps and the costly effort of switching from paper during the most critical time of our company’s lifecycle – going commercial,” says Joe Maguire, Head of GMP Automation and Data at Lyell. “We need an MES that we could rely on during our transition from R&D to clinical readiness and for potential future commercial phases in order to ensure successful tech transfers and GMP compliance as we scale up.”



Cloud based MES

## Leveraging cloud MES, managed by Körber & AWS

To meet these requirements, Lyell opted for Werum PAS-X MES as a Service. Not without reason, since all FDA-approved CAR-T manufacturers rely on Werum PAS-X. With PAS-X MES as a Service, Körber offers its market-leading pharma MES fully managed and in the cloud. The cloud solution is provided by AWS to deliver security, reliability and high availability.

The implementation followed the ready-to-run approach for rapid deployment: Lyell picked the business-specific cell & gene solution with its standardized software, services and content packages and benefited from the fit-for-purpose solution without further customization. PAS-X MES as a Service enables digitization and eliminated many manual steps and human errors, speeds up time-to-market and boosts manufacturing efficiency and compliance.

Körber and Lyell work closely together towards Lyell’s vision of accessing all data available from the manufacturing process. The aim is to curate and evaluate the data to build a holistic understanding of the process and leverage those insights for continuous improvements and ultimately correlating to patient response. With the Oracle ERP already integrated, Lyell continues to plan later phases for system integrations, leveraging PAS-X standard connectors, with the goal to drive release times down to get quality products out to patients as expeditiously as possible.

“We value our strategic partnership with Körber,” says Lyell’s Joe Maguire. “Lyell invested in an early system strategy to support the complexity of autologous cell therapy. Together with Körber, we are achieving our ambitious GMP technology roadmap that enables our teams to focus on the core business – the production of therapies for people with cancer.”



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