

CASE STUDY

CELL & GENE THERAPY PLATFORM

The implementation of L7|ESP across comPACT and imPACT neo TCR-T cell manufacturing and all upstream and downstream QC processes.

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L7 has assessed what's lacking in the current ecosystem of solutions in precision medicine and lab diagnostics and has developed this extensive platform that is going to be able to not only address the needs of these companies today but would be the right choice as these companies tailor their products going forward.

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Ashish Kheterpal
Chief Information Officer
PACT Pharma

INTRODUCTION

PACT Pharma is a clinical-stage company with the goal to treat patients with personalized neoTCR-based therapies across a broad range of tumor mutational burdens and solid cancer types.

Currently PACT is conducting a phase one clinical trial with recruiting and dosing patients at multiple sites within the US. From a business priority and IT standpoint, with a heavy focus on analytics, they wanted to develop secure and compliant systems and to provide visibility into data for AI scientists and operations that create translational, clinical, and operational insights that ultimately optimize the processes. With the learnings from their clinical trials PACT wanted to focus on automation to improve throughput, and reduce needle to needle turnaround time.

To achieve these goals, PACT wanted an underlying infrastructure that provides an enterprise data management layer that easily integrates all their systems, including custom systems, and information while driving insights, reducing turnaround time, and remaining secure and compliant.

METHOD

Working with L7 Informatics, PACT started with focusing on LIMS and lab automation with complex workflows. The goal of the project is to streamline all processes by implementing automated workflows, combining all instruments and associated metadata in a single data store, and provide a single chain of identity and custody system of record. The L7 team worked with PACT at implementing L7|ESP across PACT's comPACT and ImPACT neo-TCR-T cell manufacturing and all upstream and downstream QC processes. This included the automation of liquid handlers, data analysis systems, and integration of electronic batch records, manufacturing execution systems, and their supply chain systems.

RESULTS

L7|ESP enabled the PACT processes to be more efficient and provided a reduction in PACT’s turnaround time by automating the workflows. For instance, PACT’s entire workflow for many complex QC assays is now fully automated, providing the ability to do assays in a much shorter time with not only workflow automation but with generation of the CFAs for the final cell product. PACT has been able to drastically reduce turnaround time by almost 10 days for their cell product release.

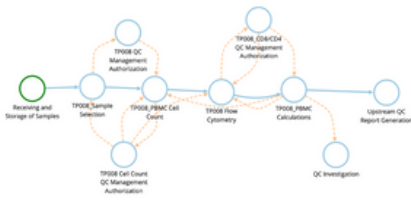


Figure 1. Upstream Sample QC



Figure 2. Downstream Sample QC - Cell Product



Figure 3. Downstream Sample QC - Plasmid Product

CONCLUSION

L7|ESP is a unique regulatory-compliant and secure platform that provides an integrated enterprise software platform for cell and gene therapy companies with various features including EBR, MES, and QC LIMS. The platform simplifies data management and digitalizes and automates workflows in therapeutics to enable breakthrough efficiencies, better compliance, reduced costs, and improved operational velocity.

With the L7 partnership and the implementation of L7|ESP, as a single validated software solution, L7|ESP was able to automate PACT’s QC workflows and provide data management with TCR discovery and validation efforts thus reducing turnaround times and creating more process efficiencies for PACT’s needle to needle workflow.



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About L7 Informatics

The L7 mission is to revolutionize the scientific process by streamlining process and data management thereby accelerating precision health across life sciences, healthcare, and food value-chains. L7 Informatics provides software and services that enable digital transformation for scientific research and development.

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