L7|ESP Enterprise Science Platform™ CASE STUDY


# Empowering Gradalis with a Robust Regulatory-Compliant Platform for Managing Data in Cell Manufacturing, QC, and Clinical Trials of Transfected Immune-Stimulated Cells

## INTRODUCTION

Gradalis is a biotechnology company focused on the development and commercialization of novel personalized therapeutics to treat cancer. Vigil® utilizes the patient's own cancer cells to create a fully personalized cancer immunotherapy, with the goal of activating the patient's own T-cells against their cancer cells.

Vigil® requires an autologous manufacturing process. Prior to implementing L7|ESP®, Gradalis issued paper-based batch records that were completed by hand-writing in observations, data, and signatures. All calculations were manually performed and written to complete the process step, and allow for subsequent QA review. Additionally, Gradalis' records were siloed based on function, with evidence of completion or accountability captured on various forms. This led to a series of paper-based forms and/or logs requiring hand-entries for tracking the movement and location of materials and samples. All these predicate records were associated with the manufacturing process at various time points, and were used to either permit or restrict the operator from proceeding. The challenge for Gradalis was consolidating this information into a single source.

## METHOD

L7|ESP utilizes dedicated applications and bidirectional connectors to integrate all aspects of a product's life cycle into a single platform.

By integrating previously siloed information from disparate instruments, software, and quality management systems, L7|ESP alleviates the pain points routinely associated with data analysis, reporting, regulatory submissions, and audits, which ultimately improves an organization's efficiency, product quality and safety, compliance, business velocity, and enterprise capabilities.

For Gradalis, L7|ESP puts Vigil® Batch Production into a real-time electronic system. Additionally, L7|ESP gives a complete history of the supply chain. Gradalis is able to trace the life cycle of every entity in the system, from its generation to consumption, expiry, or discard.

## RESULTS

Gradalis has been successfully using this "Paper on Glass" approach since 2018. Through barcode implementation, L7|ESP also acts as a Laboratory Information Management System (LIMS), tracking every sample that was produced, from the source tissue to the final retained sample. These labels are pre-printed and unassigned until placed on a sample and scanned. Process controls ensure that the right label is associated with each sample, and that each label is unique, negating the need for label reconciliation.

Chain of custody and chain of identity are maintained in L7|ESP with operational reports indicating which samples are processed, stored, and dispensed by whom, and where.

L7|ESP also acts like a MES system, taking data from the instruments that Gradalis uses in manufacturing and incorporating those records directly into the batch production record.

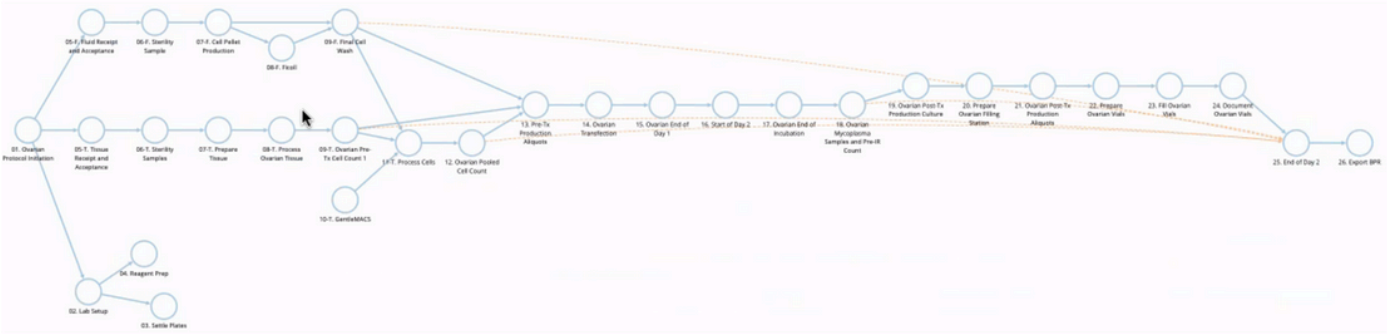

Figure 1. A single unified "validated" platform with MES, EBR, LIMS QC, Inventory, COI, COC, CTMS, eTMF with integrations to instruments, Equipment, ERP and Logistics (World Courier, CryoPort, FedEx)

## CONCLUSION

L7|ESP is a unique regulatory-compliant platform that provides an integrated 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.

Through the implementation of L7|ESP, which Gradalis leveraged as a single validated software solution, it was able to automate its entire multi-day manufacturing process and quality control.

*We were looking for the ability to maintain chain of identity and chain of custody, as well as touchpoints throughout the entire process. L7|ESP provides a single platform to assure both control and compliance, while providing a seamless transfer of clinical operations to manufacturing operations.*

***- Ernie Bognar, Chief Operations Officer Gradalis, Inc.***

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