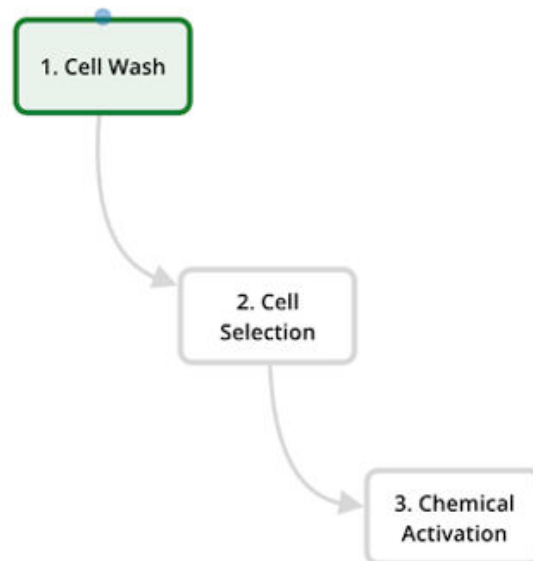




Supporting Cellipont Bioservices in Their Mission to Advance Cell Therapy Development and Manufacturing

To advance cell therapy development and manufacturing, Cellipont Bioservices opened a new, state-of-the-art manufacturing facility in The Woodlands, TX. Digitalizing their processes and automating batch records from the start ensures that their facility meets current and future regulatory standards while enhancing quality and efficiency across all cell therapy processes. This opportunity enables Cellipont to replace non-compliant spreadsheets and an error prone, paper-based, and inefficient sample and data processing approach. Digitalization also allows them to make quality assurance (QA) review more efficient and aligned with the rest of the manufacturing process.

Implementing an efficient data and manufacturing management process to enhance operational efficiency using the Manufacturing Execution System (MES) which is fully embedded in the L7|ESP® Unified Platform, also enables them to optimize their inventory management for streamlined distribution and consumption processes. The Unified Platform L7|ESP with its Workflow Orchestration and Data Contextualization was chosen as the central data platform to accommodate complex and growing manufacturing requirements, increasing efficiency and scalability, and employing fully digitalized and templated batch record workflows using L7 MES.



L7|ESP HELPS ACHIEVE CELLIPONT'S GOAL AND PROCESS CHALLENGES

Challenge	L7 ESP Provides the Solution
Digitalizing complex, paper-based batch records and processes for manufacturing	<ul style="list-style-type: none">• Flexible and fully featured MES application that streamlines entire workstreams and enables review-by-exception manufacturing• Configures recipes using the L7 ESP entities, such as protocols, workflows, and workflow chain components• Supports all data types fit for manufacturing execution systems, including configurable electronic signatures, sample plan management, and end-of-batch label reconciliation• Addresses several aspects of life sciences process manufacturing, including Electronic Batch Records (EBR), Bill of Materials (BOM), Sample Plan Management, Specifications, Quality Review, Signature Sign-Off, and automatic Batch Reports• Creates transparency across manufacturing which results in enhanced, company-wide efficiency• Digitalizes batch records and captures complex manufacturing processes and data<ul style="list-style-type: none">◦ Automates batch record reporting• Templatizes workflows for cell therapy processes• Automates calculations and barcode scans to reduce manual input errors• Supports efficient task management• Enables reviewing and assigning tasks to specific technicians
Inefficient QA processes	<ul style="list-style-type: none">• Supports the built-in of quality review processes• Defines strict Signature Flows to follow for quality signoffs and hand-offs<ul style="list-style-type: none">◦ Enables users to sign asynchronously or enforces user uniqueness• Supports role, workgroup, and user-level task management<ul style="list-style-type: none">◦ Enables more efficient assignments for quality reviews
Manual sample tracking	<ul style="list-style-type: none">• Automates sample tracking• Integrates with BarTender for label printing and barcode system<ul style="list-style-type: none">◦ Gathers and integrates data from L7 ESP for various BarTender label templates (e.g., entities, assets, items, containers, and kits)◦ Removes manual label writing◦ Supports label printing in bulk• Reduces time and errors via a connected barcode scanner system• Kicks off accessioning and prints labels ahead of time<ul style="list-style-type: none">◦ Supports better planning and preparation
Error-prone inventory (reagents and equipment) management	<ul style="list-style-type: none">• Manages the registration and receipt of inventory items in bulk via the Materials Receipt Applet• Manages the storage location of all inventory items via Containers• Tracks the status of each item, including the amount left and specific item pricing• Manages equipment throughout a facility/the entire organization and keeps record of maintenance information

Value Add: L7|ESP, with L7 MES, brings organizational excellence and efficiency to Cellipont's cell and gene therapy processes by digitalizing and centralizing manufacturing processes and data, facilitating project, sample, and data tracking, optimizing quality review and inventory management, and increasing processing throughput and end user quality of life. The system not only allows for efficient task management, but also increases connectivity, communication, and tech transfer between various manufacturing groups and sites.



The Unified L7|ESP Platform is the ideal solution for us to digitalize, modernize, and improve our internal Excel spreadsheet- and paper-based processes to formalize our manufacturing processes and data and to optimize quality review and inventory management.

- Mike O'Mara, Chief Operating Officer, Cellipont Bioservices



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L7 Informatics reimagines data intelligence for modern life sciences and healthcare organizations. Beyond simple data management, L7 provides tools that optimize the flow of information between processes and people, unlocking innovation at every stage of the clinical, research, and manufacturing value chains.

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