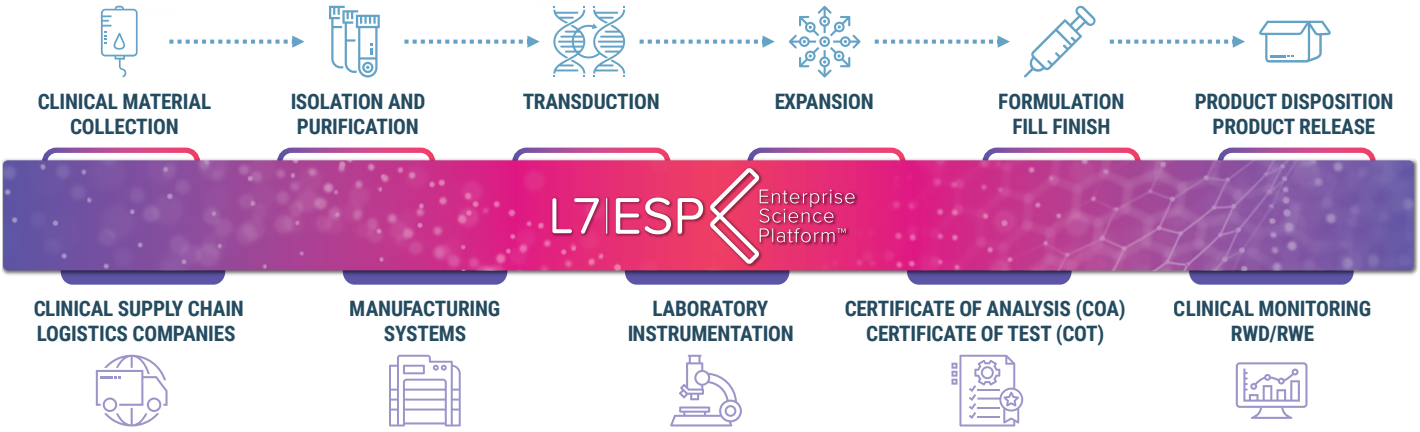
L7|ESP Enterprise Science Platform™ L7 MES

L7 MES App is a Comprehensive Manufacturing Execution System for the Precision Therapeutics Workflow



CURRENT CHALLENGES

Manufacturing of pharmaceutical products is complex and time-consuming, often resulting in delays, deviations, and unplanned, increased costs. Traditional processes often operated with complex, paper-based ecosystems, rigid manufacturing electronic systems, and non-compliant spreadsheets bottleneck operations resulting in delayed product dispositions.

Digital technologies, like L7 MES, have emerged in the pharmaceutical manufacturing industry to streamline entire productions while enabling review-by-exception manufacturing.

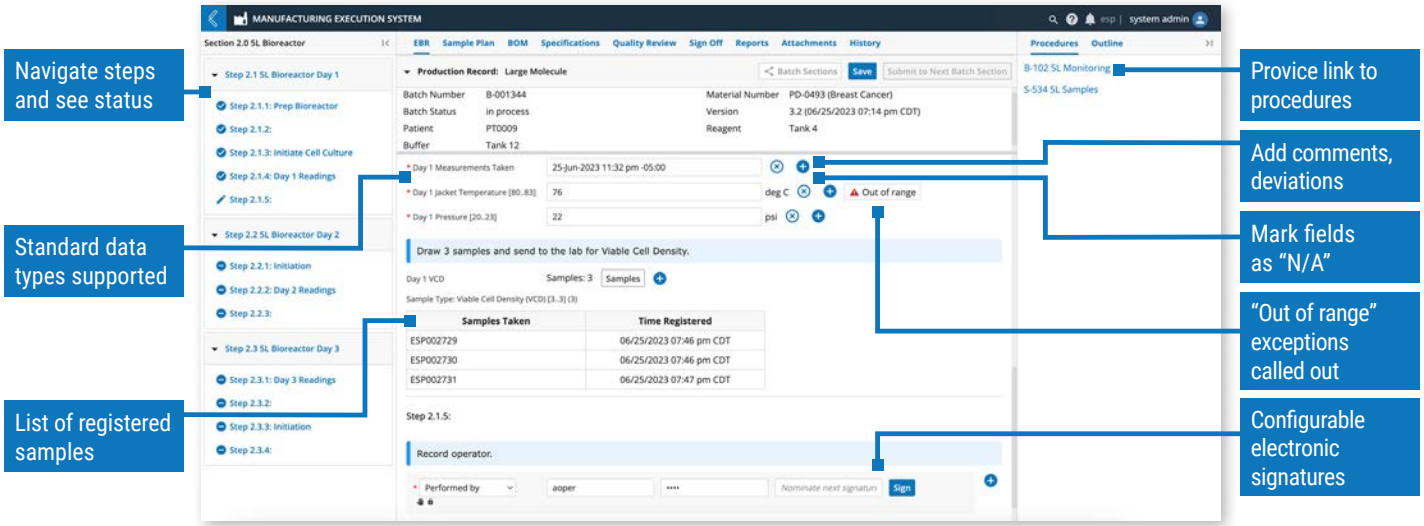
KEY CHARACTERISTICS

- Is a flexible, digital, and process-oriented solution designed to overcome traditional pharmaceutical manufacturing bottlenecks.
- Ensures 21 CFR Part 11 compliance for production of small molecules, biologics, and CGT products.

KEY BENEFITS

- Rapidly configures Master Batch Records, Intermediate, and Drug Product recipes.
- Supports configurable electronic signatures, sample plan management, and label reconciliation.
- Enables Electronic Batch Records (EBR), Bill of Materials (BOM), Sample Plan Management, Specifications, Quality Review, Signature Sign-Off, and automatic Batch Reports.

USING EBR FOR DATA PROCESSING



L7 MES IS PART OF THE L7|ESP™ UNIFIED PLATFORM WITH ITS WORKFLOW ORCHESTRATION SYSTEM

L7 MES is part of a unified platform where manufacturing execution system data resides in the same database as LIMS and inventory data. It uses existing L7|ESP workflow chain configurations to represent the manufacturing process and gathers samples during the manufacturing process to send to LIMS. L7|ESP can be extended with data trending and charting tools for single-batch and cross-batch trending and reporting.

L7 MES OUTPERFORMS TRADITIONAL MANUFACTURING EXECUTION SYSTEMS

	L7 MES	Traditional MES Providers
Life Sciences Standardization	**Standard Life Sciences Recipes** – Bimodal solution enables rapid reusability, simplified interoperability, and exchange across multiple environments/systems.	**System-specific Recipes** – Solution-specific, hard-coded recipe files limit reusability, interoperability, and exchange across multiple environments/systems.
Digitalization	**DigitalFirst™ Implementation** – Low-code/no-code environment supports quick builds, configuration, and publishing of EBRs, process specifications, and sampling and execution plan capabilities.	**Digitization and Electronic Solutions** - Paper-under-glass solutions require creation of documents prior to digitization results=ing in unstructured data and limited reusability.
Change Management	**Citizen Developer Ready** – Scientist/engineer/technical writer self-service authoring tool to quickly revise complex manufacturing environments without the reliance of IT/OT support.	**Traditional IT/OT Support Model** – Configuration requires IT/OT resources for daily change management and process definition updates resulting in delayed time to production.
Review by Exception Manufacturing	**Real-time Quality Reviews and Approvals** – Native quality review, compliant electronic signatures, and quality approval capabilities within the EBR for exception and deviation management.	**Waterfall Quality Oversight** – Collaboration, review, and approval via quality management operates outside of the MES which results in delays & impacts to batch disposition timelines.
Dynamic Routing and Conditional Logic Handling	**Flexible Workflow Engine** – L7|ESP executes complex operations with configurable conditional logic, dynamic statements, and built-in protocol actions preventing further customization through coding.	**Rigid Workflow Management** – Predominantly simplistic, sequential native process handling which requires IT/OT customization for complex process operations, conditional rules, and recipe branching.
Platform versus Point Solutions	**Digitalization Platform Enabled** – Seamless integration with a myriad of Apps (e.g., LIMS, Inventory, and Sample Management) streamlining operations between QC, Materials Management, and Quality Operations with holistic data reporting, visibility, & analytics.	**Point Solution Creates Process Data Silos** – Point solutions require complex and rigid integrations with LIMS and sample/inventory management applications generating data across applications and limiting a single-source of truth.
Cloud Native Architecture	**Flexible Cloud-Native Architecture** – High availability container-based cloud architecture for speed, multi-site scaling, efficiency, and purpose-built regulated environments with inherent auditing controls.	**Disruptive and Difficult Scaling** – SaaS-based manufacturing execution systems require regular updates resulting in a disruption of regulated environments, increased validation, and prevention of real-time data access.

L7 MES is for:

- **Manufacturing, Quality, and Process Development Operations Leaders** – including Directors/VPs, MSAT, QA, supply chain, quality operations, and materials management
- **Operational end users** – including process/manufacturing engineers, materials management associates/handlers, manufacturing operators, QA specialists, and product specialists

"By utilizing L7 MES as part of a unified platform with LIMS and other apps within L7|ESP, manufacturers benefit from accelerated batch disposition, reduced technology transfer timelines, faster batch processing, review by exception, and rapid recipe configuration. This ultimately leads to improved quality control in a streamlined process with faster time to market for their products."

L7 INFORMATICS

L7INFORMATICS.com

1219 W 6th Street
Austin TX 78703 USA
+1 888 461 5227
info@L7informatics.com

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.