ESP Enterprise Science Platform™

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ESP Solution: Precision Therapeutics

introduction

Precision medicine and new classes of biological treatments, including cell and gene therapies, require a new category of companion informatics that automate and synchronize complete manufacturing, quality management and treatment processes.

L7's Enterprise Science Platform (ESP) is a scientific information management (SIM) platform that utilizes dedicated applications and bidirectional connectors to integrate all aspects of a sample's life cycle into a single platform. By integrating previously siloed information from disparate instruments, software, and quality management systems, ESP alleviates pain points routinely associated with data analysis, reporting, regulatory submissions, and audits, which ultimately improves the organization's efficiency, product quality and safety, compliance, business velocity, and enterprise capabilities.

ESP puts the entire quality system into electronic format while relating the original patient sample to the drug product that is being produced so the company is able to operate in a state of control. With ESP, the QA staff can track, in real time, each step of the batch record as manufacturing, shipping and QA executes through it.

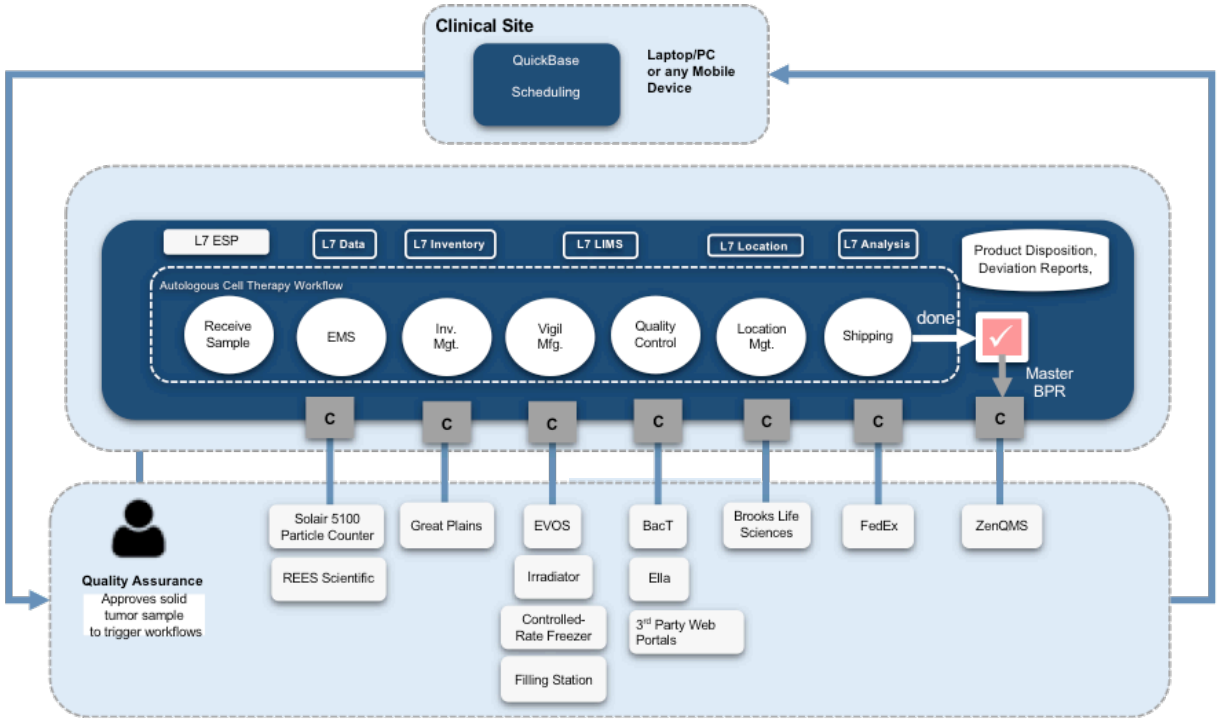
the challenge

There are many challenges leading to increased cost including:

1. Manual selection, entries & calculations
2. Siloed software and instruments
3. Siloed quality management systems
4. Process and data integrity by manual verification
5. Ad-hoc QA oversight

ESP delivers quantifiable business impact

1. Real-time process or sample monitoring
   - Issuance of deviations
   - Immediate interviews & investigations
2. Complete history of supply chain
   - Track from generation to consumption or expiry to discard
3. Integration of data from multiple sources
   - Methods to typically include offline analytics
   - Ability to allow ESP to mine data and provide analytics
4. Traditional Quality Systems operate in background to batch production records
   - Equally create workflows for each Quality System and link to BPR to assure state of control
   - Data source assessment for data integrity
5. Holistic view of subject selection, manufacture, treatment and follow-up
   - Link subject clinical data, medical records and outcome to MBR data and perform analytics across manufacturing and clinical spectrum



why customers use ESP

- Rapid implementation: from kick off to go live in as little as 5-6 weeks
- Configuration vs customization: easy-to-use interface supports the automation of complex life science processes
- Large library of pre-built connectors to life sciences instruments, bio-process equipment and software tools
- Extend capital investment shelf life: overlay ESP on top of legacy software and process equipment
- Extensibility - new bio-processes, apps and connectors can be built by customers

pre-built connectors

- NGS (NextSeq, HiSeq, MiSeq, iSeq, Novaseek, RS II, Sequel, ON Torrent, Sanger)
- CELL THERAPY (BacT/ALERT 3D, ELLA, Solair 5100 Particle Counter, BioStore III Cryo -190C, Via Freeze Due CRF, Olympus IX83, Cellometer Vision, Irradiator, Electroporator, ATFS, Centrifuge)
- Wetlab (LightCycler, LabChipGX, Spectramax, Biomek)
- QC Instrumentation (BioAnalyzer, NanoDrop, QuBit, DropSense, Tapestation, Fragment Analyzer)
- External Systems (EMS, BMS, LIMS, ELN, Billings Systems, EMR, ERP, Inventory Management, Shipping, Ordering, Label Printing)

pre-built apps

- Samples, LIMS, Locations, Inventory, eMBR, CTMS, eQMS, Projects, Data, Analysis, Global Search, Ingest Data, Admin & Dashboards

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