

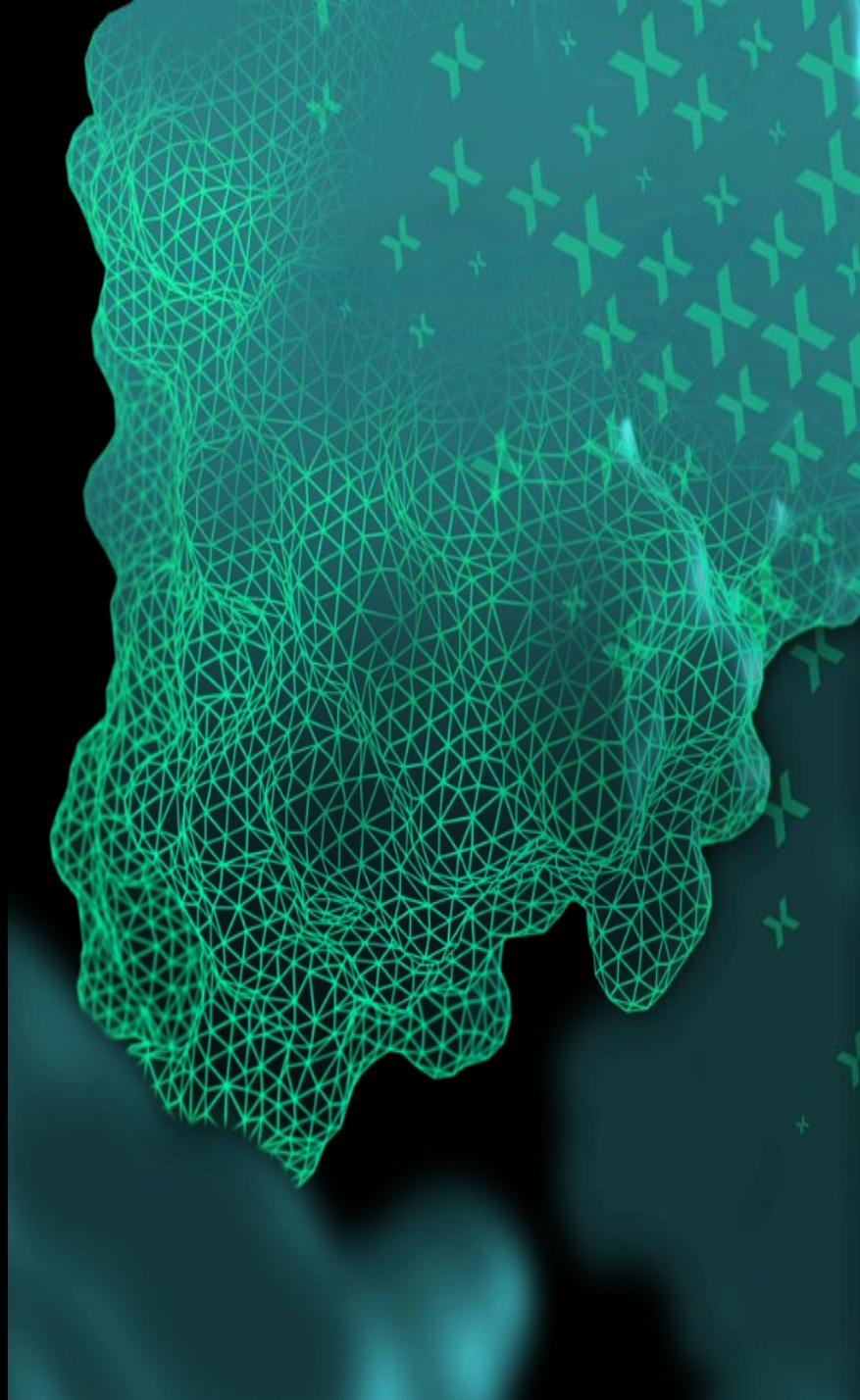
[RESILIENCE

Digital Integration in Cell Therapy: Enabling Scalable MES and Accelerating Manufacturing

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Resilience Philadelphia

Center of Excellence for Cell Therapy PAD and Manufacturing

Acquired in January 2022

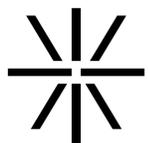
85,000 ft² facility, including 30,000 ft² expansion space

Key Differentiators

- One Site for Process & Analytical Development and Clinical Manufacturing of Cell Therapy Product
- In-House QC testing, including filed 5-day rapid sterility testing
- Integrated capabilities designed to accelerated clinical manufacturing



Cell Therapy Industry Outlook



Manufacturing Processes

Patient-specific
Low-volume
High-complexity



Rapid Evolution

Need to progress quickly
PAD →
Clinical →
Commercial



High Expectations

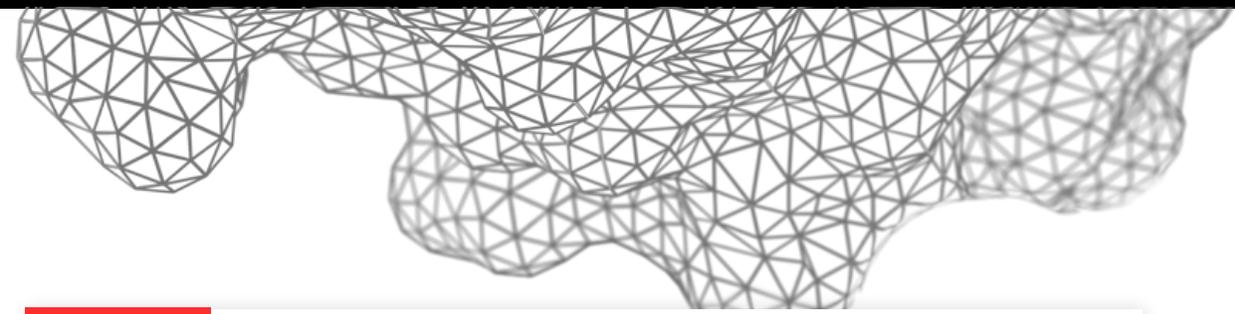
Regulatory scrutiny with
limited tolerance for
error



Increasing Velocity

Increasing pressure to
accelerate tech transfer
timelines

Agenda



Digital Integration
How do you select the right systems and unlock their potential by having them work together seamlessly?



Accelerating Tech Transfers
How does this get you the clinical production faster?

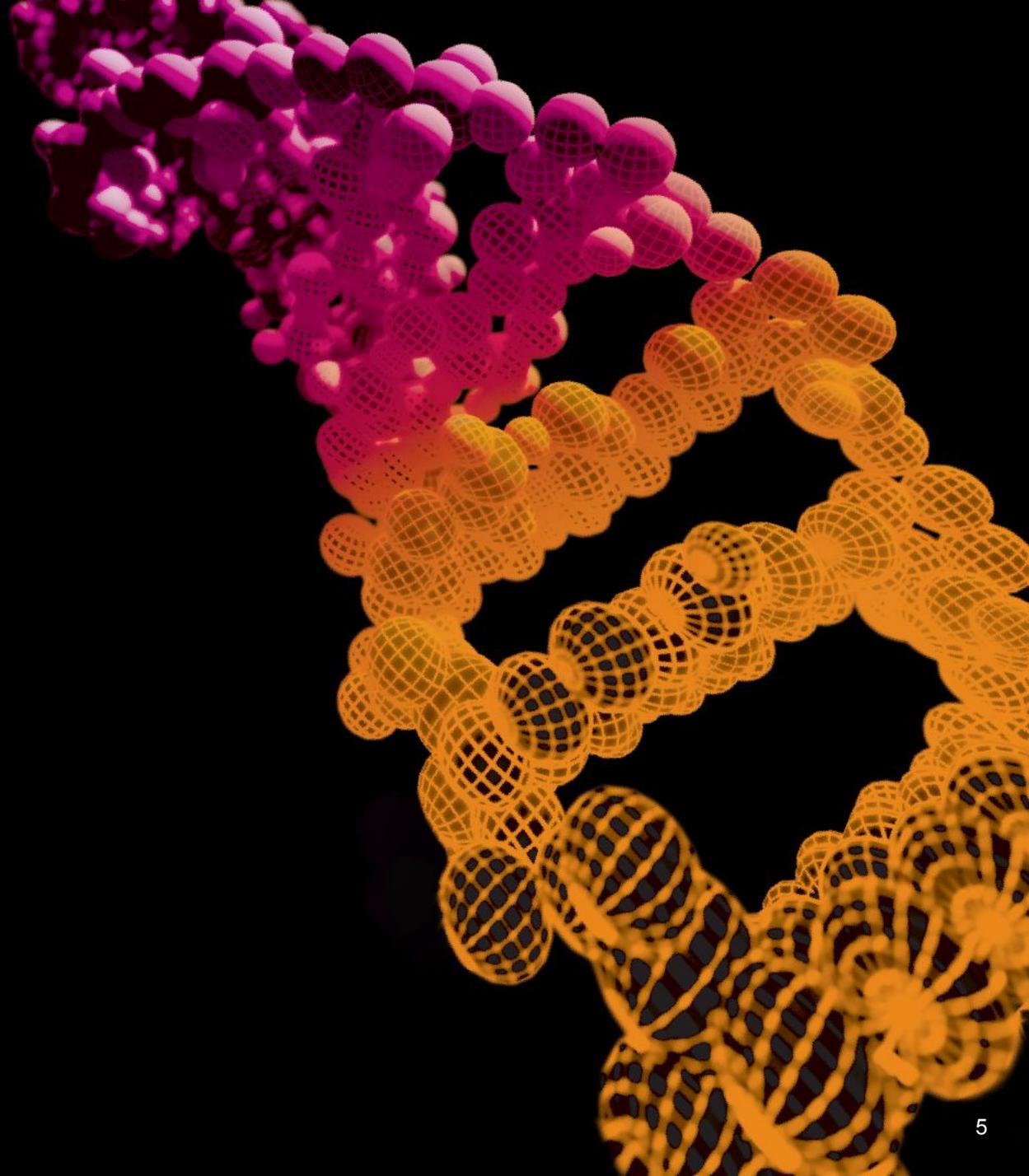


Recipe Management
How to handle development, validation, and change management in such a highly regulated environment?



Results
How does the investment of time, effort, and money lead to important benefits that translate to more therapies reaching patients sooner?

Digital Integration



MES Selection and Implementation





Manufacturing Execution Systems (MES)

The digital backbone that orchestrates, documents, and controls
GMP manufacturing execution

Execute

Guided digital workflows and data capture

Integrate

ERP/LIMS/QMS data workflows

Comply

Traceability, data integrity, audit readiness



Why Traditional MES Falls Short in Cell Therapy

- Linear workflows
- Customization burden and validation debt
- Poor fit for patient-specific batch records



MES Platform Selection Criteria for Cell Therapy

- Out of the box functionality
- Flexible, configurable workflows
- Optional automation
- Strong Electronic Batch Record (EBR) capabilities
- Vendor provided Validation package and support
- Equipment-agnostic integration
- Standardized data exchange
- Scalable from clinical to commercial

CGT success depends on selecting an MES designed for variability—not mass production.



MES Implementation

Modern validation strategies enable speed without compromising compliance.

- Industry shift from CSV to CSA approach
- Leverage what is available from the vendor
- Clearly define intended use
- Risk assessment connecting functionality to patient/product impact
- Evidence that critical functions were adequately tested
- Ongoing system performance monitoring
- Guidelines for maintaining recommended updates



Integration

- MES value is unlocked when it is fully integrated, not implemented in isolation.
- Other systems within the digital ecosystem:
 - ERP (materials, inventory, scheduling)
 - LIMS (QC data, release testing)
 - QMS (SOPs, deviations, change control, CAPAs)
- Eliminating manual transcription, delays, and data silos
- Cloud-based integration platforms reduce custom coding and accelerate connectivity.

Recipe Management



Lifecycle Governance and Compliance





Essential Procedural Guidelines

Clear ownership and proceduralized governance are critical to sustaining MES performance over time.

- System Administration
- Recipe and Configuration Change Management
- Recipe Risk-Based Verification and Testing



Cross-Functional Support

- Proceduralized design review with clear roles and responsibilities
 - Digital
 - MSAT
 - Manufacturing
 - QA
 - Supply Chain
- Early involvement in process mapping and URS authoring
- Designing workflows that reflect reality, not theory



Training Strategies

- Role-based training models
- Sandbox and simulation environments
- Adoption metrics: deviations, review cycle time, operator feedback

MES success is driven by people and process, not just software.



Lifecycle Management

- Versioning and configuration control
- ALCOA+ principles embedded within recipe design
- Risk-based validation approaches
 - Focus on patient safety, product quality, and data integrity
 - Test what matters, more deeply
 - Less scripted testing, more exploratory and unscripted testing
- Managing revisions without disrupting operations
- Change intake meeting with standard and accessible form for requesting updates

Strong governance enables agility while maintaining compliance

Accelerating Tech Transfer

Early MES and Process Alignment as a TT Accelerator





PD-Integrated MES Development

- Building digital workflows in parallel with Process Development
- Leverage established, validated operations
- Early definition of CPPs, CQAs, and data needs
- Standard naming conventions to help map data for accessibility
- Designing recipes alongside process optimization studies
- Reduces time required for transition from development labs to GMP space
- High ROI on proper training and previously established operations



Digital Enablement of Real-Time Visibility & Reporting

Manufacturing data is structured and governed to enable meaningful insight into process performance

Centralized data lakehouse architecture

GMP-controlled execution data is standardized, contextualized, and made query-ready across MES, LIMS, and other supporting systems.

Analytics and querying enablement

Data models support rapid analysis, trending, and cross-batch comparison without manual data reconciliation.

Data visualization platforms and custom dashboards

Role-based, configurable dashboards provide customers with real-time visibility into in-process performance, trends, and key milestones.

Digital visibility enables proactive tech transfer and faster, more confident decision-making.



Added Value of MES for Early Stage Processes

- Access to more data when you need it most – early on when the process is still being characterized
- Laying the framework to start to address commercial readiness questions early on
- Fewer late-stage changes required if they are made along the way
- Implementing early in a clinical trial allows for the recipe to evolve **with** the process, not chase after it

Results

Data access and turn around time





Digital Systems Supporting Our Manufacturing Operations

Our digital ecosystem is designed to support GMP execution, data integrity, and sponsor visibility across the manufacturing lifecycle.

Manufacturing Execution System (MES):

Electronic batch execution, guided workflows, exception management, and real-time traceability

Laboratory Information Management System (LIMS):

Sample management, sampling plans, sample labeling, laboratory execution for QC assays, and material release, enabling streamlined testing and faster batch disposition

Data Lakehouse Architecture:

Centralized, GMP-controlled manufacturing and QC data structured for analytics and visualization

Data Visualization Platforms:

Role-based dashboards providing real-time insight into process performance, trends, and milestones

Validation & Governance Frameworks:

Risk-based validation, configuration management, and change control aligned with CSA principles



Benefits

What we have established

- ✓ Fit for purpose MES implemented, integrated, validated
- ✓ Procedural guidelines in place for authoring, testing, and managing process specific recipes
- ✓ Tech Transfers focus on getting into MES and organizing the data early on

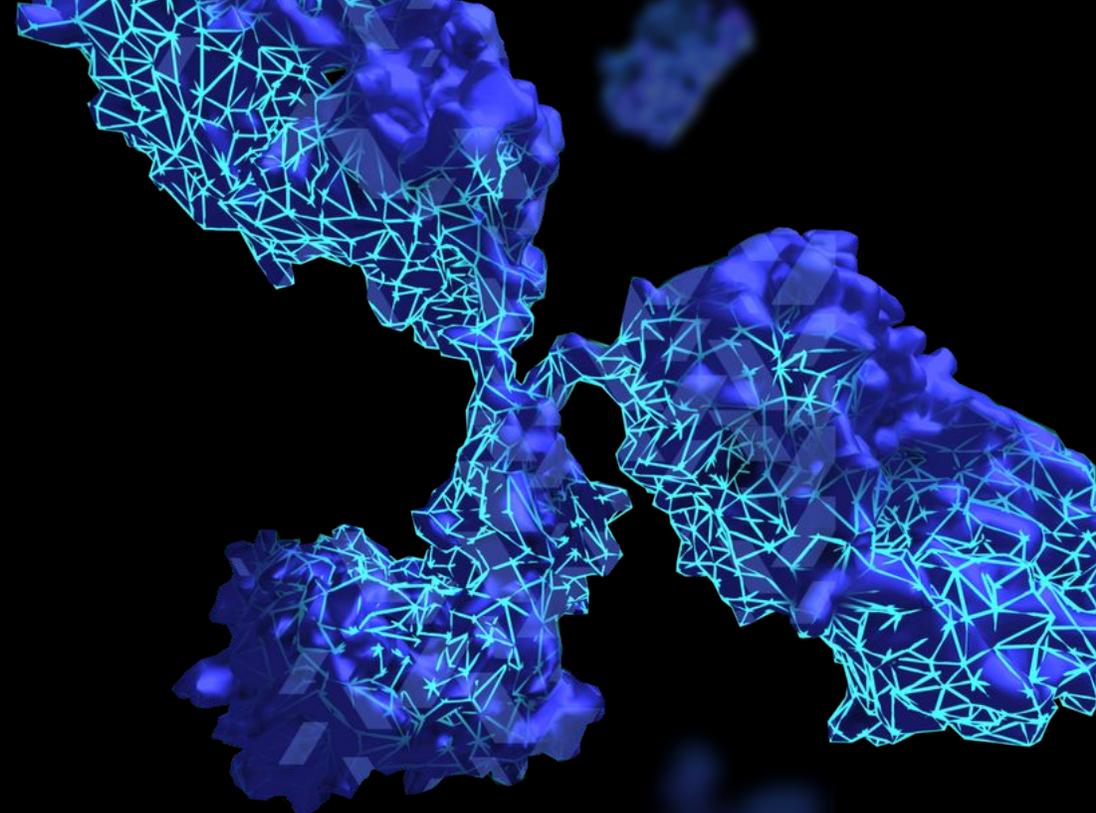
What sponsors experience

- Faster GMP readiness
- Reduced deviation frequency
- More detailed traceability
- More informed decision making
- Shorter batch review
- **Faster batch release**
- **Improved success rate**
- Increased inspection readiness



Key Takeaways

- MES platforms must be cell therapy–specific and fully integrated into the digital ecosystem
- Validation strategies should be risk-based, efficient, and aligned with CSA principles
- Cross-functional engagement across MSAT, Manufacturing, Quality, and Digital is essential
- Strong lifecycle governance enables scalability without sacrificing agility
- Early digital integration accelerates tech transfer and supports faster clinical execution
- Data integrity, transparency, and traceability are foundational to patient safety and compliance
- Digital alignment builds trust, improves communication, and drives long-term partnership success



Thank You

