

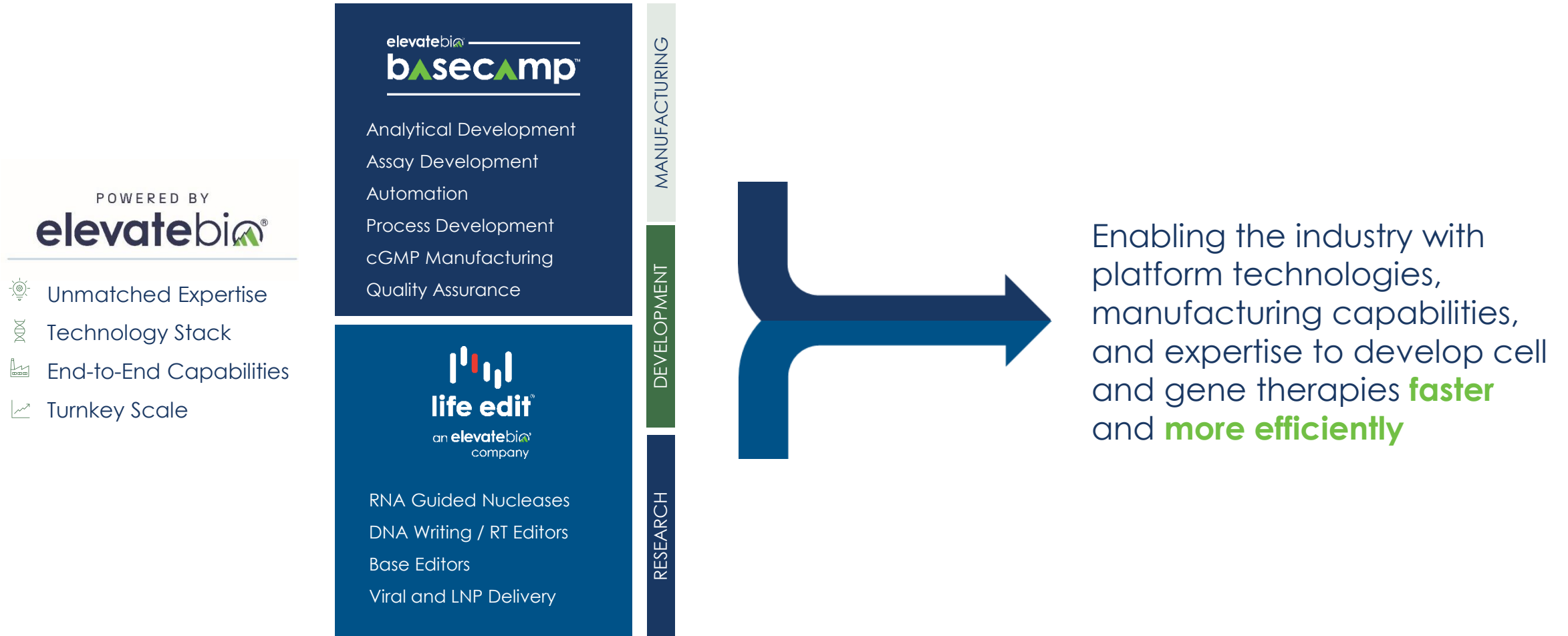


# Successfully Implementing Lean Manufacturing for Late Phase and Commercial CGT

CAR-TCR SUMMIT – LATE PHASE  
MANUFACTURING TOPIC

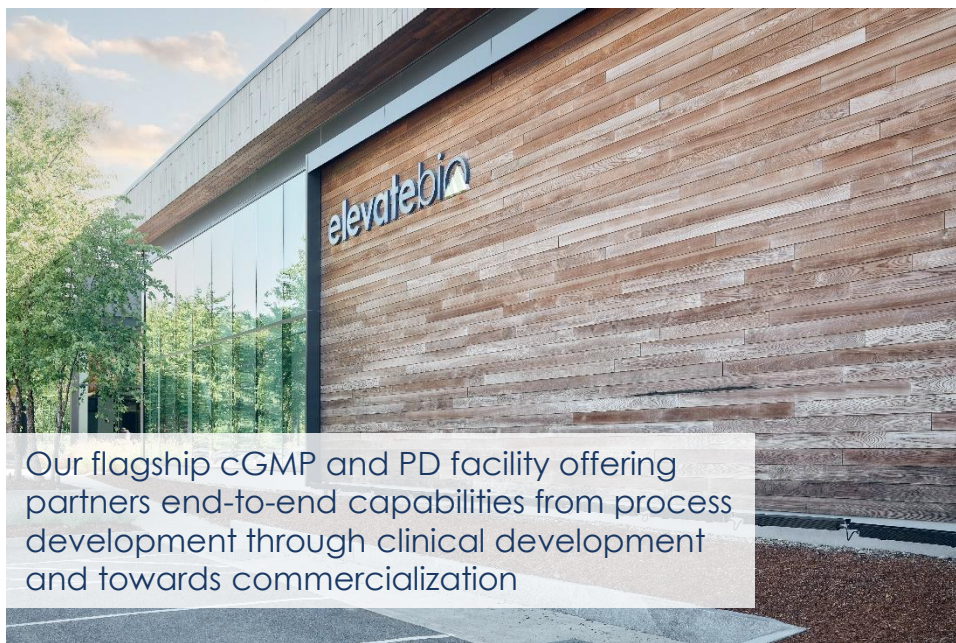


# ElevateBio: Unlocking the potential of genomic medicines through integrated manufacturing and technology stack



# Our BaseCamp biomanufacturing centers are designed to accelerate your medicines to and through the clinic

**BaseCamp Waltham: ~140,000 SQUARE FEET**



**BaseCamp Pittsburgh: ~125,000 SQUARE FEET**



## Wide breadth of PD/cGMP modality capabilities

**TCR-T and CAR-T cells**

**Gene edited HSCs**

**mRNA therapeutics**

**mRNA vaccines**

***In vivo* gene editing**

**AAV gene therapies**

**Lentiviral gene therapies**

**Engineered Treg and B cells**

**Allogeneic T cell therapies**

**iPSC-derived cell therapies**

# Investing in Your Manufacturing Process



## Needed Capabilities

- Automation
- Digitization
- Advanced QC Instrumentation & Manufacturing Equipment



## The Vision

- Streamlined process
- Minimal touch-points
- Lower cost per batch
- Higher employee satisfaction
- Improved Quality



**TIMING OF THIS INVESTMENT INTO LEAN SYSTEMS IS CRITICAL, AS IS THE NEED FOR A DEPLOYMENT STRATEGY**

# Case Studies in Master Batch Records

## PAPER BASED MASTER BATCH RECORDS

- Missing and/or damaged pages
- Human errors
- Paperwork churn
- **Lesson learned:** *Although paper batch records offered convenience, they became unsustainable as manufacturing frequency increased*

## ELECTRONIC MASTER BATCH RECORDS

- Laborious validation process and failure to launch
  - **Lesson learned:** *One size doesn't fit all*
- A simple update related to a deviation CAPA takes 6 months
  - **Lesson learned:** *Apply digitization to consistent, established processes and consider ease in making changes when selecting an eBR system*
- A software calculation data-pull error was not detected until 3 months post-deployment of a software update
  - **Lesson learned:** *Importance of a robust validation process and minimize software customizations*

# Batch Record Journey at ElevateBio

- Electronic Batch Records (eBR) were deployed in July 2022
- For early-phase partners, a hybrid approach is applied:
  - Paper batch records which provide greater agility and reduced initial costs
  - Electronic material and equipment scanning to enhance traceability
- For late-stage & commercial-ready partners, batch records are converted to electronic format
  - To date, 15 eBR deployments have been successfully completed across 3 partners

WE CUSTOMIZE  
THE PAPER VS.  
ELECTRONIC  
APPROACH  
BASED ON  
PARTNER  
NEEDS AND  
PRODUCT  
STAGE





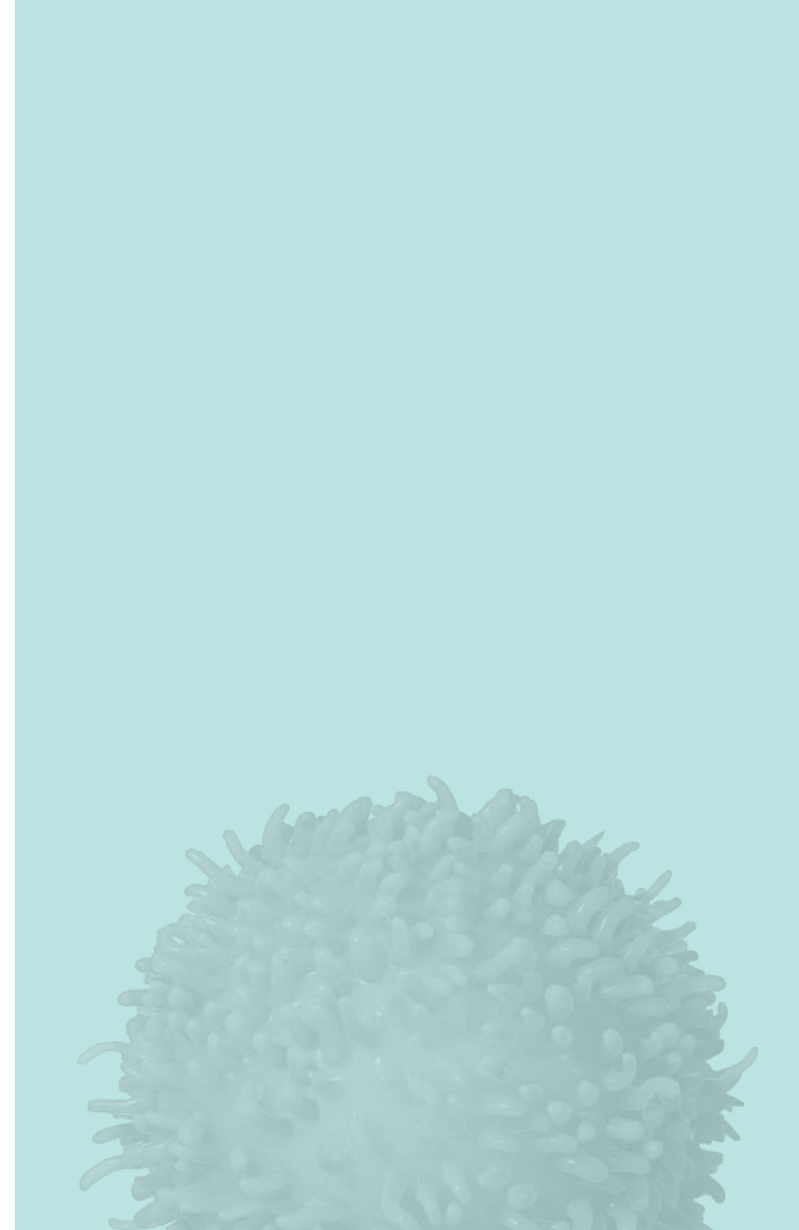
# Maintain a Balanced Approach Between Electronic and Paper Batch Records

Pros: Electronic Batch Records	Cons: Electronic Batch Records
<ul style="list-style-type: none"> <li>Human performance improvement</li> </ul>	<ul style="list-style-type: none"> <li>Cost of implementation</li> </ul>
<ul style="list-style-type: none"> <li>Less deviations</li> </ul>	<ul style="list-style-type: none"> <li>Partners may prefer reviewing paper-based PDF</li> </ul>
<ul style="list-style-type: none"> <li>Greater batch success rate</li> </ul>	<ul style="list-style-type: none"> <li>Time to implement - meeting tech transfer schedule</li> </ul>
<ul style="list-style-type: none"> <li>Faster release timeframe</li> </ul>	<ul style="list-style-type: none"> <li>Programming issues or validation errors</li> </ul>
<ul style="list-style-type: none"> <li>Improved data integrity</li> </ul>	<ul style="list-style-type: none"> <li>Difficulty in revising batch records</li> </ul>

- As manufacturing frequency increases, the shift toward electronic systems becomes necessary
- However, it's important to acknowledge the potential challenges associated with electronic batch records
- ✓ The **ideal approach** balances the efficiency of electronic batch records with the cost-effectiveness and agility of paper-based processes

## Other Examples of Lean / Digital Investment

- LIMS / eLogbook Integration
- QC Instrumentation Digital Solutions
- Environmental Monitoring Sample Management
- Data Collection & Analysis Tools



# Deployment Strategies

- ✓ **Promote a culture of ownership at the execution level**
- ✓ **Prioritize the human element in change management**
- ✓ **Seek user feedback**
- ✓ **Align strategic investment objectives with product volume goals**
- ✓ **Leverage peer networks to validate digital solutions**
- ✓ **Adopt a scalable approach – start small, then expand**
- ✓ **Anticipate constraints and build flexible processes to minimize disruption**
  - **Establish dedicated response teams**
  - **Implement and regularly test a user-centric business continuity plan**
  - **Avoid over-customization of electronic systems**

# Conclusion



**THE IMPORTANCE OF  
EFFICIENCY INCREASES  
AS MANUFACTURING  
RATES AND DEMAND  
GROW**

Balanced integration of lean principles enables a reliable and predictable manufacturing process, ultimately increasing the number of patients treated

**Thank you!**

**Any Questions?**

