From Clinical Success to Commercial Readiness

Mastering the Transition in Cell Therapy Manufacturing

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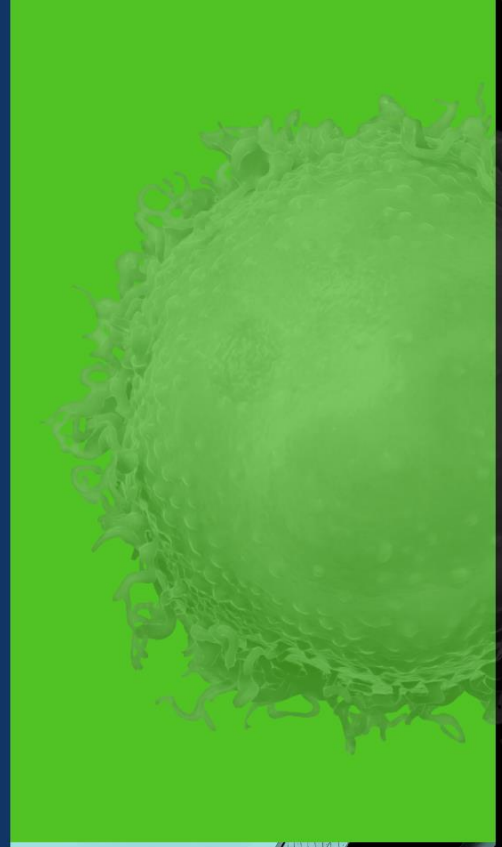

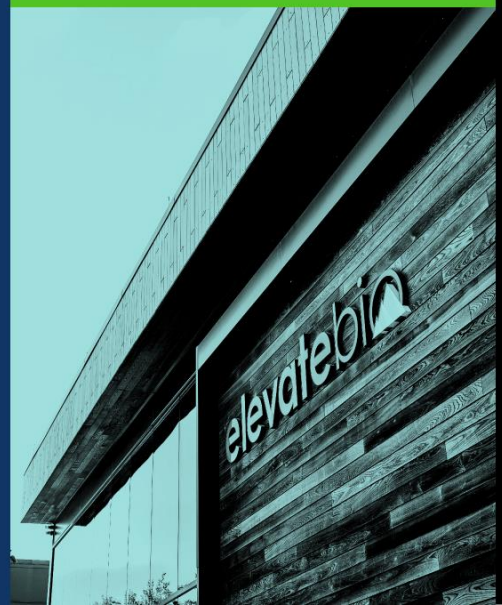

SEPTEMBER 2024

A Case Study

A sponsor is seeking a contract development manufacturing organization to supply autologous cell therapy to a Phase II study with eventual pivotal and commercial supply.

What are the elements that they need to consider for compliance, scale, and partnership?

Let's analyze how BaseCamp® has scaled and prepared for commercial scale production.

REDEFINING THE FUTURE OF MEDICINE

ElevateBio®: disrupting the genetic medicines industry

OUR VISION

To be the world's **most indispensable genetic medicine technology company**, changing how companies operate, how products are created, and how disease is treated.

OUR PURPOSE

Revolutionize development by **building and integrating the broadest collection** of technology platforms and end-to-end manufacturing capabilities.

OUR MODEL

Apply our disruptive technologies and capabilities through partnerships to deliver value to the biopharmaceutical industry.

REDEFINING THE FUTURE OF MEDICINE

elevatebio®

Scaling the world's first integrated genetic medicine foundry to accelerate the design, development, and manufacturing of transformative therapies

life edit® an elevatebio company

elevatebio basecamp™

Innovative therapies to patients

Next-Gen Gene Editing

- BASE EDITORS
- RT EDITORS
- TYPE II/V NUCLEASES
- DIVERSE PAMS

Cell Engineering

- LENTIPEAK™ LENTIVIRAL
- C-BASE EDITORS
- CIRCRNA
- NON-VIRAL

Gene therapies and Delivery

- AAV
- LIPID NANOPARTICLE

Process Development

- PROCESS DESIGN
- OPTIMIZATION AND SCALE-UP
- PROCESS CHARACTERIZATION

Analytical Development and Quality

- ASSAY DEVELOPMENT
- QC RELEASE TESTING
- STABILITY
- QUALITY ASSURANCE AND VALIDATION

cGMP Manufacturing & Automation

- CELL THERAPIES (T CELL, B CELL, IPSC, HSC)
- VIRAL VECTORS (AAV, LENTIPEAK LVV)
- MRNA

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basecamp™

Building a Genetic Medicines Best in Class Service Provider

2017

ElevateBio® was **founded**

BaseCamp Opened

1st Tech Transfer

1st Clinical Batch

LentiPeak™ LVV Platform

BaseCamp Pittsburgh

BaseCamp Waltham Expansion

20+ Partnerships

Today

EU Ready EoY

1st Commercial Partner 2025

Our Flagship cGMP Facility: BaseCamp Waltham

BaseCamp Waltham: ~140,000 SQUARE FEET

Our flagship cGMP and PD facility offering partners end-to-end capabilities from process development through clinical development and towards commercialization

cGMP Corridor

cGMP Clean Room

Building Utility Room

Current:

- **Six (6)** Grade B Cell Therapy suites (450 sq. ft each)
- **Five (5)** Gene Therapy/xRNA suites
- Fill/finish suite
- Separate cell, gene, micro, raw material QC labs

2024-2025 Expansion:

- **Three (3)** Grade B Cell Therapy suites (650 and 100 sq. ft. each)
- Expansion Space for Additional **Three (3)** Cell Therapy Suites.
- Operational **Q4 2025**
- EU Ready **Q1 2025**

ElevateBio BaseCamp Waltham

CNBC DISRUPTOR 50 2023

The Boston Globe TOP PLACES TO WORK 2023 MASSACHUSETTS

FOYA 2021 Facility of the Year Awards CATEGORY WINNER Operational Excellence

elevatebio basecamp

FOYA Award Winning

ISO 14001 & ISO 45001 Certified

Favorable Type C with FDA

BaseCamp Continued Expansion

Process Development Labs: ~180,000 SQUARE FEET

BaseCamp Pittsburgh: ~125,000 SQUARE FEET

Expanding footprint through long-term partnership with the University of Pittsburgh and $100M grant from RK Mellon

Waltham – Wyman Street PD Labs

- Less than **1 mile** from cGMP Facility
- Unmatched process development innovation
- Industry leading analytics
- NGS lab

BaseCamp Pittsburgh

- Eight (8) Cell Therapy Suites
- Two (2) Gene Therapy/xRNA Suites
- Additional 2,500 sq. ft. Expansion Space for customization
- Operational early 2027

Transitioning from Clinical to Commercial Manufacturing

CLINICAL MANUFACTURING

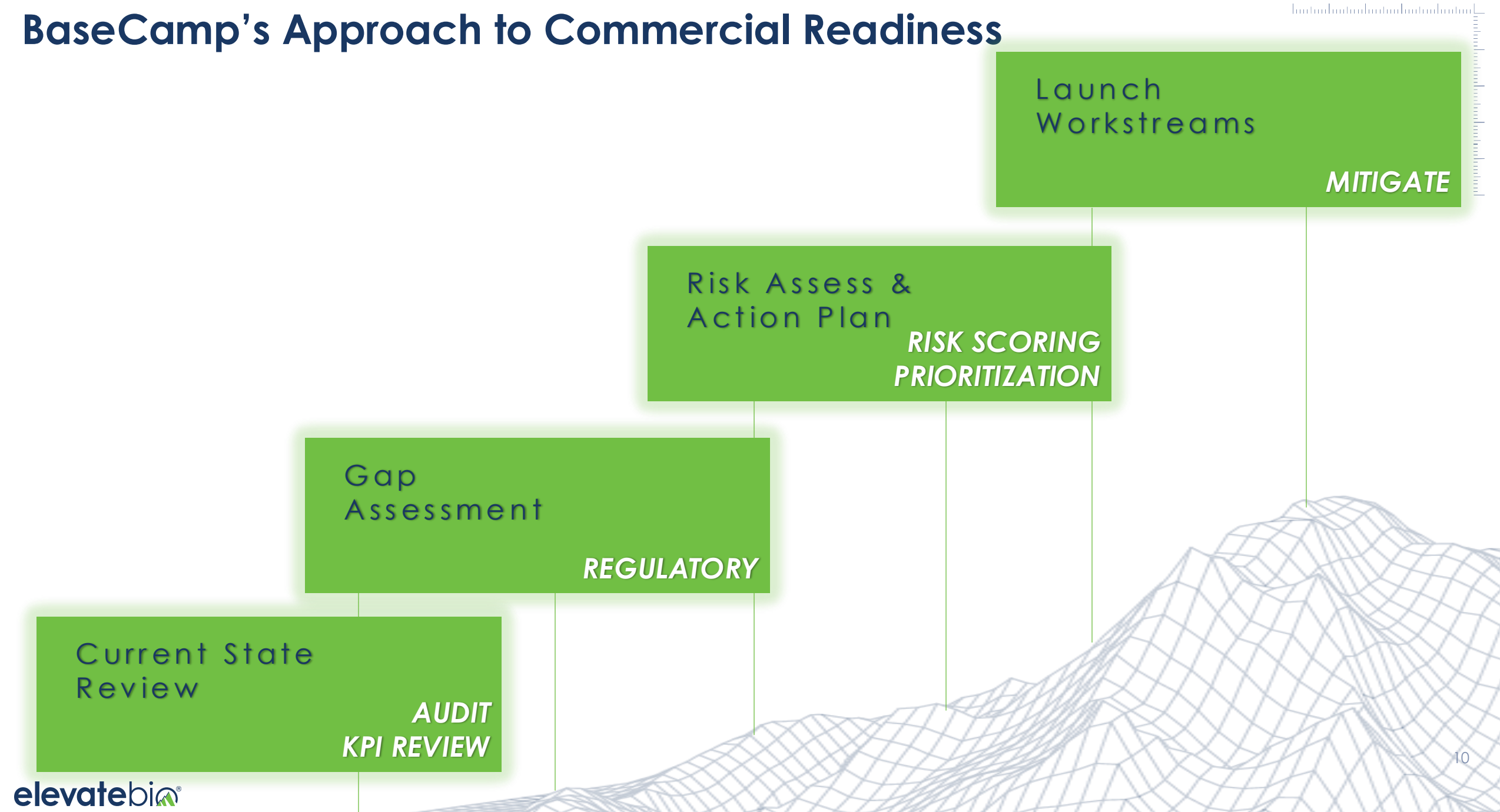
- Early phase FIH trials
- Unpredictable patient enrollment
- Need to be flexible, process is still developing
- Typically, lower batch volumes

COMMERCIAL MANUFACTURING

- Routine high-volume demand
- Emphasis on repeatability and reproducibility
- Process and CQAs are defined

Preparation → **Identify and Establish Workstreams** → **Commercial MFG Ready** → **Partner PAI**

BaseCamp's Approach to Commercial Readiness



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BaseCamp's Approach

Launch Workstreams

MITIGATE

Materials Management

- Raw Material Testing
- Supplier Qualification
- Master Data Handling
- Supplier Qualification

Contamination Control Strategy

- Ensuring Alignment to EU Annex
- EMPQ
- Regulatory flows

Quality Event

- Risk Management
- Lot disposition
- QE Workflows and Metrics
- Deviations/Change Controls/OOS/CAPA
- LIR

Partner Readiness

- Concurrent Manufacturing
- Spare Parts
- APS
- Single-use Design

Other Support

- Regulatory Affairs
- IT/Automation Systems
- Facilities & Engineering

A Case Study, Continued

- Partner chose a **dedicated** capacity model
- Clinical batch demand at BaseCamp: **2-6 patients** per month
- Expected Commercial batch demand at BaseCamp: **up to 12 patient**s per month
- Turn-around-time for release: **9-days** post harvest
- Site-to-site **Comparability** required during Engineering Run Campaign

REDEFINING THE FUTURE OF MEDICINE

As BaseCamp, we focus on:

1. Compliance
2. Capacity
3. Staffing
4. Training

REDEFINING THE FUTURE OF MEDICINE

Evaluate Compliance

Contamination Control Strategy

- EU Annex I gap assessment

Partner Readiness

- Controls for concurrent manufacturing
- Tech Transfer speed
- Capacity expansion

Training

- Quality workflows and metrics
- Maturing "Train the Trainer" program

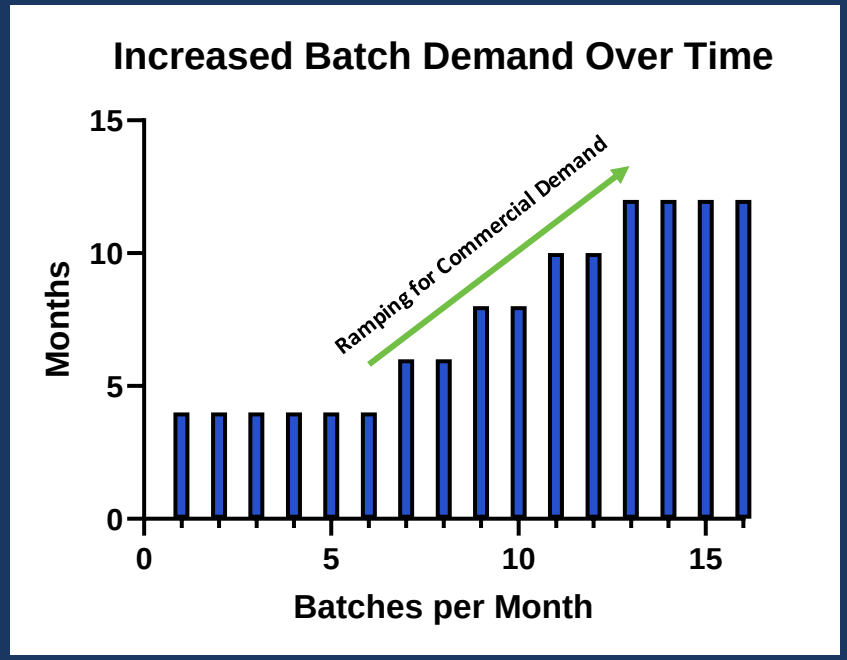
Raw Materials

- Updates to Supplier Qualification Program
- Raw Material Control and Testing

Evaluate Capacity

Considerations for Scaling Capacity

- Suite space square footage
- Layout of Processing Equipment
- Process Duration
  - Length of Days (Hours per Day)
  - Numbers of Processing Days
- Resources and staffing
- Training for new staff



Evaluate Staffing

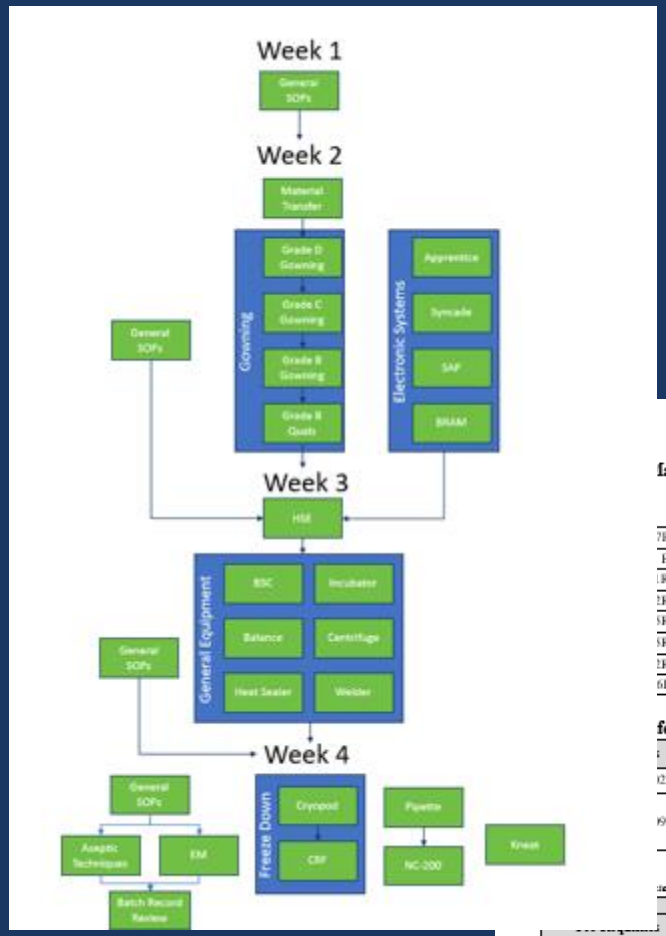
Shift Options

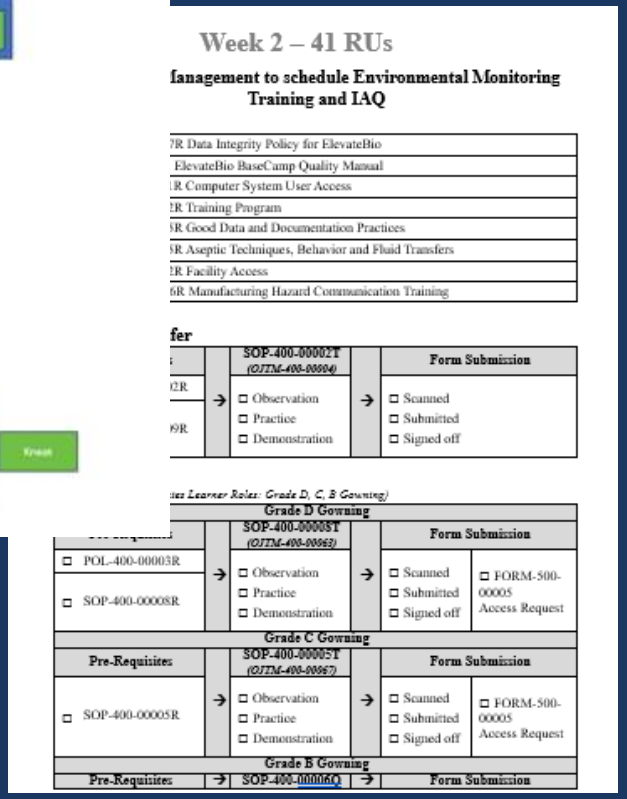
- Process Duration
  - Length of Days (Hours per Day)
  - Numbers of Processing Days
- 7 Day Manufacturing Model - Rotational Schedule, 12 Hour Shifts
- Increased hiring over time to account for on-boarding

Evaluate Training

Training Program

- Mature "Train the Trainer"
- 8 to 10 Week Onboarding Plan
- Aseptic Qualification
- Creation of BaseCamp Training Lab





A Case Study, Result

- Currently in Clinical manufacturing actively supplying current trial
- Aggressive increase in manufacturing throughput through continued capacity and staffing model assessments consistent with provided forecasts
- Evaluating BLA strategy

REDEFINING THE FUTURE OF MEDICINE

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Continue the Conversation Our Team

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