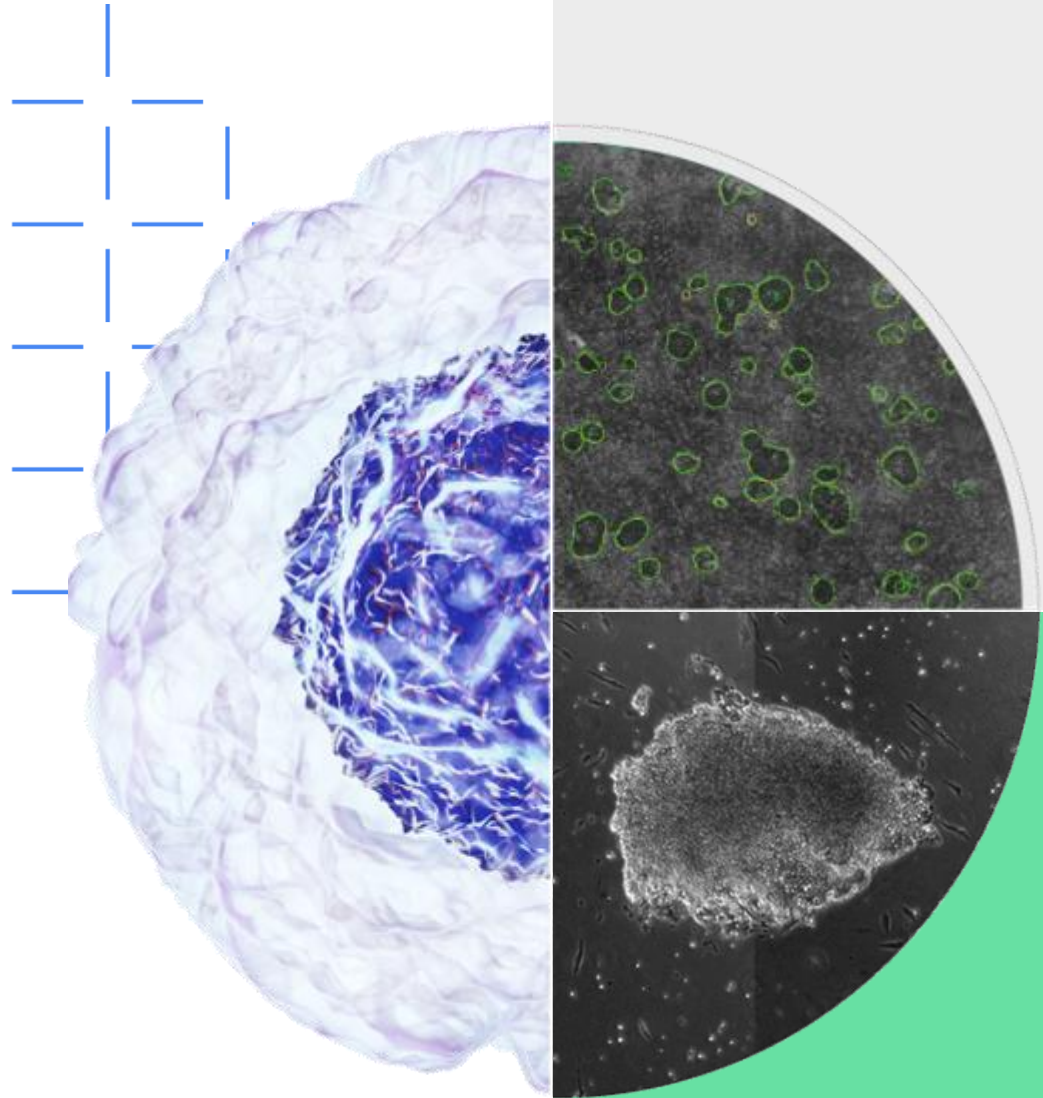**CellX** TECHNOLOGIES

Pioneering intelligent stem cell processing

Advancing Clinical iPSC for Regenerative Medicine Part 1

Lynne Frick
CEO
Cell X Technologies, Inc.
April 22, 2025

Contents

- About Cell X

- What is the problem we are solving?

- The Celligent™: System and Platform Solution

- Case Studies

- Translational services

The problem:
Automating complex, labor-intensive stem cell processing

Subjectivity

- Current cell processing approaches are consistently inconsistent
- Heavy reliance on human skill leads to inconsistency of ~40% between operators
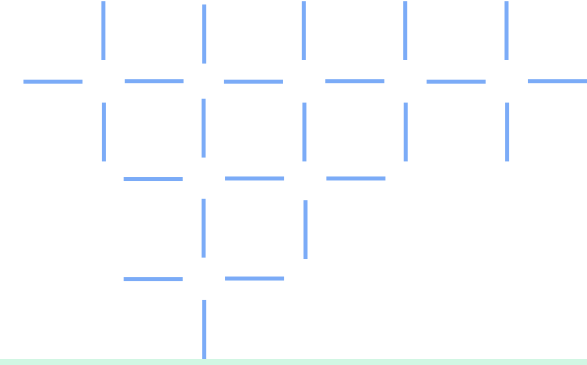
Poor scalability

- Adherent stem cell cultures require substantial manual labor
- Millions of dollars spent on personnel annually

Regulation

- GMP (good manufacturing practice) demands process consistency
- Increasingly stringent requirements on quality
- Substantial documentation burden

The questions that drive us

Quality comes first

Can we drive toward process control?

Reliability built in via automated, repeatable protocols and data acquisition, algorithms and data annotation

Automation can reduce risks in clinical manufacturing

Can we replace the manual, repeated motions and decisions of each step of the process?

- Positive and Negative cell selection
- Imaging consistency
- Liquid and plate handling

Reliable AI requires a foundation of quality data

Can we replace the manual process and decisions in an **application-agnostic way**

AND

maintain the quality metrics needed for successful regulatory filings?
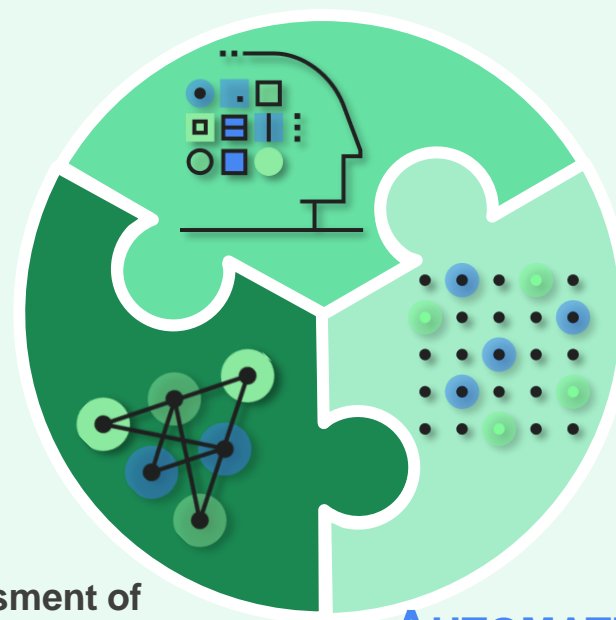
Celligent

Intelligent Cell processing

purpose-built platform leveraging AI to automate cell processing for stem cell cultures

AI & ML
Learns a process from human operators/ SME to develop reproducible protocols

IMAGE-BASED ANALYTICS
- Autonomous visual assessment of morphology to eliminate subjective decision-making
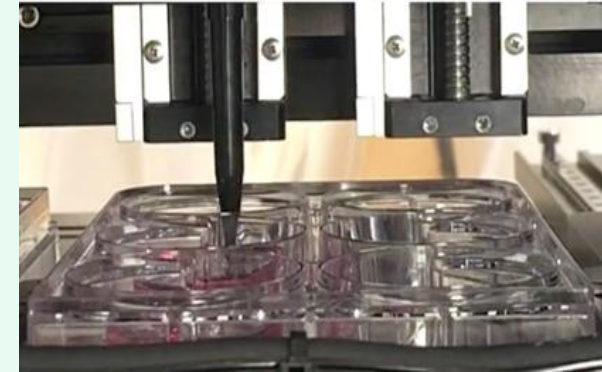- Automatic, passive documentation

AUTOMATION
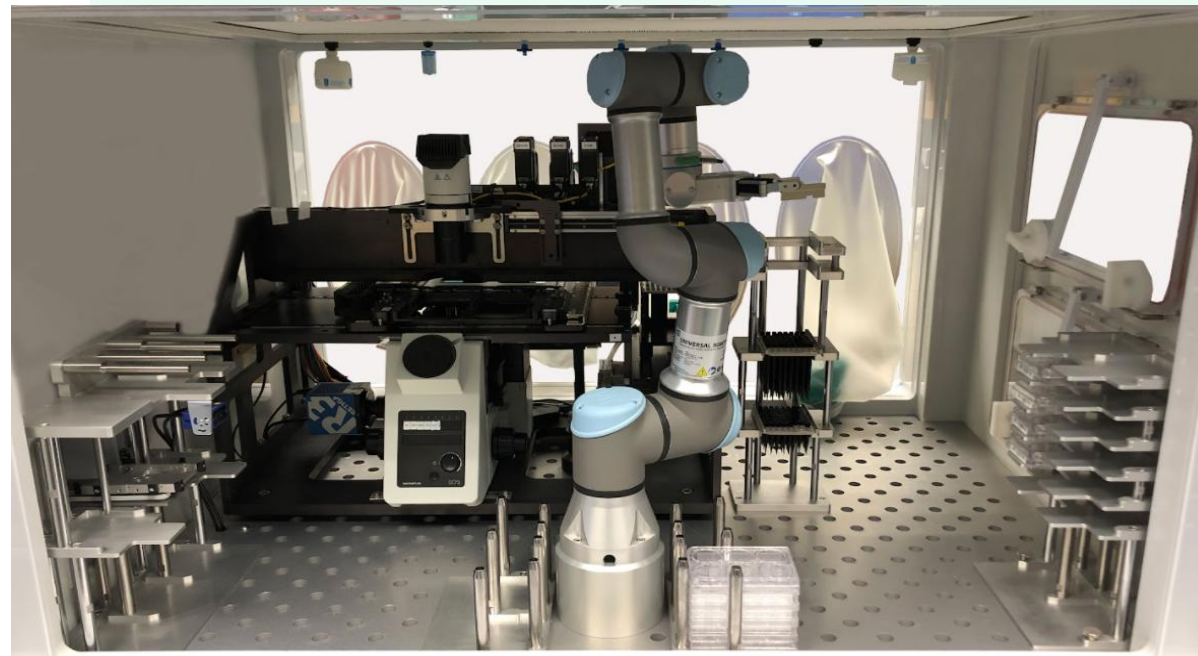- Robotics with surgical precision (+ and - selection)
- Operating 24/7
- Mimicking manual process

CellX
TECHNOLOGIES

We are pioneering robotic automation solutions for stem cell therapies

Celligent deck

✓ GMP-ready
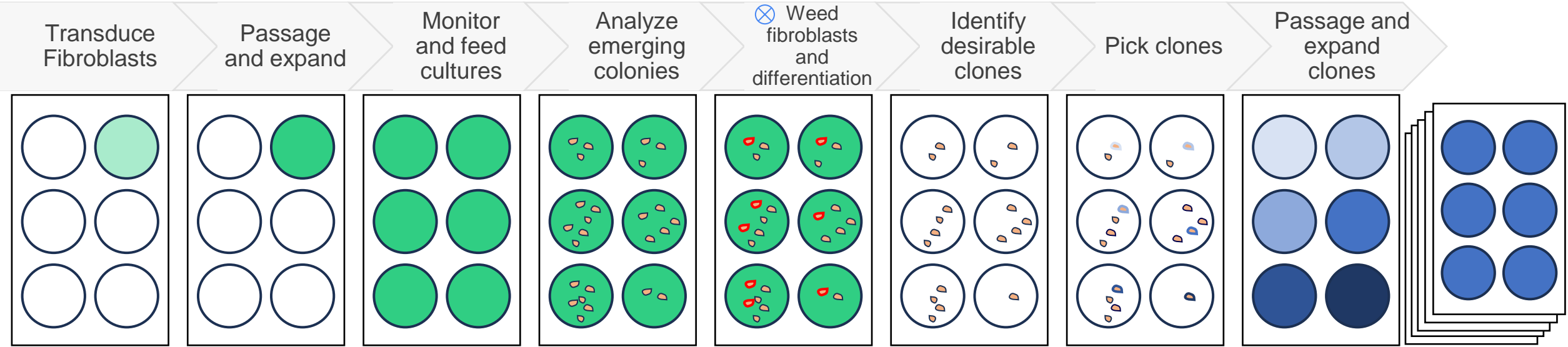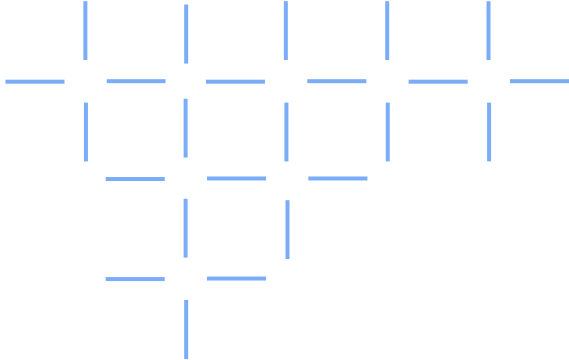
✓ 21 CFR Part 11 compliant

✓ End-to-end integration

Celligent in environmental chamber integrated with 6 axis robot and automated incubator

cellxtechnologies.com   6

Celligent Platform
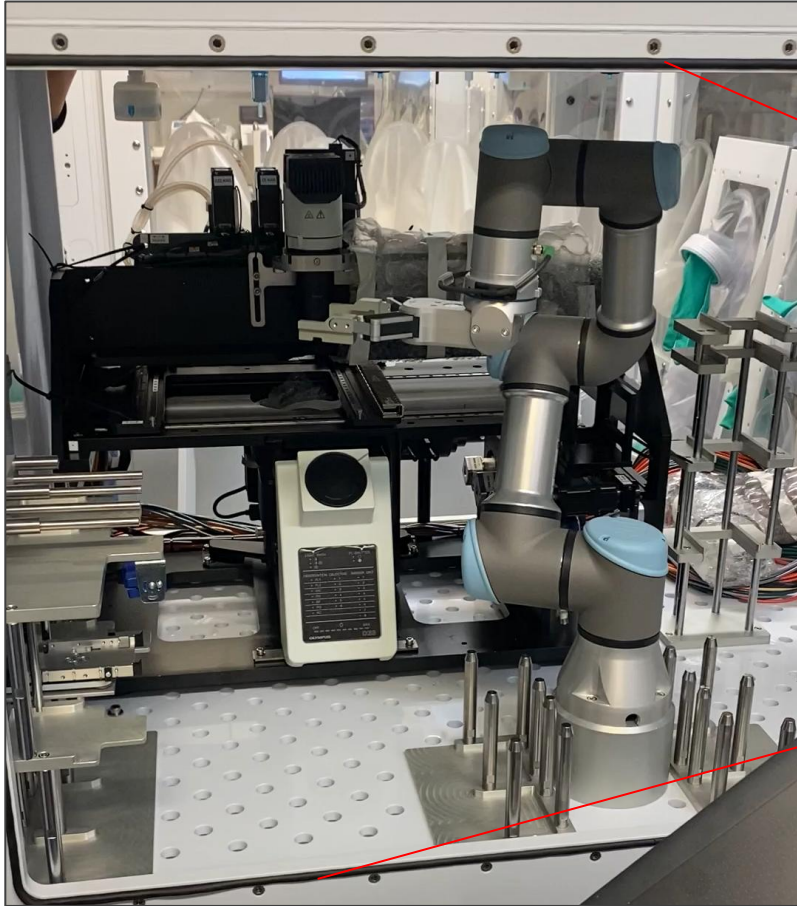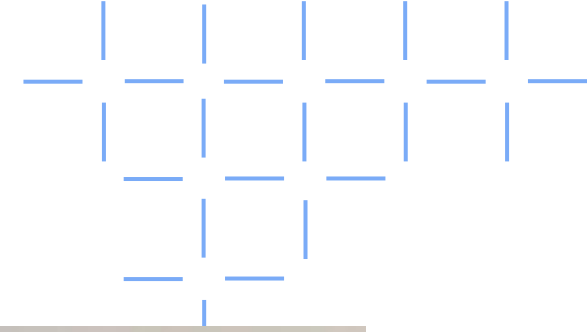
Operating installation of Celligent™ platform at Cleveland Clinic, Lerner Center for Regenerative Medicine

Working example in 6-well plates

| Transduce Fibroblasts | Passage and expand | Monitor and feed cultures | Analyze emerging colonies | ⊗ Weed fibroblasts and differentiation | Identify desirable clones | Pick clones | Passage and expand clones |

Customer Testimonial

"I've been weeding and picking these cells by hand for eleven years! Automation will be a game-changer for this industry"

Monitor and Feed Cultures

Documenting the reprogramming phase provides key insights into the specific attributes that define your process.
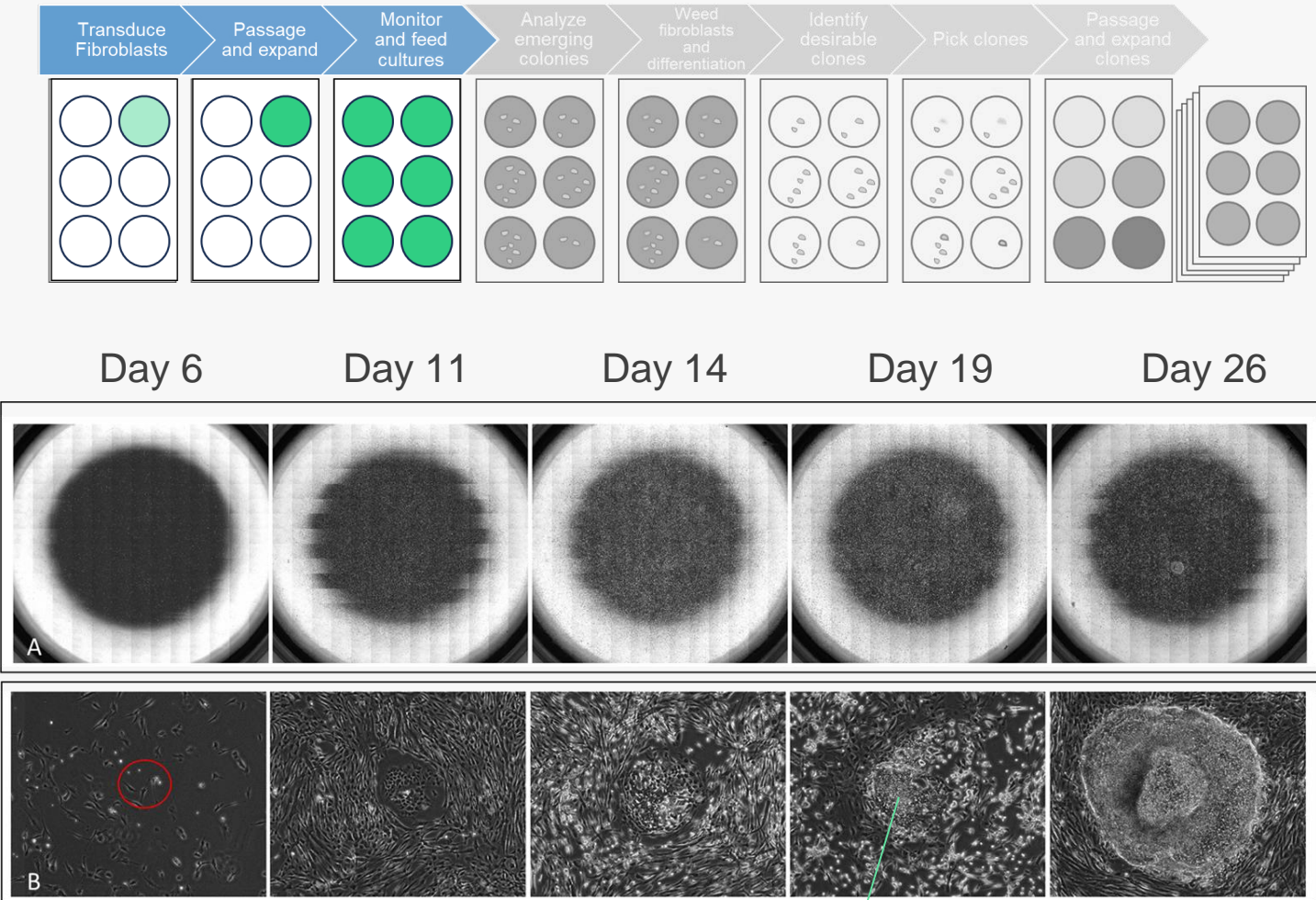
Analyze Emerging Colonies

As colonies emerge, Colonyze allows the user to identify clones that meet their CQAs.

Automated analysis ensures that clonal cultures are established from colonies that meet or exceed defined metrics.
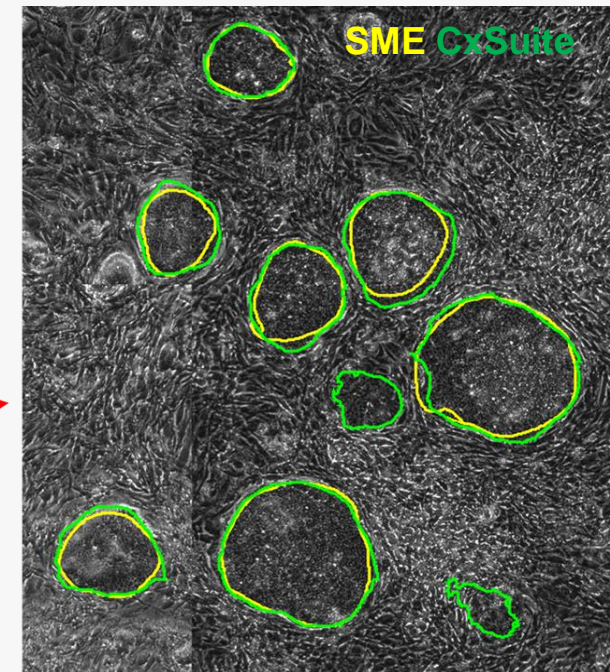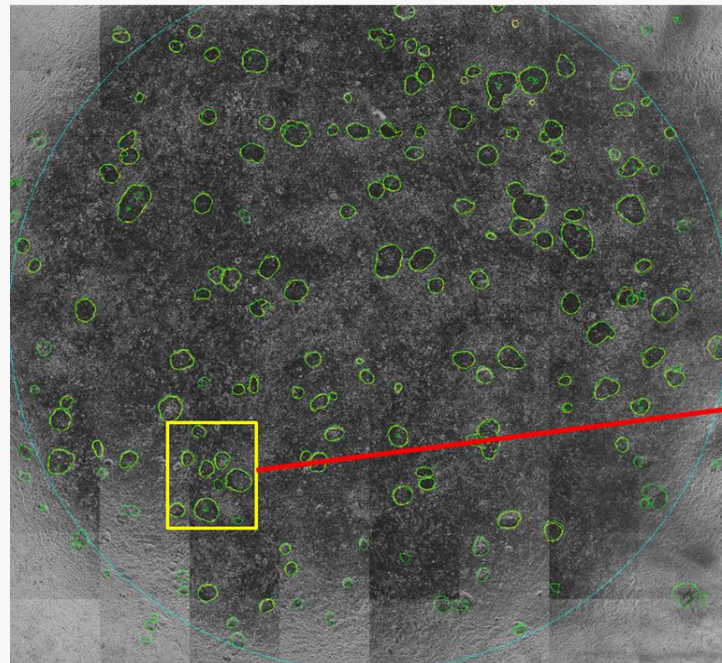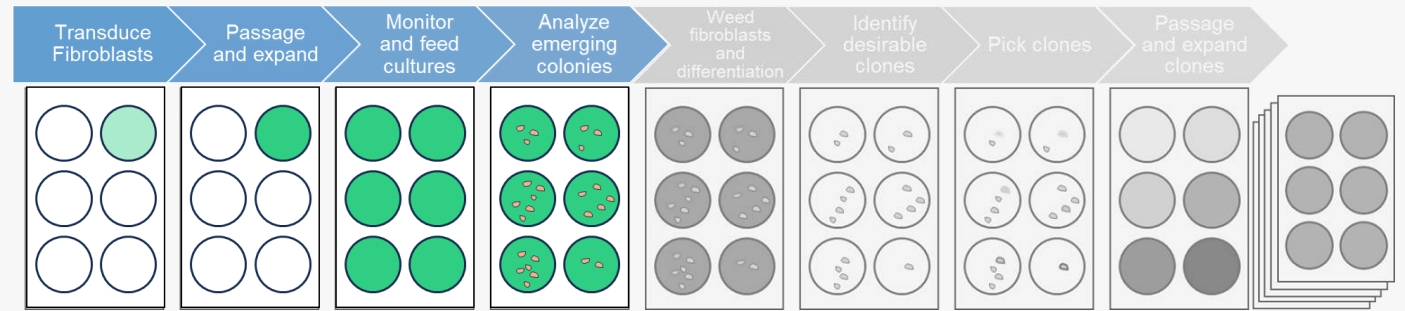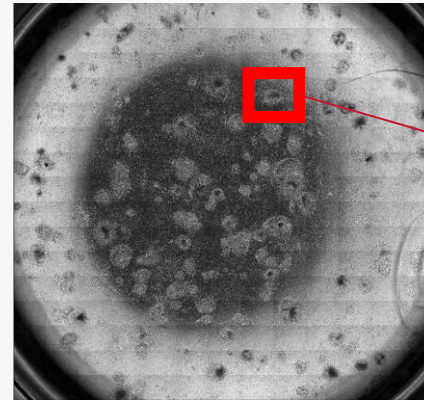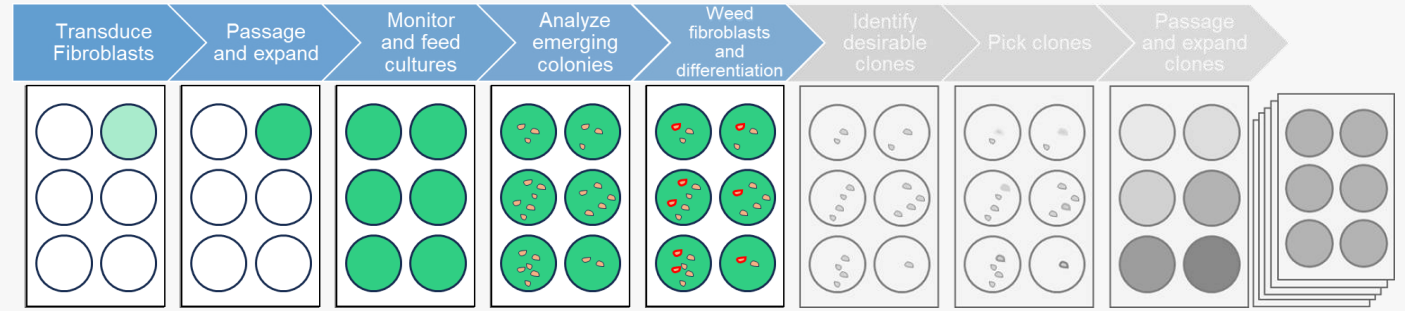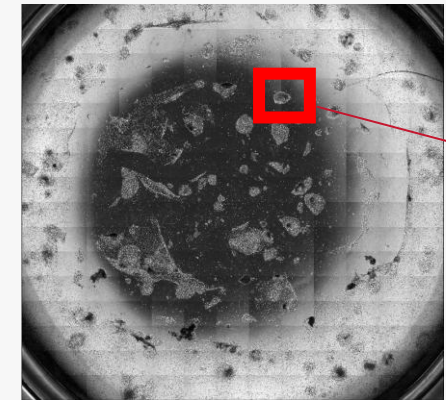
Weed Fibroblasts and Differentiation

Precisely remove fibroblasts and poor quality cells or colonies with a pipet tip, mimicking manual methods and preserving colony architecture.

Weeding movements can be optimized to remove fibroblast lawns and areas of low quality.

Before

After

Identify Desirable Clones

Use visual assessment of images or Colonyze software to identify clones that will be used to establish cultures.

Areas of spontaneous differentiation can be removed utilizing the weeding protocol prior to picking.

Good colony morphology
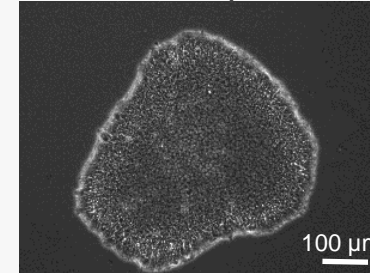
Spontaneous differentiation shown in circled regions
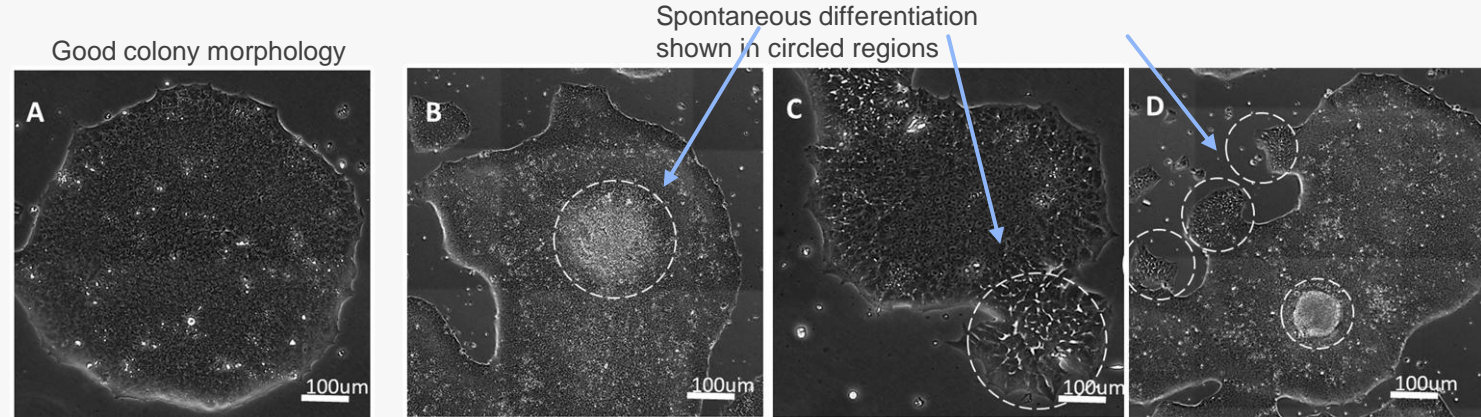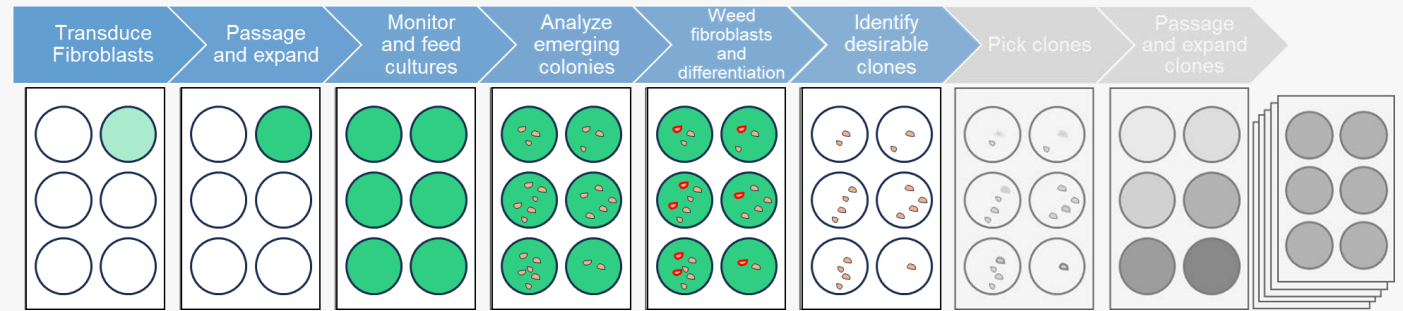
Pick Clones

Atraumatic picking uses a pipet tip to aspirate cells in clumps similar to manual cutting protocols.

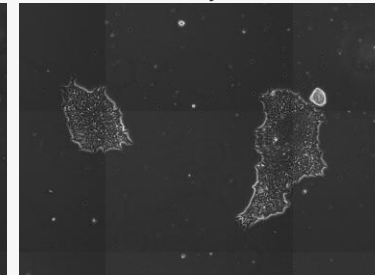Cells adhere to destination wells and expand, allowing the user to establish clonal cultures.

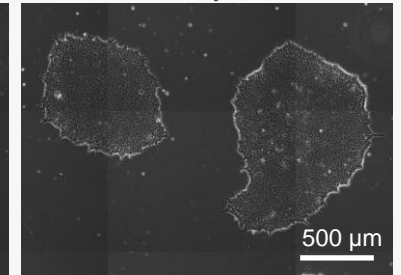| Transduce Fibroblasts | Passage and expand | Monitor and feed cultures | Analyze emerging colonies | Weed fibroblasts and differentiation | Identify desirable clones | Pick clones | Passage and expand clones |
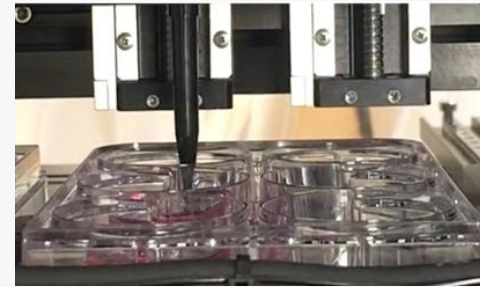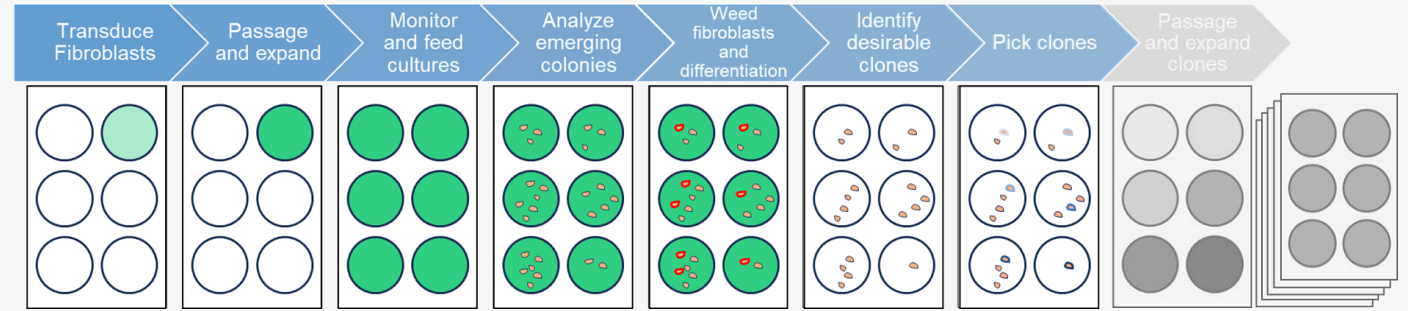
Before pick

After pick

100 μm

Post Pick: Day 1

Day 2

Day 3

500 μm

Celligent GMP Platform

Fluid Management

1-2

Automated
Incubators

Control
Cart

Processing Chamber

Dual
Pass
Through

Laminar Flow Hood
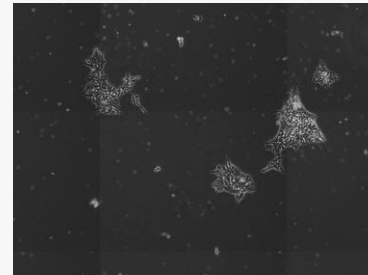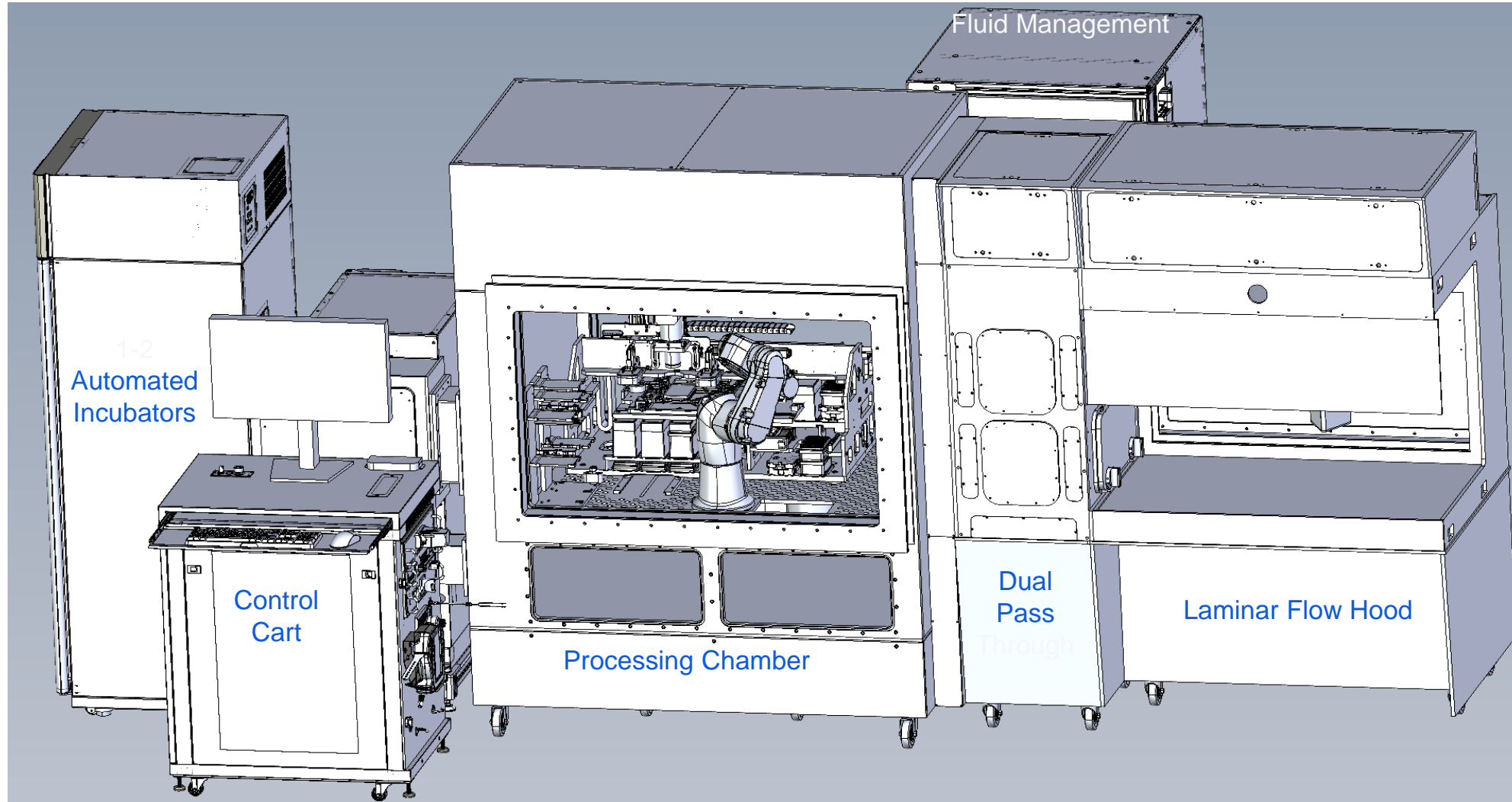
Delivery 3Q 2025

Case Studies

- Autologous photoreceptor replacement

- Allogeneic Cardiomyocyte CQA assessment

- Autologous cell therapy
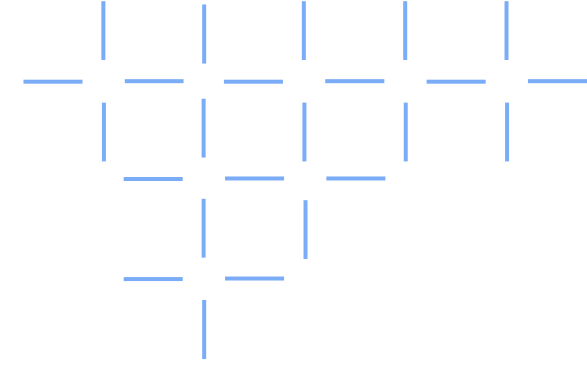
Production of clinical grade patient specific iPSCs

Courtesy of Dr. Budd Tucker, University of Iowa

Precise picking leads to better clones

Project included:

- Fibroblast culture to iPSC generation

- Clonal expansion

- Retinal differentiation
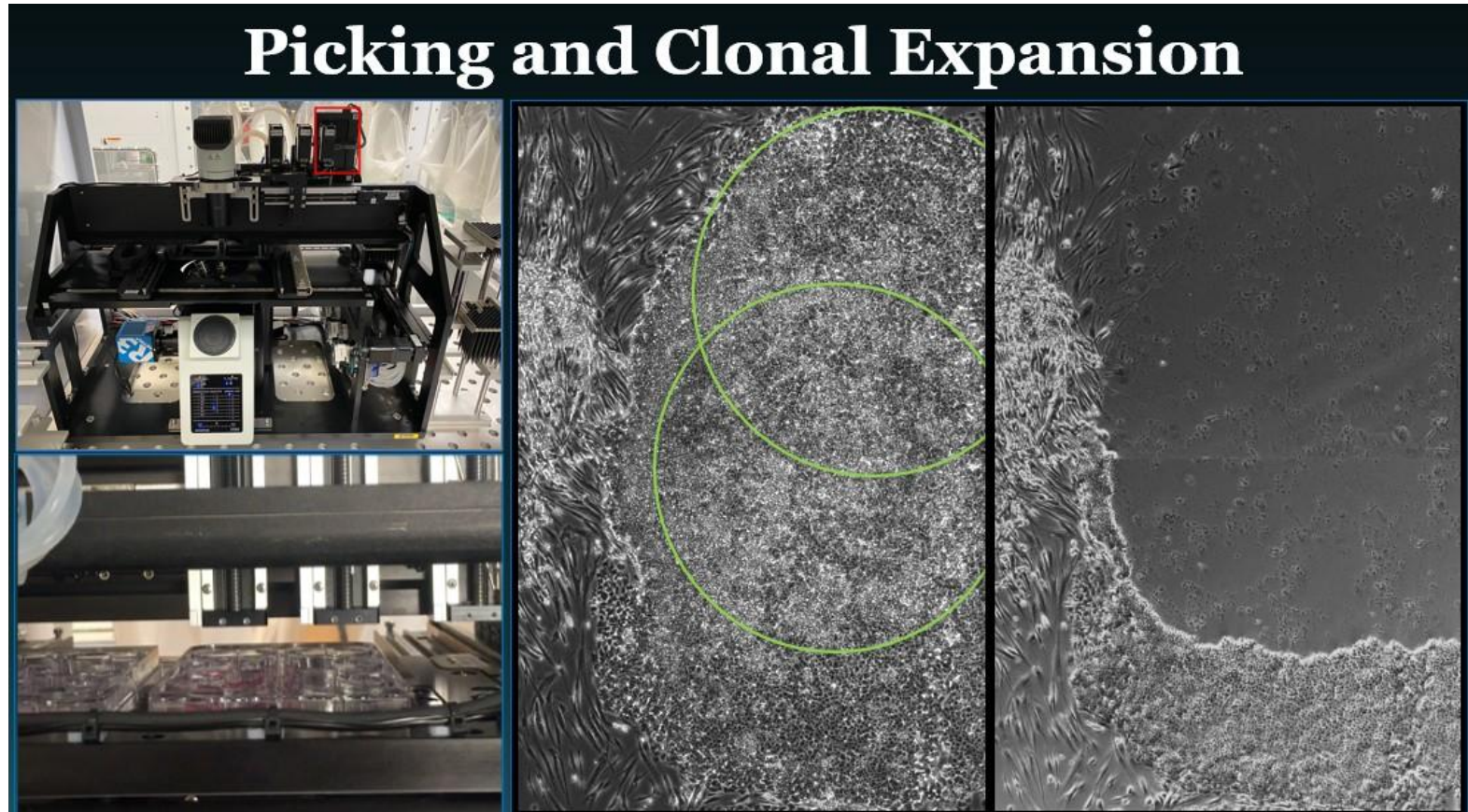
Courtesy of Dr. Budd Tucker, University of Iowa

# Advance Regenerative Medicine Institute/ BioFAB: Novel passaging methodology by selective colony picking

- Cardiomyocyte CQA project

- Allows for the selection and expansion of specific colonies

- Enhances line cleanliness and differentiation efficiency by avoiding areas with potential spontaneous differentiation
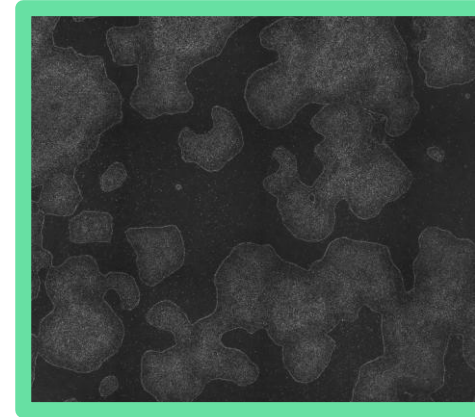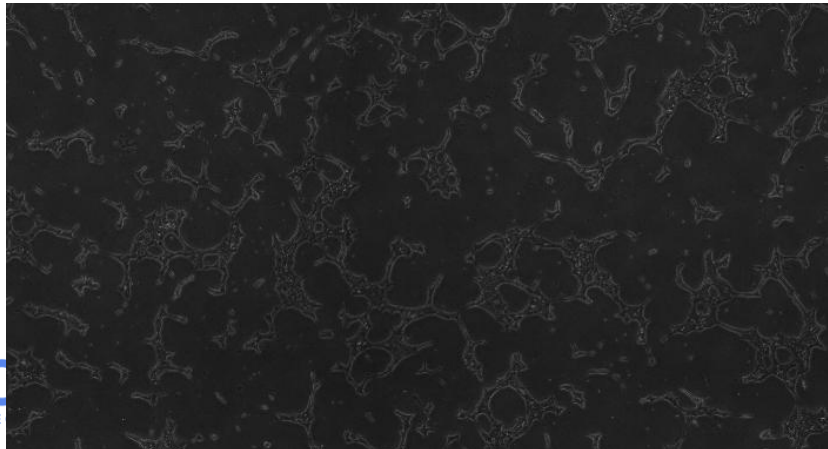
- Only feasibly through automation!
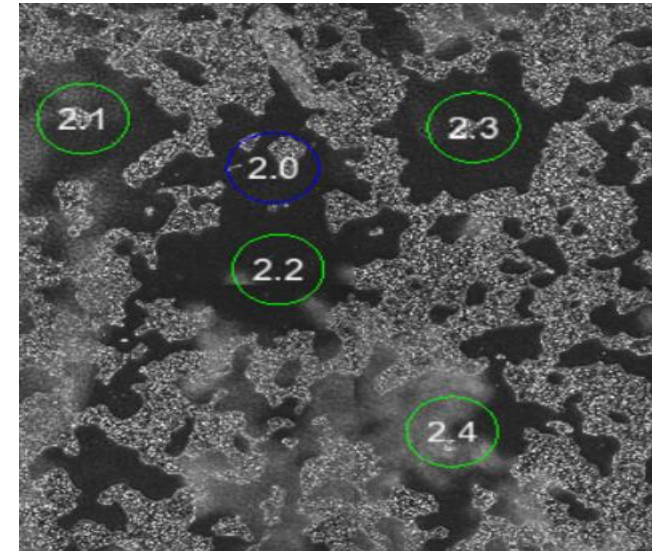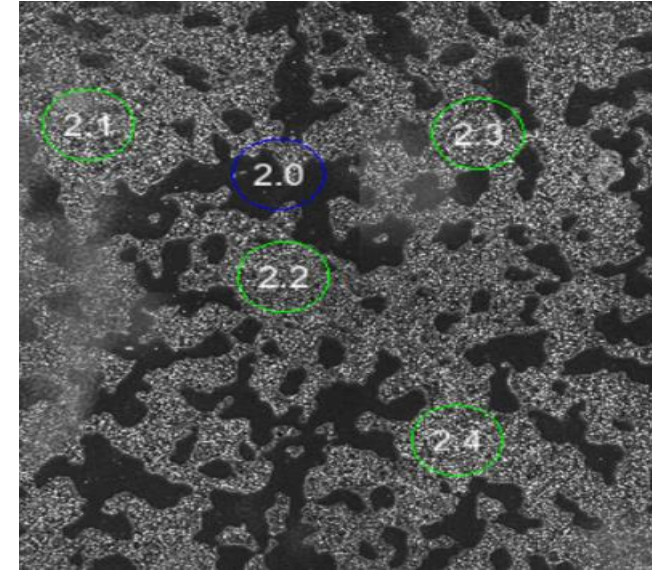
Comparison of passaging strategies
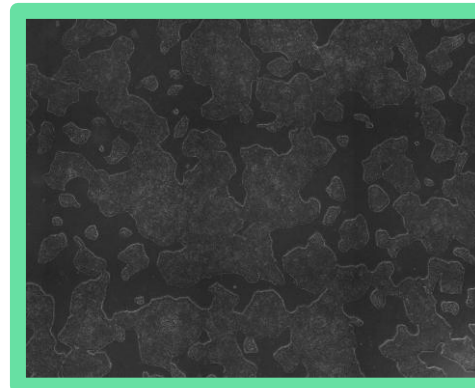
Positive and negative release picking
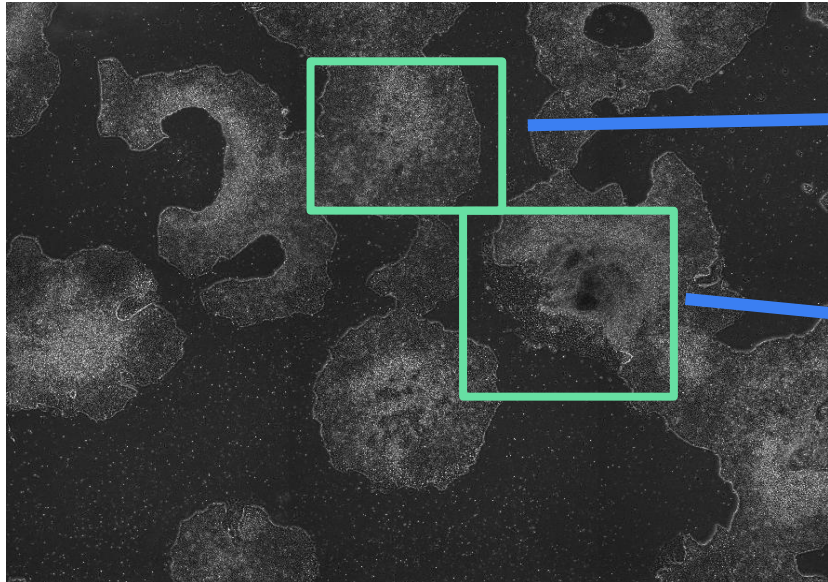
Manual bulk passaging
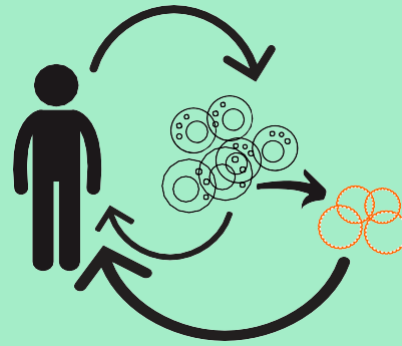
Pos Picks

Neg Picks

Manual bulk

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Services

We understand that each process is unique and has its own dynamics
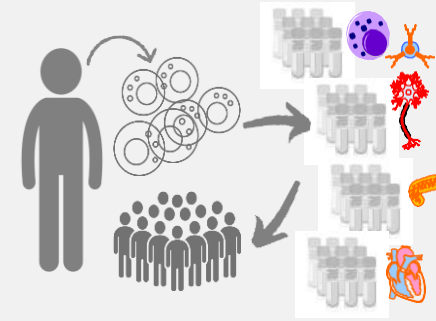
Our services are designed to solve significant obstacles:

- Custom processes
- Translation to GMP
- Product and process variability
- High-cost manual processes
- Aggressive timelines
- Technology Transfer packages
- Pre- CDMO

Autologous and Allogeneic iPSC derivation

Automated iPSC derivation - clones intentionally selected with your application in mind

Allogeneic iPSC lines

Allogeneic iPSC line generation selected
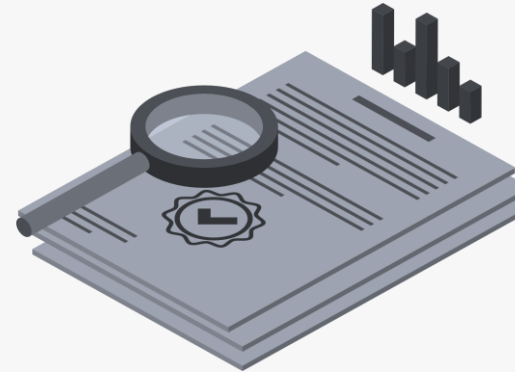by terminal differentiation efficiency

GMP ready

Automation of workflow processes tailored to transfer from Process development to Manufacturing

Enabling early and speedy CQA and CPP discovery

De-risking regulatory process

Optimization of manufacturing process

How we work with customers

- Celligent system or platform installation with support

- Broader licensing and collaboration deals

- Targeted services to support early Process Development/ Translational work (pre-CDMO)

- Shared Program Management in step with company funding, leading to GMP

Thank you!
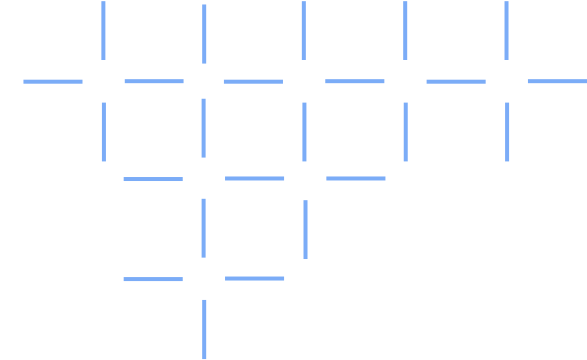
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