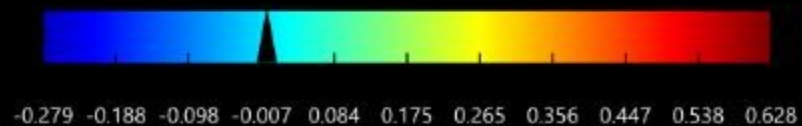
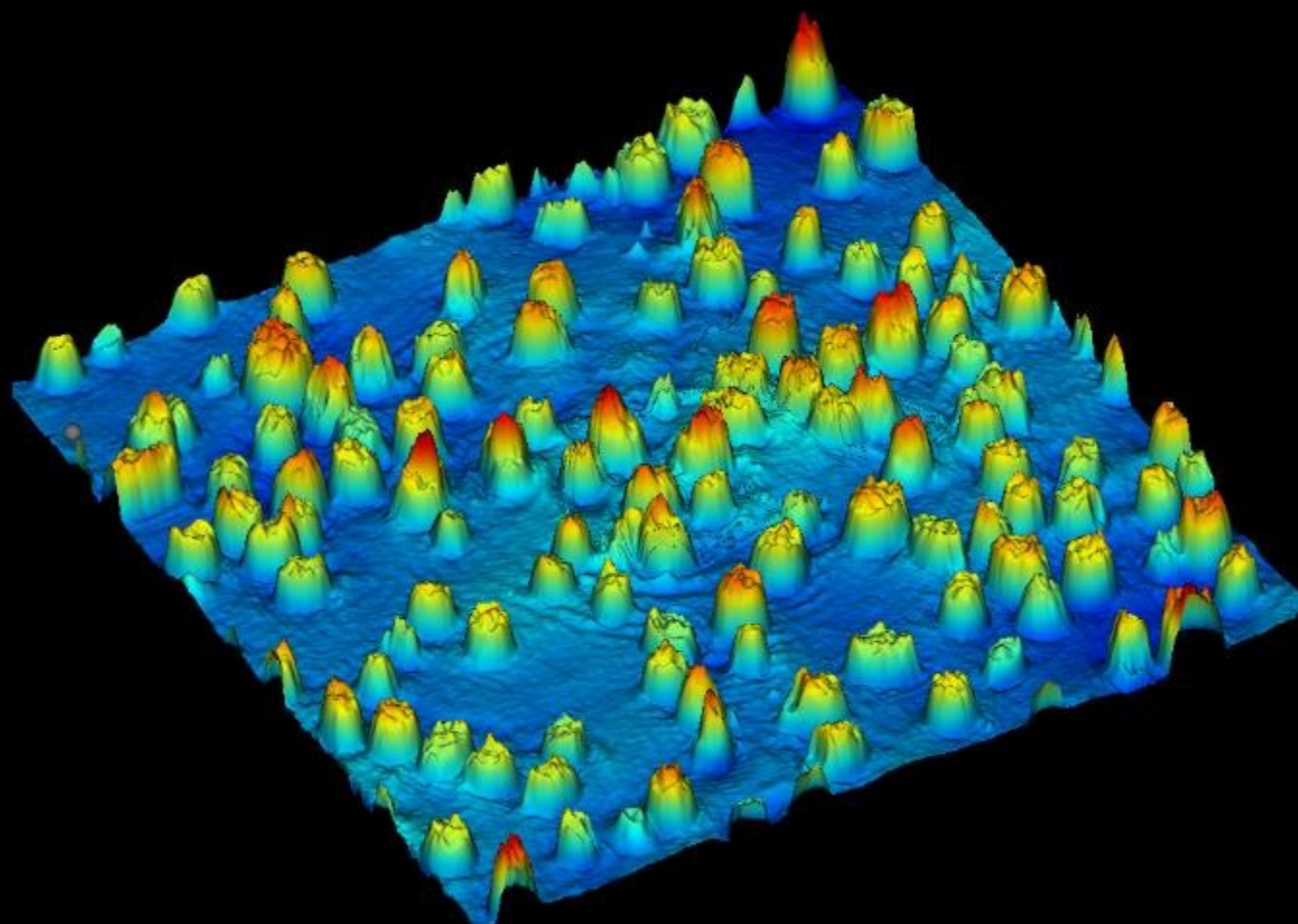


SHED LIGHT ON YOUR CELLS

AUTOMATED CELL MONITORING
IN REAL-TIME & LABEL-FREE

Ovizio Imaging Systems &
Bristol-Myers Squibb

ASGCT - Boston
MAY, 14 2020



COMPANY SNAPSHOT



COMPANY FOUNDED IN 2009
BELGIUM - BASED



16 PEOPLE
50% TASK FORCE IN HARDWARE & SOFTWARE



INTELLECTUAL PROPERTY
13 PATENTS FAMILIES



BIOPROCESSING MARKET

TOP APPLICATIONS:

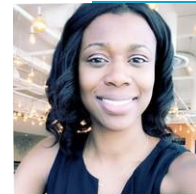
- **CELL & GENE THERAPY**
- **RECOMBINANT PROTEINS PRODUCTION**



SPEAKERS



Emilie Vey, PhD.
CEO at Ovizio Imaging Systems
emilie.vey@ovizio.com



Ivie Aifuwa, PhD.
Senior Scientist at Bristol-Myers Squibb

ANY LAB FACE BOTTLENECK CHALLENGES WHEN SCALE-UP ACTIVITIES

1 MANUAL SAMPLING

2 SAMPLE PREPARATION

3 STAINING

4 FEED TO OF-LINE INSTRUMENT

5 READ OUT BY TRAINED OPERATOR

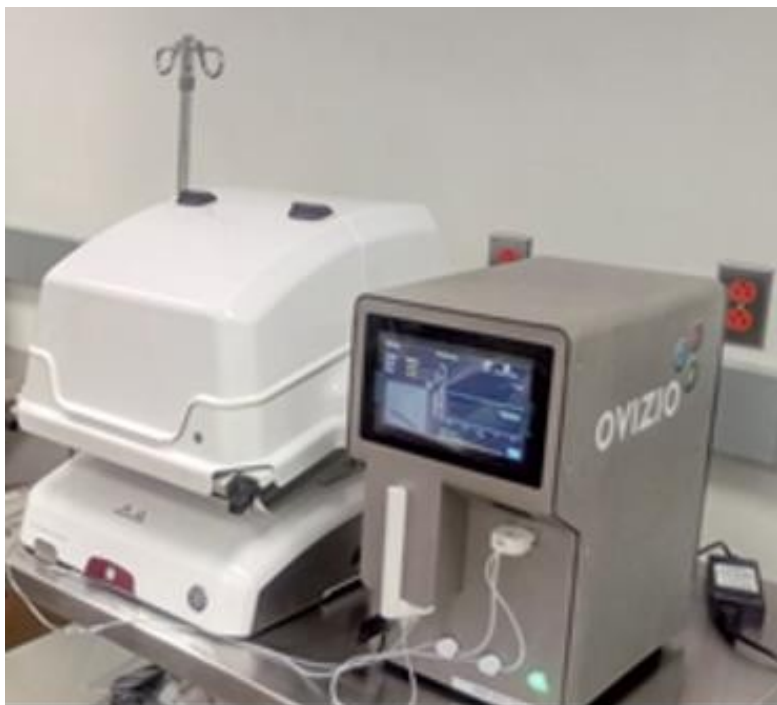
6 DISPOSAL OF SAMPLE

CELLS IN CULTURE VESSEL

OVIZIO'S VALUE PROPOSITION: BRINGS AUTOMATION IN CELLS EXPANSION



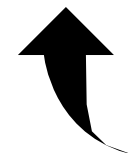
ON-LINE MONITORING & DYE-FREE



BIOSAFETY RISKS



REAL-TIME



QUALITY & PROCESS
CONTROLS



AUTOMATION



DYE-FREE



DEVELOPMENT &
OPERATIONAL COSTS

SUMMER 2020



OUR CONNEXION IS BIOREACTOR AGNOSTIC



SINGLE-USE & VERSATILE



SMALL SCALE
BIOREACTORS



SINGLE USE
BIOREACTORS



ROCKING MOTION
BIOREACTORS



1:1
BIOCONNECT



BENCHTOP
BIOREACTORS



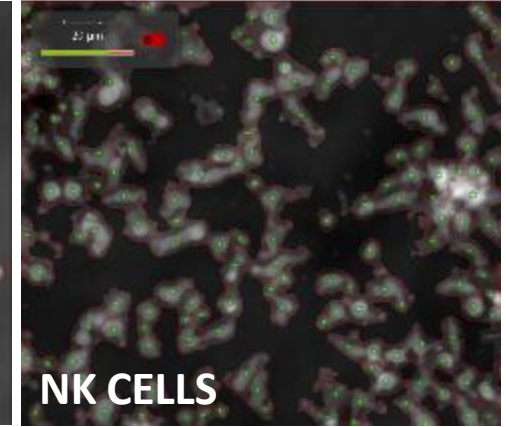
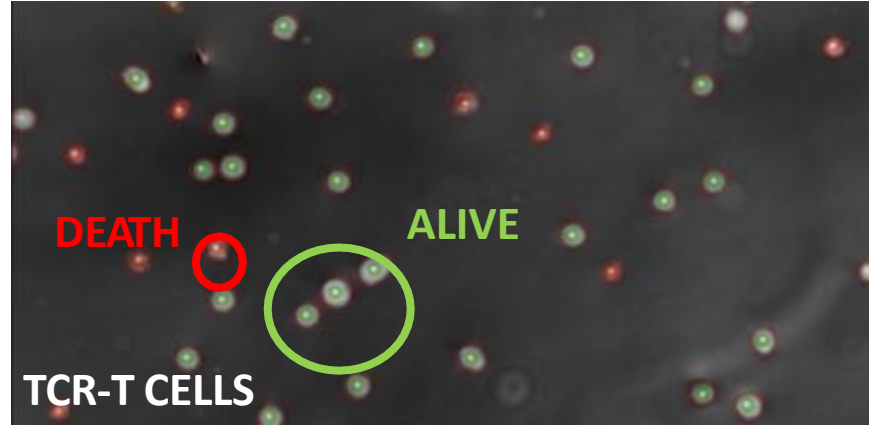
STAINLESS STEEL
BIOREACTORS

ASEPTIC CONNECTIONS: WELDING (C-FLEX OR PVC), LUER LOCK CONNECTION OR USING A NOVASEPTUM STERILE CONNECTION.

IMMUNE CELLS FINGERPRINTS: 3D IMAGE-BASED ANALYSIS



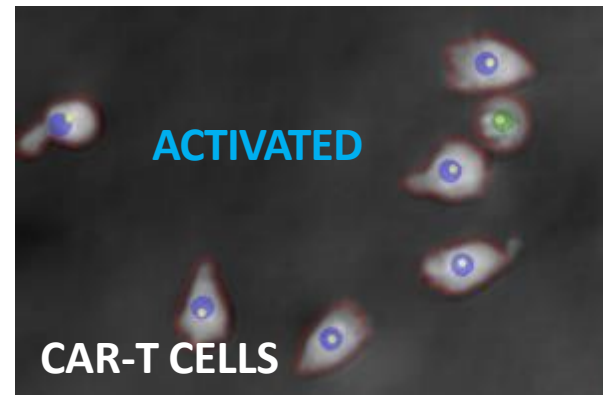
ASSESS CELL VIABILITY - CELL COUNTING



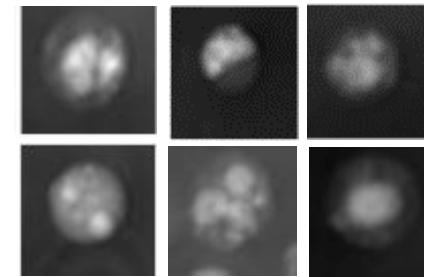
CLASSIFICATION OF BEADS



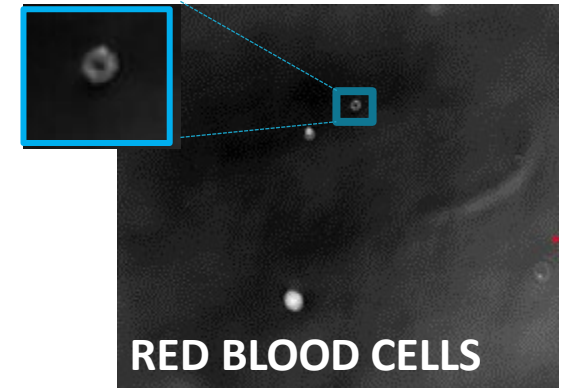
TRACK CHANGE OF STATE



CLASSIFICATION OF SUBTYPES



EXHAUSTED CELLS



RED BLOOD CELLS

PHASE IMAGES (DIFFERENTIAL DIGITAL HOLOGRAPHIC MICROSCOPY)

Automation of T cell Expansion Using the iLine F

May 14, 2020



PAT Gaps and Considerations for Cell Therapy

Process Analytical Technology (PAT) consists of “*designing, analyzing and controlling manufacturing through timely measurements (i.e., during processing) for critical quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality*”

Guidance for Industry: PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance. (2004)

PAT should provide real-time assessment of :

Critical Process Parameters

- Viable Cell Concentration (VCC)
- Media metabolites/nutrients
- pH/DO

Critical Quality Attributes

- Cell Phenotype
- Cell Functionality
- Cell Health

Cell Therapy PAT platforms should:

Provide real time monitoring of attributes

Interface with bioreactor/cell therapy processing equipment

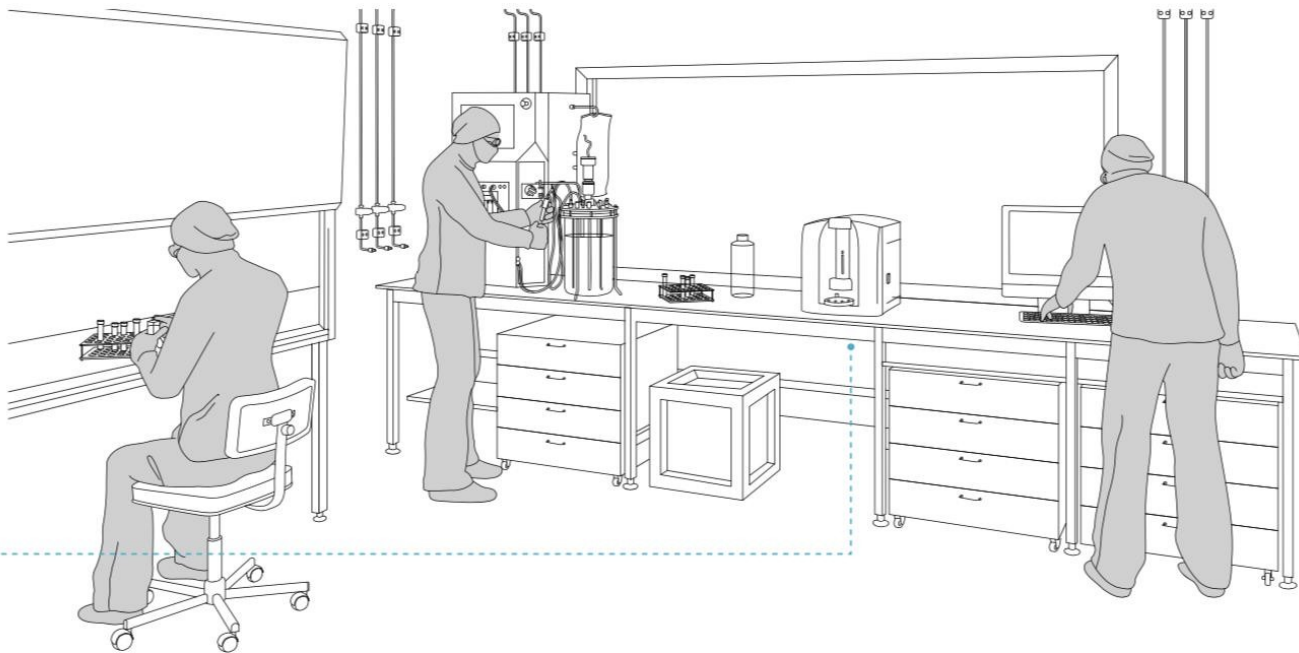
Interface directly with control automation

Utilize pre-sterilized, single-use product contact surfaces

Enable non-invasive/non-destructive analysis

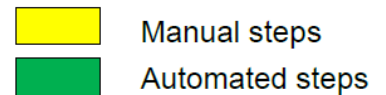
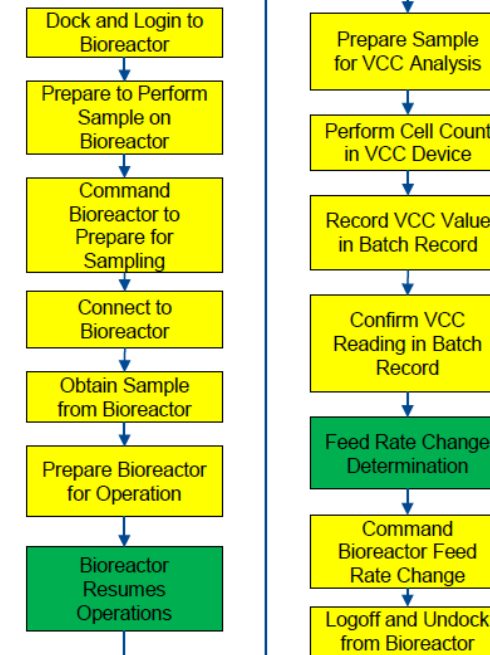
Expansion workflow - Manual Expansion

Manual expansion



Current Sampling & Bioreactor Method Progression

Automated

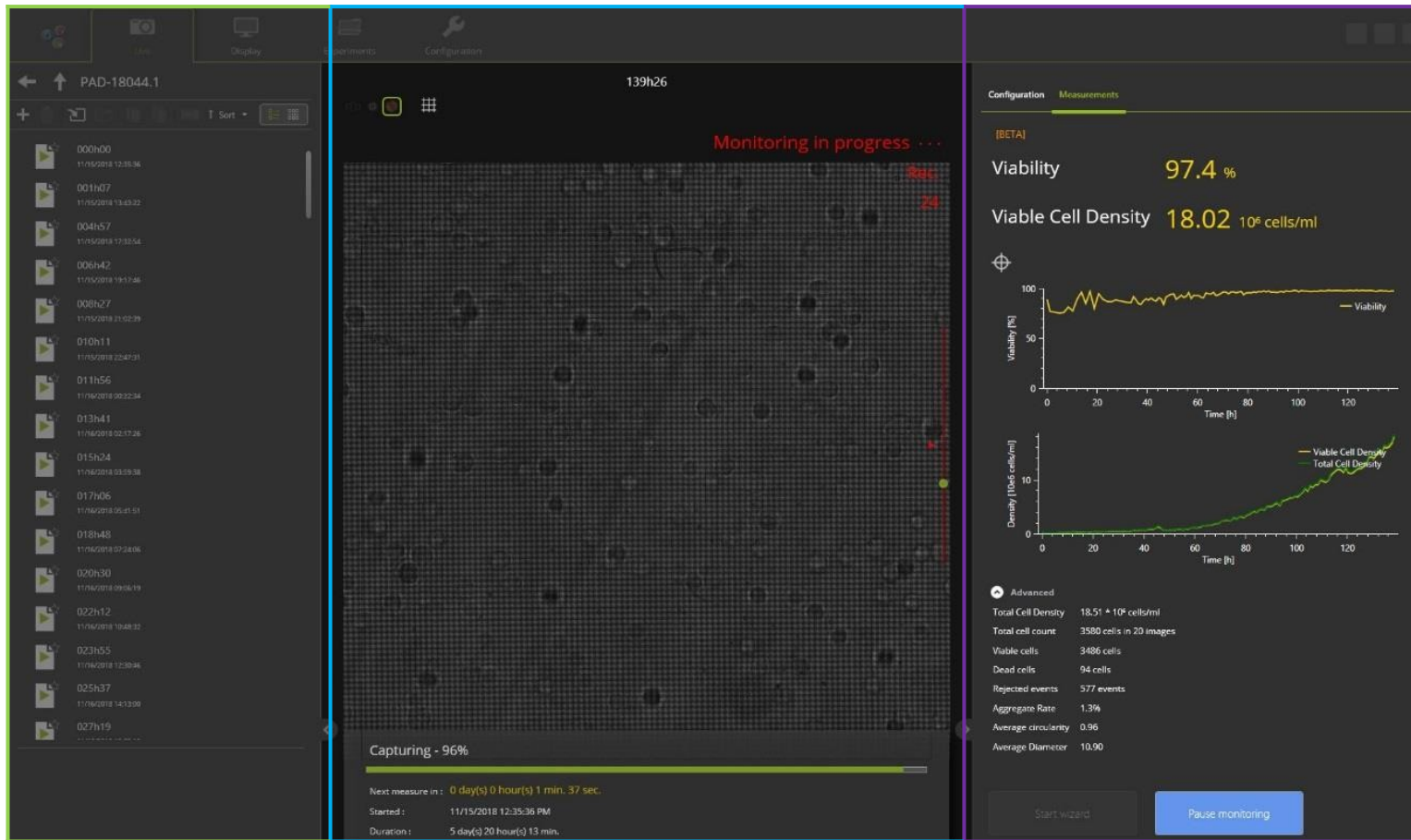


Ovizio iLine F - Online Viable Cell Concentration and Viability



- The iLine F is an **on-line cell counting platform**
 - Dye-free approach to viable cell counting
- BioConnect SUS enables **closed cell processing**, reducing the risk for bioreactor contamination during sampling steps
- **Bioreactor agnostic**
- With OPC UA and WebServices capabilities, the iLine F can interface with process control systems to enable **automated CAR-T bioreactor operation**

iLine F Operation: Image Acquisition



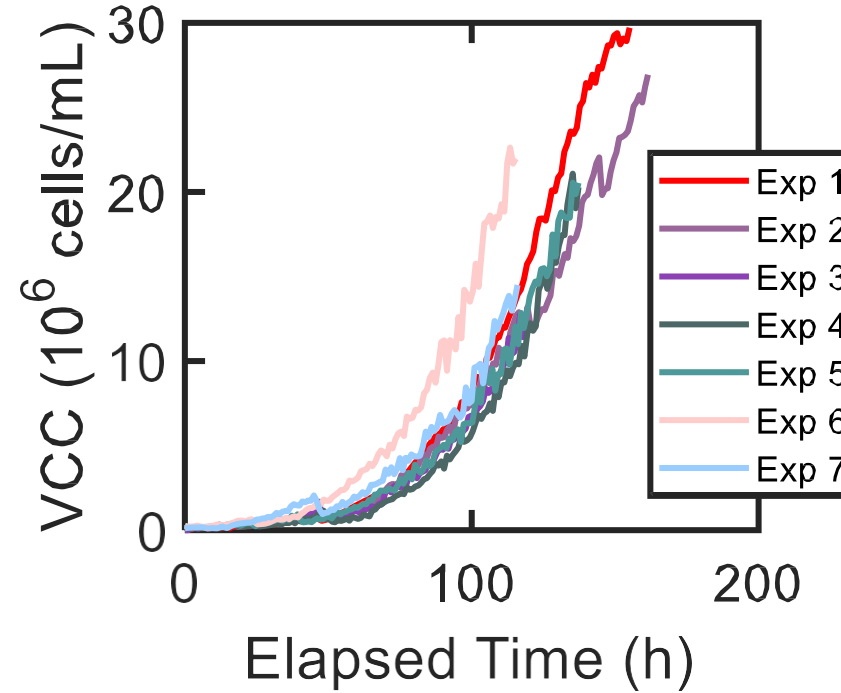
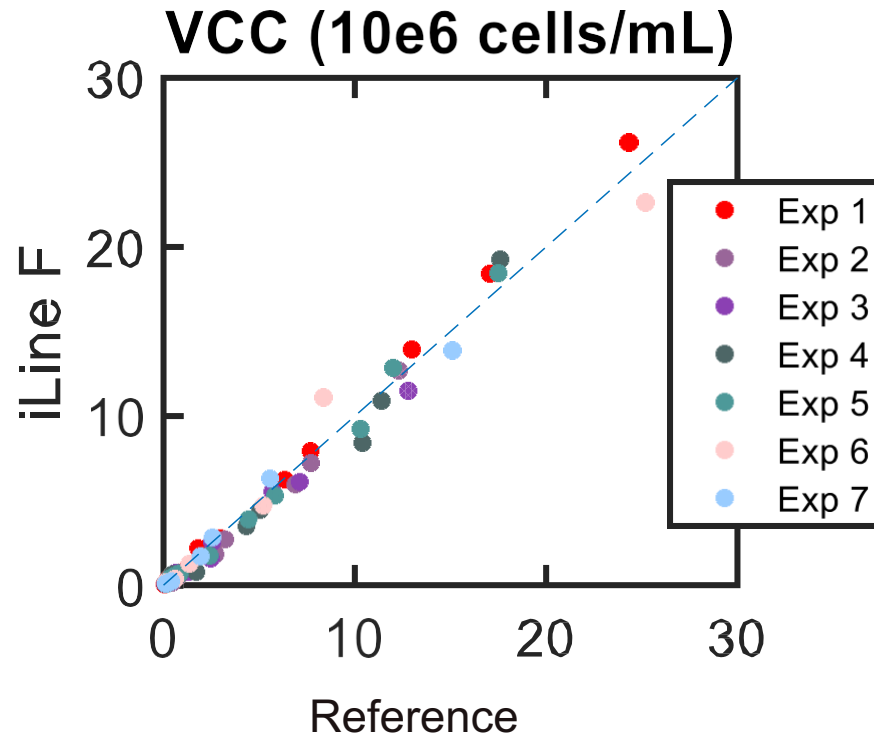
- Captures 20 images per acquisition per time point
- Captures Z-stacks of each image frame
- OsOne displays the cells within the imaging field of view, as well as process performance attributes

iLine F Operation: Image Analysis - single cell



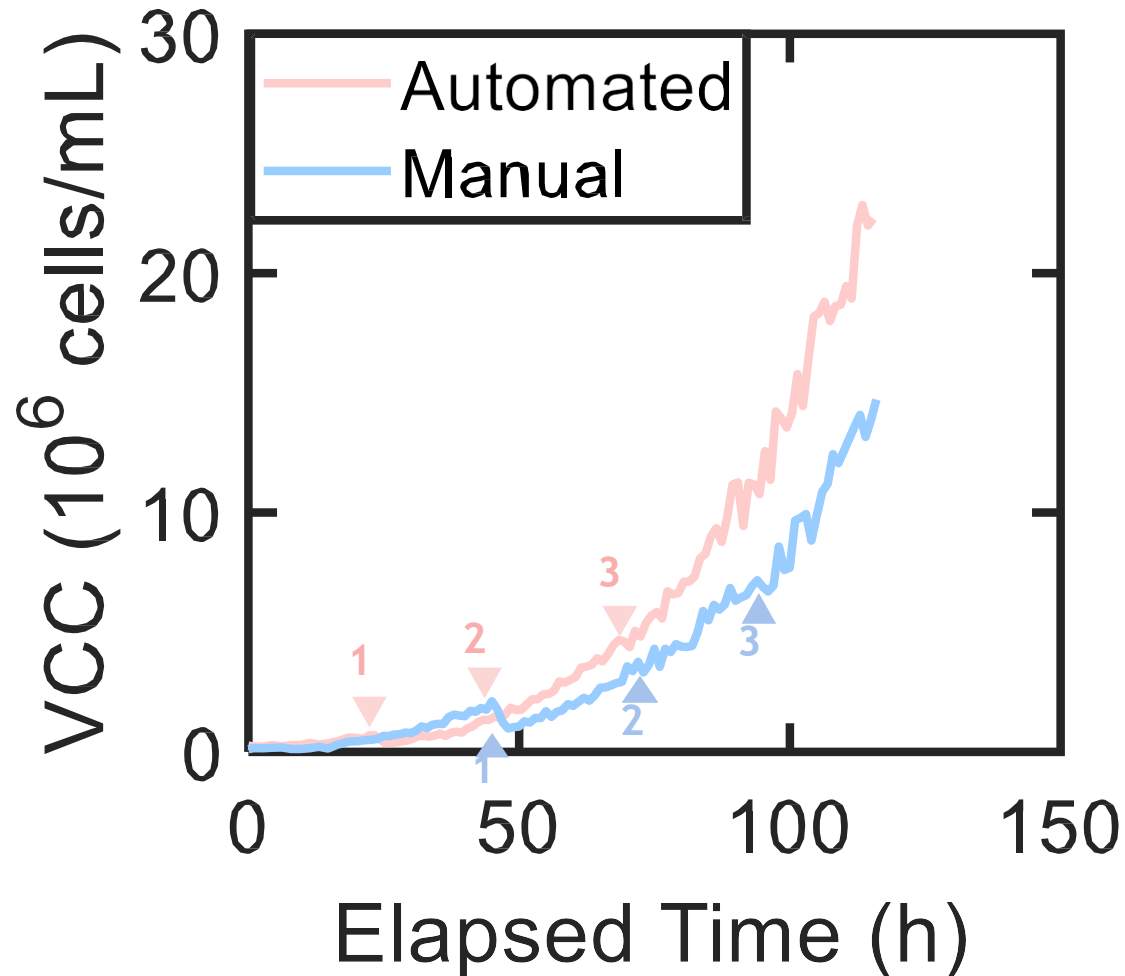
- Acquired cells undergo image segmentation and analysis
- OsOne then assigns cell viability status and other object classifiers (viable, dead, debris, cluster, etc)
- OsOne displays these classifications in the object/segmentation overlay

iLine F performance strongly fits reference method



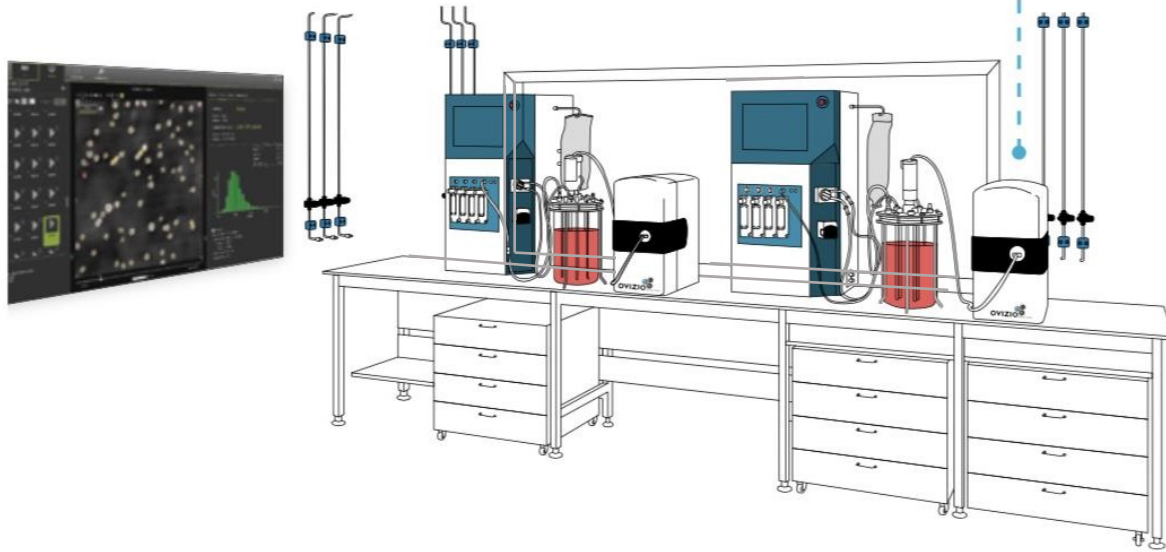
- Successfully executed >250 bioreactor expansion runs leveraging iLine F Platform
- iLine F demonstrates **good performance within multiple Cell Therapy processes**
- iLine F demonstrates **good comparability with reference cell counter**
- iLine F demonstrated no negative impact to existing Cell Therapy processes

Bind real-time CQAs monitoring (iLine F) & media feeding: increase of growth rate and get higher cell density



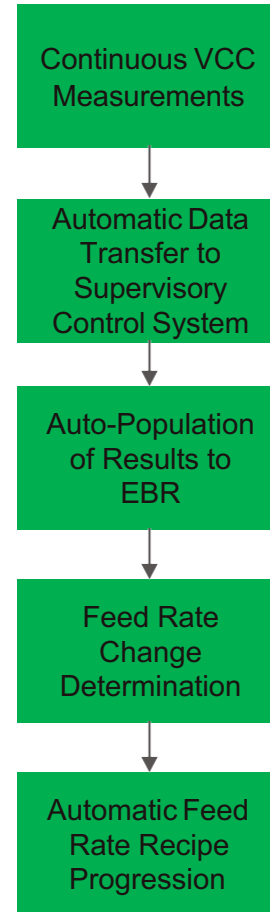
- Successfully executed >75 fully automated bioreactor expansion runs leveraging iLine F Platform
 - Shorten the expansion process by 1 day
- Automated expansion may
 - improve cell growth kinetics
 - reduce process variability through timely media feed adjustments

Automated Bioreactor operations



Operators can inoculate the bioreactor and walk away until harvest is required

Automated Bioreactor Sampling & Recipe Progression



Manual steps

Automated steps

iLine F for Cell Therapy Expansion



- Improve process & product understanding through real-time attribute monitoring
- Reduce process & product variability through feedback process control
- Promote closed Cell Therapy processing
- Reduction of COGs
- Accelerate process development and characterization



Contact

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CEO

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<https://www.linkedin.com/company/ovizio-imaging-systems/>

www.ovizio.com