



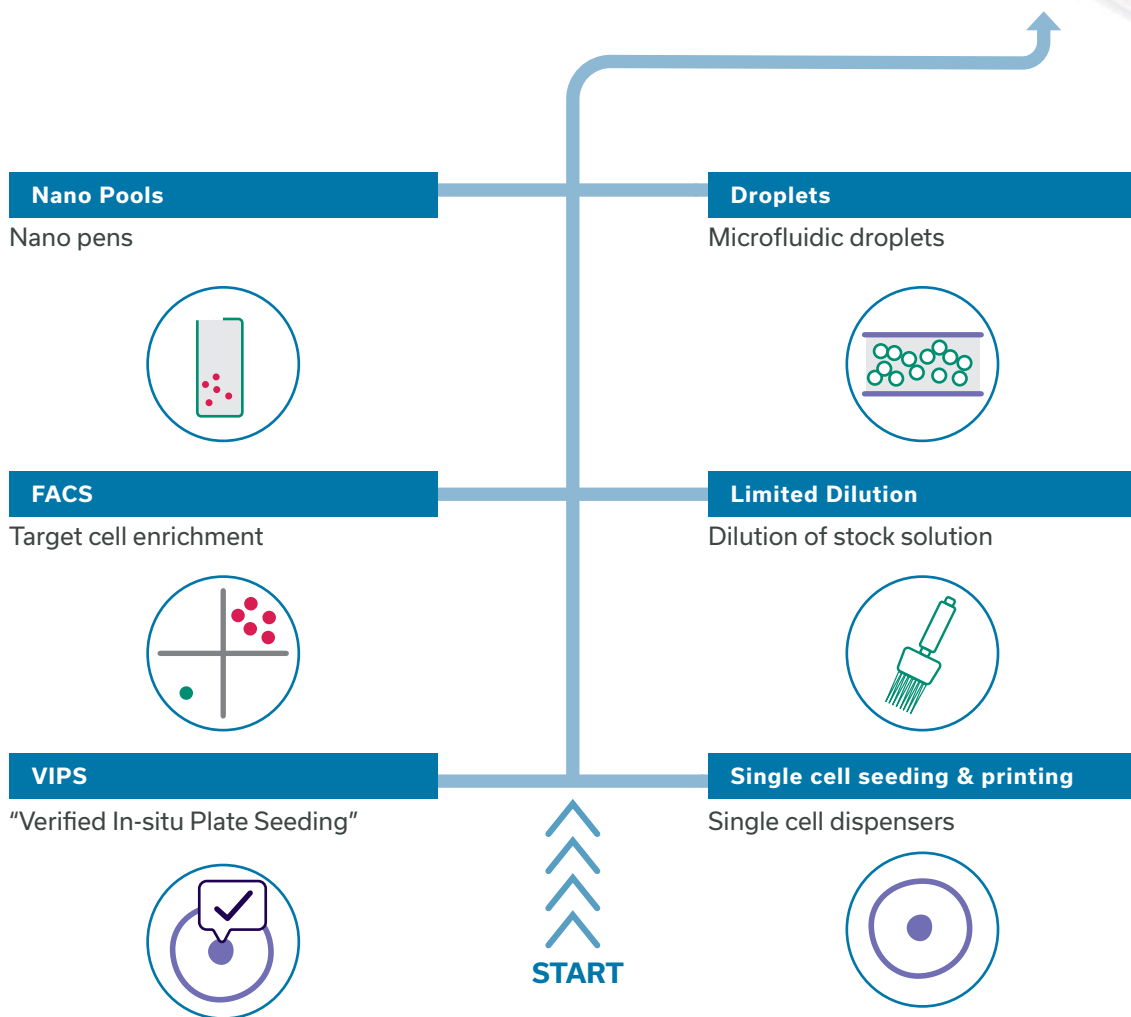
## Cell Metric<sup>®</sup>

The trusted standard for clonal assurance

High contrast imager for single cell identification  
and clonal outgrowth characterization

# Image-based assurance of clonal derivation

Cell Metric provides unambiguous, time-line based evidence of a single cell's journey through outgrowth to clonally derived colony. Specialized, high quality images enable the user to observe and clearly annotate single cells. Single cells can be discriminated from doublets and wells not containing cells.



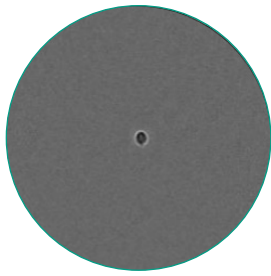
## Workflows for regulated environments

Cell Metric standardizes evidence of single cell derivation defining best practice for Master Cell Bank production. Used globally in most of the world's leading pharmaceutical and biotherapeutics companies, Cell Metric is the leading solution for providing regulatory information on clonality for Investigational New Drug (IND) submissions.

Cell Metric combines high quality images with data continuity, providing daily imaging with recorded evidence of single-cell to clonal growth.

## Save time, resources and financial investment

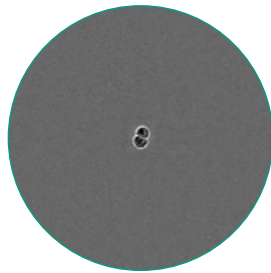
Such is the confidence in data originating from the Cell Metric®, workflows, such as those involving sub-cloning, mini-pools or repeated limited dilution rounds, can be significantly compressed, saving time, resources and financial investment.



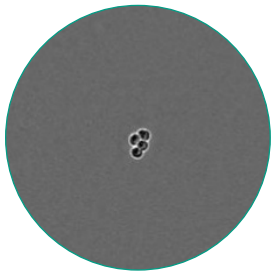
**DAY 0** >>



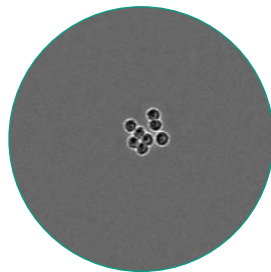
**Evidence that it started as a single cell**



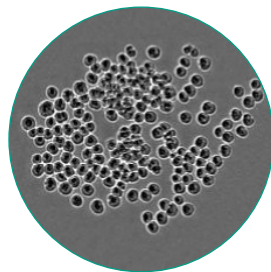
**DAY 1**



**DAY 2**



**DAY 3**



**DAY 7**

Whichever approach you use to seed cells, laboratories need to capture crucial evidence of the 'day 0, single-cell' and subsequent outgrowth. A multiday timeline of clear, image-based evidence is essential when demonstrating to regulators that outgrowth originated from a single cell.

*Imaging systems are frequently combined with other cloning tools... providing a visual evaluation of the techniques' "success" in real time. For this reason, from a development perspective, imaging technology offers an attractive way of providing supportive data to assure clonal derivation of production cell lines in lieu of additional laboratory work.*

**U.S. Food and Drug Administration Joel T. Welch and N. Sarah Arden, Biologicals\***

### Linking Data

Data-sync connects cell information from Solentim's VIPS (Verified In-situ Plate Seeding) system through to Cell Metric and can be exported in an encrypted manner to STUDIUS™.



VIPS™



DATA SYNC

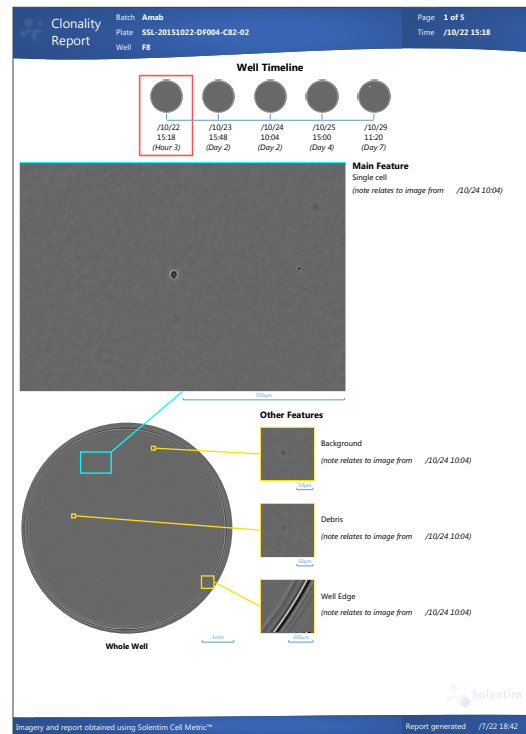


Cell Metric® CLD



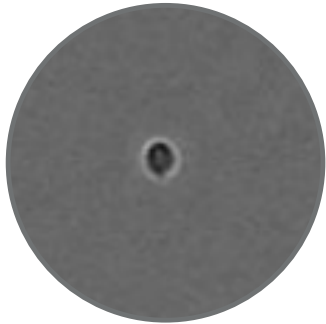
## Cell Metric Clonality Report

The complete outgrowth history, from single cell to colony, is documented in the fully integrated clonality report. Not only does this simple to create, annotated document deliver clear evidence of clonal derivation, it also provides an extra level of assurance. The report provides an audit trail for Master Cell Bank (MCB) production and confident IND submission.





# Master Cell Bank generation

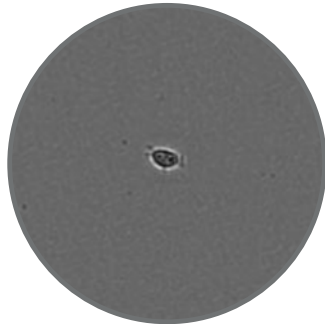


## Cell line development (CLD) for biologics

CHO, CHO-S, CHO K1, HD-BIOP3 (Horizon), CHOZN (Millipore Sigma)

### Assurance of clonal derivation

A crucial component of quality and consistency, the Food and Drug Administration (FDA) and European Medicines Agency (EMA) both seek assurance of clonally derived MCB in IND submissions.

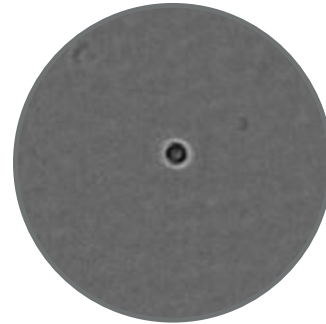


## Gene therapy

Examples: HEK293, 293T, HeLa, Sf9

### Cell lines for viral vector production

Solentim customers have developed and banked stable, high producer clones – with demonstrated clonally-derived single cell origin – in less than three months.



## Human induced pluripotent stem cells

Examples: disease models and CRISPR-edited iPSCs

### Manipulation and pluripotency

For documentation and characterisation of stem cell colony outgrowth and confluency measurements.

## A decade of demonstrated success



“By adopting VIPS and Cell Metric, the CLD team can cut our timelines for transfection to ambr15 from six months down to 10-13 weeks.”

**Jolanda Gerritsen**  
Technology Expert, Cell Line Development • Genmab



“VIPS and Cell Metric enables us to provide faster and better services to our customers.”

**Shanghai OPM Biosciences Co. Ltd.**

“ This instrument saved my life ”

Rating: 5.0 ★★★★★

**Application Area:** Proof of cell clonality

“Before this instrument, all our clonal analysis was done manually. We used to spend hours on the microscope looking for wells containing colonies possibly derived from single cells. Now, everything is automated, we since we can track the cell growth over time, we can be absolutely sure that a particular clones is derived from a single cell.”

“Essential instrument for cell culture experiments ”

Rating: 4.7 ★★★★★

**Application Area:** Cell culture imaging

“Very easy to use and produces good quality cell images, which are essential when monitoring outgrowth after limiting dilutions. The 10 plate cassette with automatic loading is very helpful for high throughput experiments, and the versatility of plate type makes the cell metric even more useful.”

*Selectscience reviews*

# Enhanced productivity workflows using VIPS, Cell Metric CLD and Robotics

Enhance your workflow by integrating high efficiency single-cell seeding technology from VIPS, automated plate handling within the temperature-controlled environment of Cell Metric CLD or downstream third party robotic integration.

+ Access Cell Metric data anytime, anywhere with Remote Data Viewer.



**VIPS™**



**Cell Metric® CLD**

## The experts on cell line development workflows

We draw on decades of high-level scientific skill in cell line development to advise our customers on modern assurance-focused workflows. Contact us to request recent case studies and to discuss your specific challenges with our expert team.

## Quality support for your cell line development process

We combine unrivalled technology and expertise to deliver complete assurance and we build quality into every step. In a changing regulatory landscape, we keep an eye to the future, providing a global network of support for our customers. We offer installation qualification/operational qualification (IQ/OQ) packages for quality-led installation, as well as on-site application and service and support packages to maximize your investment.



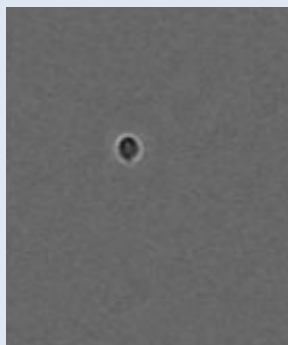
# Purpose-built for imaging assurance

Solentim technology has one goal, that of confidence. Confidence comes from clarity of data, the ability to reproducibly verify derivation from a single cell.

To that end, Solentim has developed a range of novel technologies:

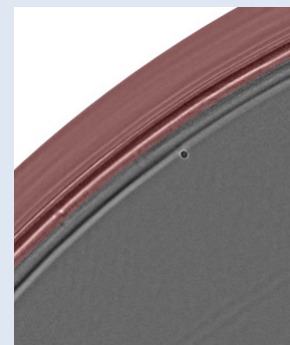
## Clarity in purpose

A highly tuned brightfield optical path maximizes the clarity of single-cell imaging for assured cell line development.



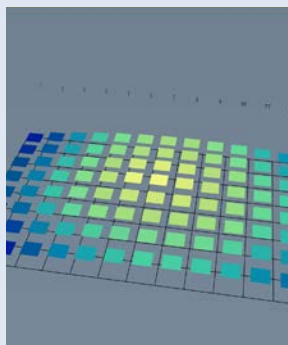
## Right up to the edge

Sophisticated methodologies to maintain image clarity right up to the edge.



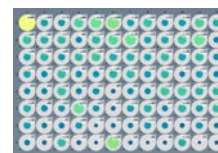
## Always in focus

Proprietary laser focussing ensures optimal focal position in each well.



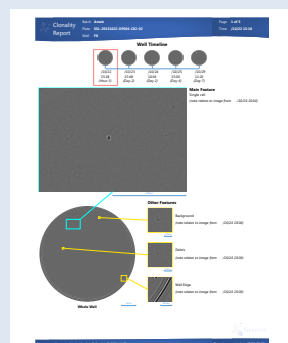
## Automated confluence determination

Quickly and automatically review wells with colony outgrowth.



## An audit of cell history

Combine data from the entire timeline into a documented clonality report.



## Fluorescence imaging for rare event detection

The option of workflow verification using rare-event fluorescent imaging.





## About Advanced Instruments

Advanced Instruments is a global company offering a novel portfolio of analytical tools including, OsmoTECH®, a robust line of micro-osmometers to support bioprocessing and quality control (QC), and Solentim, a portfolio of best in class imaging and single-cell deposition technologies for cell line development workflows and assurance of clonality for regulatory bodies.

Our Solentim portfolio enables the clonal isolation, outgrowth, and characterization of the highest value cells for monoclonal antibody upstream development and cell and gene therapy. This enables our customers to use these clones and have the documentation they were clonally-derived to confidently form their Master Cell Banks.



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ML-003 Rev:001

Request a quote or demo: [aicompanies.com](http://aicompanies.com)