

# Verified In-Situ Plate Seeding

Accelerating workflows for single-cell cloning

High efficiency, single cell cloning with enhanced, image based regulatory assurance.

Solentim:

www.solentim.com

# Single cell seeding

& in-well verification

#### **VIPS®**

(Verified In-Situ Plate Seeding)

#### **ASSURANCE ACCELERATED**

Verified In-Situ Plate Seeding (VIPS™), provides single-cell seeding and image-based clonality assurance. The multi-tasking, compact instrument delivers an efficient, 'double lock' solution for Investigational New Drug (IND) submission.

VIPS is your trusted partner for cell line development, easily fitting into a standard safety cabinet. Operating at a pressure of less than one psi, the machine gently dispenses cells in nanoliter droplets into a plate well.



Cells are imaged in multiple z-stack layers in the dry empty well before intelligence-based image analysis confirms the existence of a single cell.

The well is then filled with media.

# Choices for vector construction and transfection strategy

Your choice of transfection strategy has a major impact on process workflow and productivity. VIPS-based workflows are the perfect choice for all major methodologies, from traditional random integration to advanced transposases.

# Supplementing enrichment workflows

Use VIPS to accelerate and add assurance to fluorescence-activated cell sorting (FACS) and minipool enrichment based protocols.



Low pressure seeding = high % outgrowth

#### VERIFY IN-WELL



Multi-level z-stack imaging combined with advanced analysis provides enhanced, highfocus images for accurate single-cell recognition.





## $\mathsf{VIPS}^{\scriptscriptstyle{\mathsf{M}}}$

#### **Enhancing cell line development workflows**

VIPS is designed for complete assurance of clonality in cell line and Master Cell Bank (MCB) development. VIPS accelerates projects by maximizing workflow efficiency and decreasing operating workloads while reducing plastic consumption. With low pressure,

nanoliter droplet dispensing, VIPS delivers high-efficiency seeding and outgrowth.

VIPS more than halves the time for single cell cloning workflows when compared to a typical two-step limited dilution methodology.

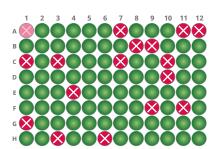
When combined with enabling reagents (including InstiGRO™ cell-growth supplements and Leap-In Transposase®), cloning efficiencies are further enhanced.

To complete the story, a clonality report is generated, cataloguing both in data and images the whole story from single cell to colony. The VIPS clonality report can be directly used as an important source of evidence, with a strong track record of IND submission success.



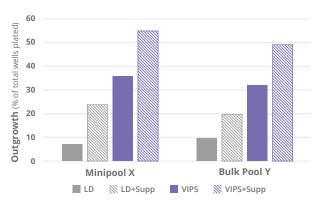
Boost cell colony survival and growth rates with InstiGRO $^{\text{M}}$  cell growth supplements.

#### HIGHER PROCESS EFFICIENCY



With healthier cells, more clones per plate and enhanced expression vectors, workflows are accelerated and plate numbers are reduced.

#### HIGHER CLONAL OUTGROWTH



Combine VIPS and InstiGRO to achieve up to seven-fold improvements in the number of colonies growing in each plate. Data from Sigma CHOZN cell line.

# SINGLE CELL SEEDING TUDENCE STEP

The clonal derivation of the production cell line is a factor with potential impact on product quality, and thus should not be considered separately from, but rather in the context of all elements comprising the control strategy necessary to support approval of a regulatory application."

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



VIPS uniquely offers the 'double lock' of assurance combining post-dispensing imaging and analysis and daily outgrowth imaging, wrapped up in a Clonality Report, ready for a confident IND submission.

High clarity imaging, resolving cells even at the edge of the well, is at the forefront of VIPS technology, generating a visual timeline backed by Al-powered imaging analysis for regulatory submission confidence.

# Outgrowth

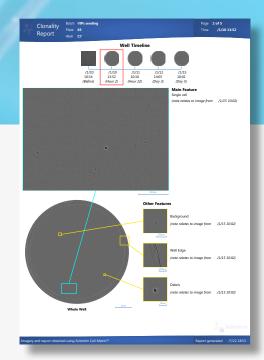
and clonal characterization



During the clonal growth phase, VIPS performs daily high-clarity whole well imaging, recording a timeline of well images and performing analysis to measure confluency. Successful clonal outgrowth can be traced back to a single cell to confirm monoclonality.

VIPS automatically captures the journey from a single cell to colony outgrowth in a comprehensive clonality report. High-clarity images and accompanying data

d accompanying data provide a unique 'double lock' of assurance for IND submission.







- High efficiency single-cell seeding
- In-well verification
- Daily outgrowth imaging
- Clonality report
- All-in-one compact instrument



# 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 and cell therapy

Examples: HEK293, 293T, HeLa, Sf9

#### Cell lines for viral vector production

Solentim customers have developed and banked stable, high producer clones - with demonstrated monoclonality - in less than three months.





#### **Human induced pluripotent stem cells**

Examples: disease models and CRISPR-edited iPSCs

#### Manipulation and pluripotency

Gentle single-cell seeding and handling for successful clonal outgrowth of high-value iPSCs

# A DECADE OF

# Success



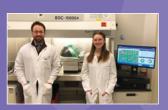
"Demonstrating monoclonality has never been more reliable and straightforward. No more ambiguity, no more ghost cells. Both our clients and our own scientists are very pleased with the data the VIPS instrument generates."

Director of Cell Line Development • ATUM



"The VIPS™ is unique, being the only single cell cloning system on the market that tracks a single cell's arrival in the actual well."

Camille Evenou



"For the VIPS, there's so little makes it easy to locate the cell and prove to the health authorities that the cell line is clonal."



"The cell line generation report (or clonality report) has satisfied our IND filing requirements for the Chinese NMPA."

Andy Tsun, PhD Co-Founder and VP of Discovery Biology

# Enhance productivity

by adding Cell Metric® to your VIPS workflow

Enhance your workflow with the seamless integration of VIPS and the Cell Metric whole well imager. Data Sync and shared reporting automatically connects seeding data, seeding images, day 0 evidence of

clonality whole well image and subsequent outgrowth time point images. Cell Metric is available as a standalone system, with a multi-plate loader or module for third party robotic arm integration.







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.

# Designed to accelerate

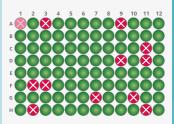
single-cell cloning workflows

Solentim technology has one goal, that of confidence. Confidence comes from clarity of data, the ability to reproducibly verify, at multiple stages in a workflow, evidence and assurance of single cell derivation.

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

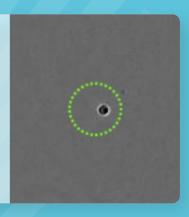
## Seeding for high clonal efficiency

We employ the simplest and safest method of single-cell dispensing, with no complex fluidics or mixed samples. VIPS uses low pressure to seed cells in nanoliter droplets into empty wells.



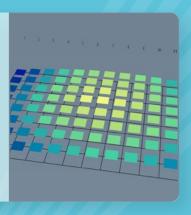
## Advanced image analysis

Using advanced image analysis technology, z-stack images are processed to confirm the presence of a single cell.



#### Always in focus

VIPS performs total plate laser focus scanning, adjusting for plate contours, to ensure an optimal focal position for each well.



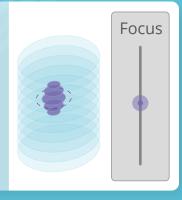
## In-line media dispensing

Immediately after confirmation of cell seeding, VIPS automatically dispenses culture media into the well, protecting your high-value cell.



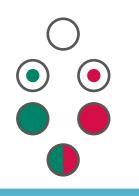
## In-well z-stack imaging

Immediately after seeding, the droplet is imaged at 20 different focal positions. This broad z-stack encompasses the optimal plane for image analysis enabling confident single cell detection.



## QC verification process

To assist in the verification of your clonality workflow, VIPS offers a verification methodology option based on rare-event fluorescence imaging.



## About Solentim

Solentim is the trusted global leader for solutions to create, isolate and characterize the highest value cells for the development of new biological medicines and therapies.

Our portfolio of proven and innovative technologies, combined with our unparalleled experience, ensures our customers achieve accelerated Master Cell Bank development and are confidently prepared for regulatory review.

### FOCUSED ON HIGH VALUE CELLS



www.solentim.com



Cert No. 12777 ISO 9001

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