



# Accelerating Assurance

Enhanced cell line development workflows  
for successful IND submissions

# Solentim technology transforming workflows

## Reducing timelines while building assurance

For over a decade, Solentim technology has helped biotherapeutic businesses to accelerate cell line development workflows, develop assured processes, maximize efficiency and deliver numerous successful INDs.

### Halving the timeline

**Genmab**, the largest independent biotechnology company in Europe.

**Previous workflow:** ClonePix

**Assurance:** two rounds of cloning plus statistical calculation

**Validation timeframe:** 1.5 years

**Workflow time:** 26 weeks

**New Solentim workflow:** VIPS and Cell Metric

**Assurance:** double-lock, image-based

**Validation:** 2-3 months for conversion

**Workflow time:** 10-13 weeks



**ADVANCED TECHNOLOGIES** Case Study

### A simple solution which has slashed cell line development times at Genmab

From introduction to virus C2D in only 10-11 weeks

The Cell Line Development (CLD) team at Genmab, a large international biotech company, wanted an end-to-end solution to speed up the development of the proprietary growing conditions for their cell lines. The team needed a solution that was easy to use, required minimal equipment, and could be implemented in a laboratory setting.

**Introduction**

Genmab is a large independent biotechnology company in Europe. Founded in 1996, the company has established a strong reputation for its expertise in antibody development. The company has been producing, manufacturing, and distributing monoclonal antibodies for over 20 years.

**A Need for Optimization**

The Cell Line Development (CLD) team at Genmab is responsible for developing and optimizing cell lines for production. The team needed a solution that was easy to use, required minimal equipment, and could be implemented in a laboratory setting.

**A Change in Approach**

Changing the Right Instruments

Step	Previous Workflow (Weeks)	New Solentim Workflow (Weeks)
1. Cell Line Development	10	10
2. Validation	10	10
3. Production	10	10
<b>Total</b>	<b>30</b>	<b>10-13</b>



### Doubling outgrowth

**Janssen R&D**, the number one pharmaceutical company in the world, based on 2020 revenues.

**Previous workflow:** ClonePix

**Assurance:** two rounds of cloning plus statistical calculation

**Cell screening workflow:** 10 weeks

**Colony outgrowth:** 18%

**New Solentim workflow:** VIPS

**Assurance:** double-lock, image-based

**Validation:** 6 weeks

**Colony outgrowth:** 31%



**ADVANCED TECHNOLOGIES** Case Study

### Doubling the Speed of Cell Line Development in a Large Pharmaceutical Company

The Cell Line Development (CLD) team at Janssen R&D, the number one pharmaceutical company in the world, based on 2020 revenues, wanted a solution to speed up the development of cell lines. The team needed a solution that was easy to use, required minimal equipment, and could be implemented in a laboratory setting.

**Introduction**

Genmab is a large independent biotechnology company in Europe. Founded in 1996, the company has established a strong reputation for its expertise in antibody development. The company has been producing, manufacturing, and distributing monoclonal antibodies for over 20 years.

**Cell Line Development at Janssen**

The Cell Line Development (CLD) team at Janssen R&D is responsible for developing and optimizing cell lines for production. The team needed a solution that was easy to use, required minimal equipment, and could be implemented in a laboratory setting.

**The Problems with the ClonePix for Clonality**

The ClonePix cloning process was complicated and time-consuming. The team needed a solution that was easy to use, required minimal equipment, and could be implemented in a laboratory setting.



# Start-up to IND

**Biotheus Inc.**, a start-up with successful IND filing

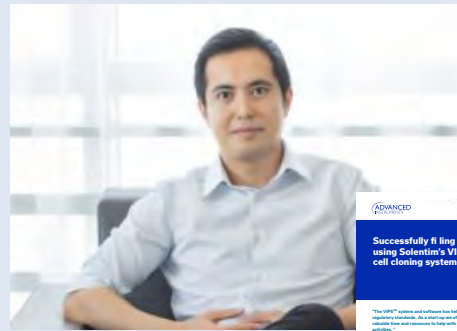
**Solentim workflow: VIPS**

**Comparison to limited dilution: three-fold faster**

**Assurance: double-lock, image-based**

**Number of plates: 20**

**IND submission: successful**



**Celonic AG**, a contract development and manufacturing organization (CDMO) specializing in biologics manufacturing from mammalian cell lines.

**Previous workflow: limited dilution and FACS**

**Assurance: statistical**

**Workflow: 29 weeks**

**Number of plates: 500**

**Colony outgrowth: 28%**

**New Solentim workflow: addition of VIPS**

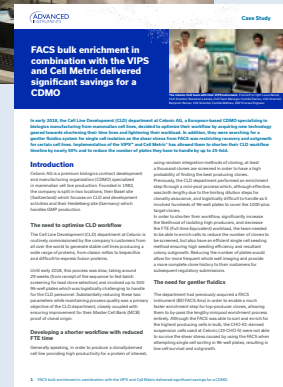
**Assurance: double-lock, image-based**

**Workflow: 17 weeks**

**Number of plates: 20**

**Colony outgrowth: 60%**

**Colony outgrowth: 31%**

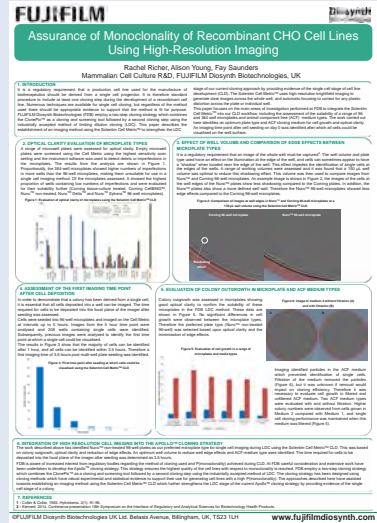


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# Micro-droplet workflow assurance

**FUJIFILM DIOSYNTH**, a CDMO using Cell Metric with Sphere Fluidics platform.

Provides visual evidence of monoclonality from different instruments at varying time points.



*"The Cell Metric clonality reports are a critical component of our CLD workflows. Following cell line development custom service projects, we provide these reports directly to our customers for use in their IND filings."*

MilliporeSigma

*"VIPS and Cell Metric enables us to provide faster and better services to our customers."*

Shanghai OPM  
Biosciences Co. Ltd.

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[www.aicompanies.com](http://www.aicompanies.com)

# The tools to build the ultimate workflow

With innovative products including Leap-in Transposase®, VIPSTM, Cell Metric®, ICON™, STUDIUSTM and the advanced Insti range of cell growth supplements, Solentim technologies are your building blocks for faster, more assured workflows. Whereas previously it took months with statistical probability-based reporting, it's now weeks with solid, double-lock, image-based confidence.

Solentim continues to invest in the future of cell line development and its expanding importance beyond therapeutic monoclonal antibodies into gene therapy and vaccine development workflows.



**Solentim**

**Cell Metric®**  
The trusted standard for clonal assurance

High contrast imager for single cell identification and clonal outgrowth characterization

**ADVANCED INSTRUMENTS**




**Solentim**

**VIPS™** Verified In-Situ Plate Seeding  
Accelerating workflows for single-cell cloning

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

**ADVANCED INSTRUMENTS**



**Solentim**

**ICON™**  
The new measure of productivity

The all-in-one benchtop instrument for the selection of leading clones.

**ADVANCED INSTRUMENTS**



**Solentim**

**STUDIUSTM**  
The new standard for cell line development

Data Management Solution for Cell Line Development Projects

**ADVANCED INSTRUMENTS**





## 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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