Solentim

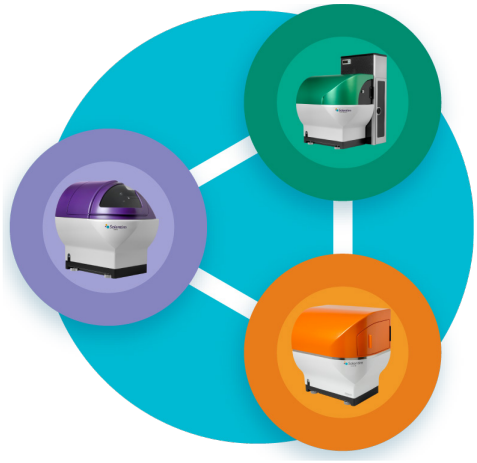
STUDIUS™

Powering the Solentim ecosystem

Data management for the highest level of consistency across the Cell Line Development workflow

ADVANCED INSTRUMENTS

Welcome to the Solentim STUDIUS powered ecosystem, bringing total consistency to the Cell Line Development process



Scientists creating Master Cell Banks (MCBs) for biotherapeutics are now able to make better, faster and more confident decisions.

The STUDIUS powered ecosystem incorporates critical data from Solentim VIPS™ single cell seeding, Cell Metric® clone verification and colony outgrowth monitoring and ICON™ cell IgG productivity assessments to provide a unique decision-making platform covering the CLD workflow from cell seeding to scale-down mini-bioreactor studies, for example with the Ambr®.

Consistency

The STUDIUS powered ecosystem provides the highest level of consistency across the CLD workflow from a combination of secure sample/clone-centric tracking and a common data management system which ensures maintenance of raw data integrity and elimination of transcriptional errors.

A Common Data Management System Ensures Maintenance of Raw Data Integrity

The current paradigm in CLD is that of multiple instruments from different suppliers generating data in different formats. This creates multiple pain points.

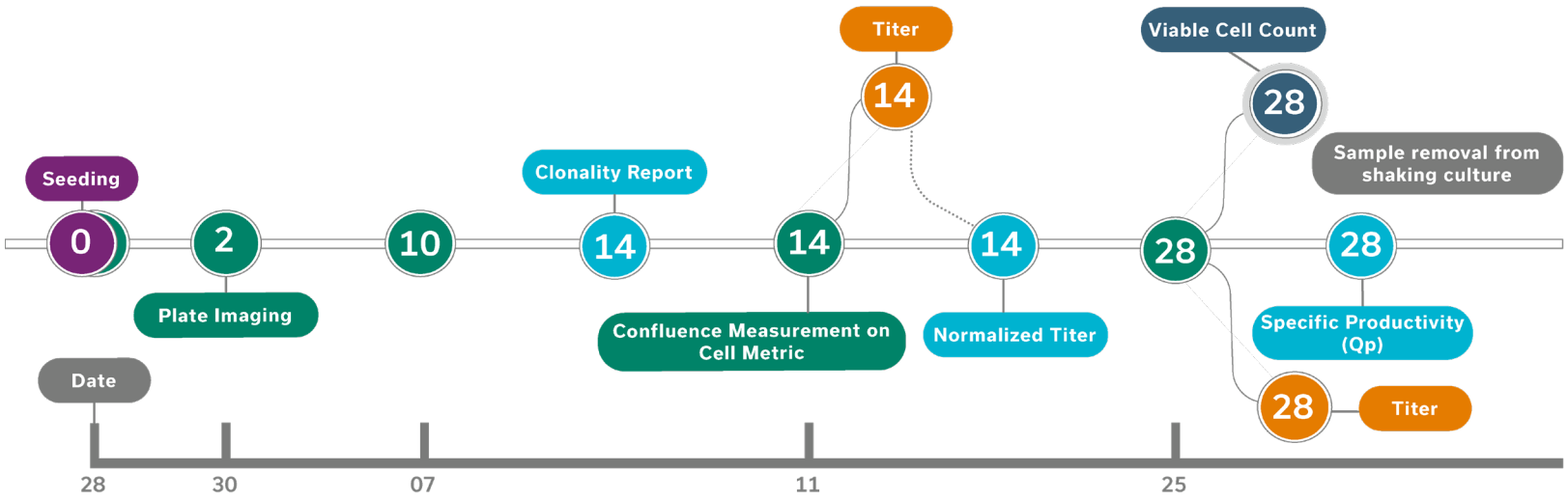
When results are held in multiple instrument locations and are exported to consolidate and reformat for analyst review, a data integrity risk is created because there is no associated audit trail. This can be compounded by the fact that the reformatting process may introduce a transformational error.

In the STUDIUS ecosystem, raw data results from all instruments go directly and securely, without external manipulation, into a single common data management system for ultimate data integrity. Regarding any use of this data for processing and reporting by the individual user, the raw data is always maintained.

Secure Sample/Clone-Centric Tracking via the *HISTORYTREE*™

A unique view of a cell's journey, *HISTORYTREE* is a dynamic navigational tool that graphically represents a cell's journey through cell line development independent of sample formats. From seeding, through growth, productivity assays, ranking and selection, each colored node on the tree represents a time point in the cell's journey offering easy access to critical data. Where an automated liquid handler is used, STUDIUS creates a map of source and destination locations that can be passed to the robot ensuring that samples are accurately moved and consistently tracked.

Furthermore, this cell-centric view establishes a clear statement of data continuity, providing confidence ahead of regulatory submission.



HISTORYTREE - a secure timeline showing a cell's journey through the cell line development process

Eliminate Transcription Errors

Because results, for example confluence, clonality and titer arrive from multiple sources and in multiple spreadsheets and various formats, the following questions arise:

"How do we quantify the inherent risk of error in our process?"

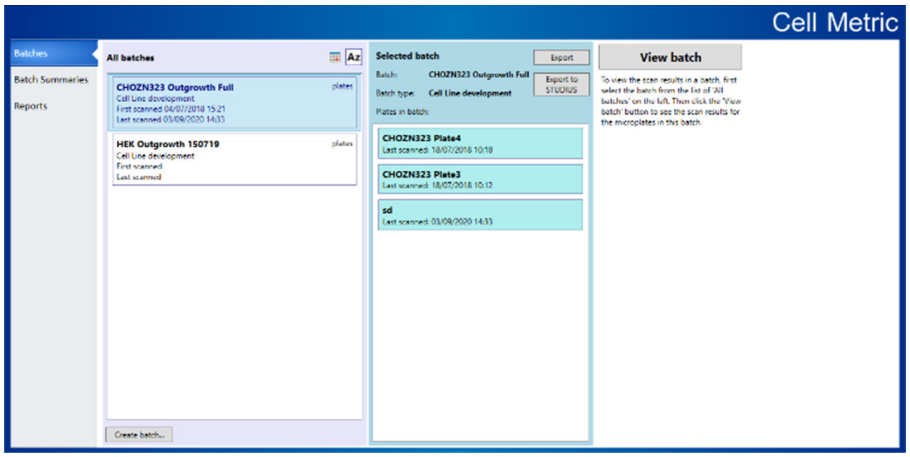
"How can we provide a secure audit trail for our selected clones?"

	A	C	D	E	F	G	H	I	J	L	M	N	O	P	Q	R	S	U	V	W	X	Y	Z	AA	AB
1		Viable Cell Density								Viability								IVCD							
2																									
3	clone	0	3	4	6	7	11	12	14	0	3	4	6	7	11	12	14	0	3	4	6	7	11	12	14
4	P6C4	0.75	8.74	16.4	17.5	21.7	14.8	16	3.26	98	100	99	95	92	86	84	15		14.2	26.8	60.7	80.3	153.3	168.7	188.0
5	P6D3	0.75	5.62	12.4	15.2	15.2	26.7	10.6	1.46	100	99	99	96	94	90	78	12		9.6	18.6	46.2	61.4	145.2	163.8	175.9
6	P6E3	0.75	8.34	17.2	13.2	12.3	8.98	13.3	2.97	99	99	99	93	97	75	75	26		13.6	26.4	56.8	69.6	112.1	123.3	139.5
7	P6E5	0.75	9.34	18.6	19.5	15.6	5.56	3.14	1.93	100	99	99	97	93	41	26	24		15.1	29.1	67.2	84.8	127.1	131.4	136.5
8	P6G6	0.75	9.08	14.1	18.3	16.1	6.31	3.3	1.57	98	99	98	93	89	42	24	14		14.7	26.3	58.7	75.9	120.8	125.6	130.4
9	P6G8	0.75	6.58	11.2	16.3	15.6	14.4	13	13.6	98	98	99	95	96	90	89	83		11.0	19.9	47.4	63.3	123.3	137.0	163.6
10	P7B5	0.75	8.17	12.7	14.5	14.1	16.2	32.2	1.46	100	99	99	96	98	85	91	8		13.4	23.8	51.0	65.3	125.9	150.1	183.8
11	P7B8	0.75	8.88	25.7	17.7	15.9	11.7	10.7	5.86	100	99	99	96	95	78	71	40		14.4	31.7	75.1	91.9	147.1	158.3	174.9
12	P7C5	0.75	0.146	0.157	0.209	3.98	3.14	0.314	0.22	93	67	83	71	86	77	77	50		1.3	1.5	1.9	4.0	18.2	19.9	20.5
13	P7B10	0.75	5.05	15.3	15.5	13.1	11.6	5.12	5.64	99	98	98	95	93	62	34	34		8.7	18.9	49.7	64.0	113.4	121.7	132.5
14	P7E10	0.75	8.83	22.4	15.7	16.2	7.53	5.31	2.6	99	100	99	91	91	51	45	32		14.4	30.0	68.1	84.0	131.5	137.9	145.8
15	P7F2	0.75	6.48	7.72	2.83	3.14	3.08	3.08	3.37	95	98	96	75	71	70	65	63		10.8	17.9	28.5	31.5	43.9	47.0	53.5
16	P7E3	0.75	3.9	5.81	3.85	3.29	3.7	4.99	2.38	100	96	96	84	72	69	83	36		7.0	11.8	21.5	25.1	39.0	43.4	50.8
17	P8C10	0.75	7.44	12.5	12.3	15.5	8.38	9.67	9.81	100	99	99	97	97	79	72	66		12.3	22.3	47.1	61.0	108.7	117.7	137.2
18	P8D8	0.75	4.97	17.8	15.8	15.3	10.7	7.31	9.01	98	100	99	96	97	84	83	83		8.6	20.0	53.6	69.1	121.1	130.1	146.4
19	P8F8	0.75	8.18	22.1	18.4	27.2	15.3	11.7	13.3	97	99	99	96	97	94	95	66		13.4	28.5	69.0	91.8	176.8	190.3	215.3

Visually comparing spreadsheets of results is laborious and error-prone.

The possibility for these types of errors restricts confidence in the process and may attract regulatory attention.

Selection of clones until now involved labor-intensive comparison of spreadsheets of results from different instruments in the CLD workflow. The analysis takes days, is error prone with no secure handover or audit trail for samples crossing between instruments. STUDIUS removes the risks inherent in visual comparison of large and complex datasets and the potential for the inconsistency of human operators to affect data interpretation.

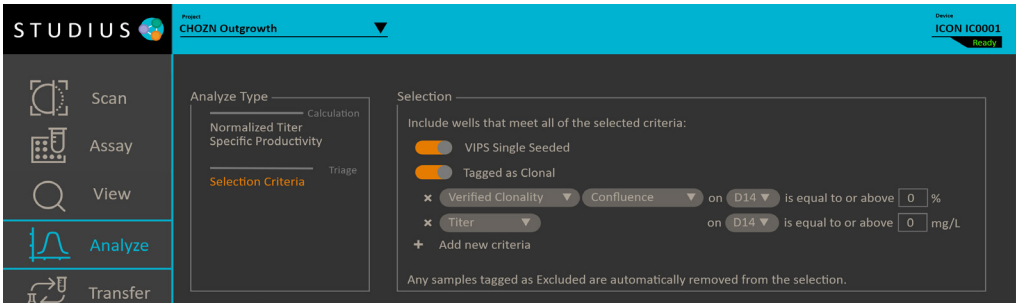


Cell Metric and VIPS results can be exported into STUDIUS and combined with ICON data.

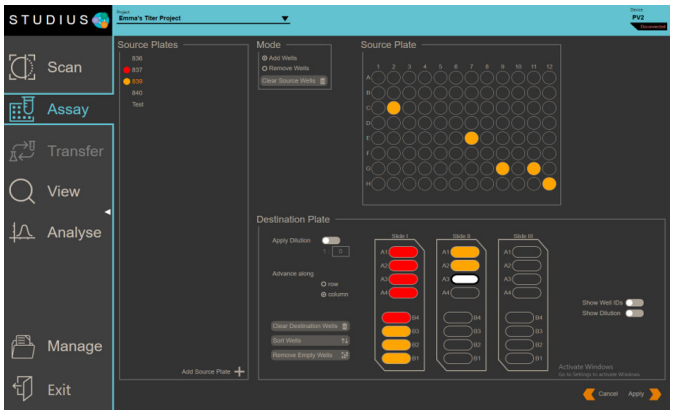
STUDIUS can combine titer and viable cell count data from ICON with clonality and confluence data from Cell Metric and/or VIPS to automatically and rapidly identify best performing clones without the need for user intervention

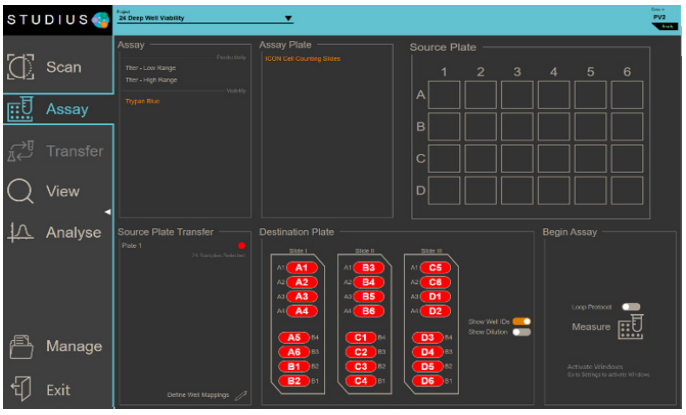
Analysis and Ranking of Best Performers in Minutes

In the STUDIUS powered ecosystem, ranking and decision-making are performed automatically and instantly, according to user-defined parameters. A process that previously took hours or days, repetitively comparing results in a variety of formats, is performed by the software to deliver ranking and selection of clones in minutes.

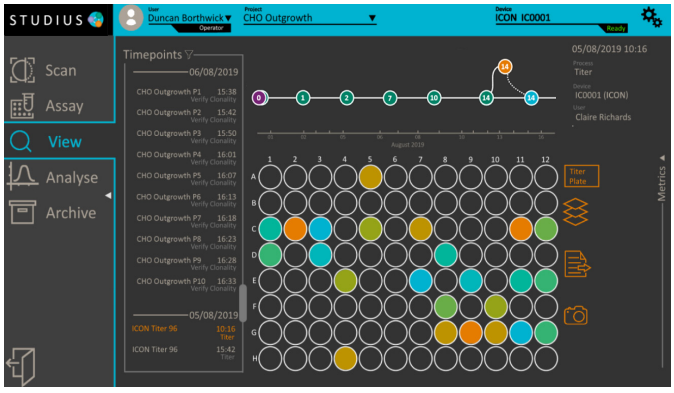


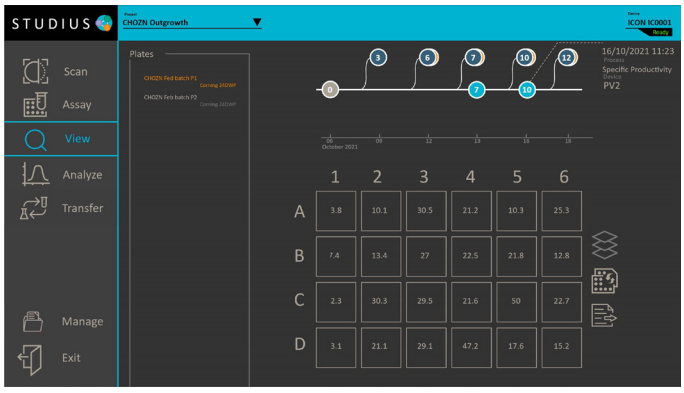
STUDIUS manages cell viability and titer results from the ICON and combines them with confluence and evidence of clonality data from Cell Metric and VIPS.



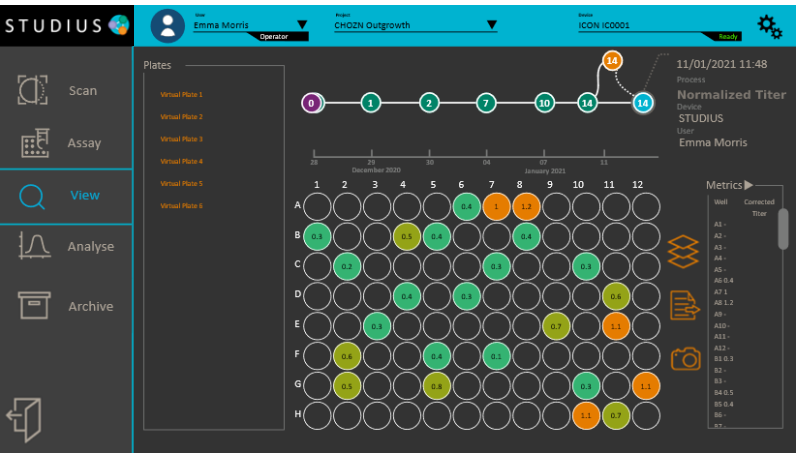


High outgrowth clones previously identified by Cell Metric or VIPS can be counted for suspension samples using the ICON's Trypan blue viability assay. STUDIUS tracks the samples from plate to counting slide and generates a secure audit trail linking the results.





The ICON IgG Titer assay can be combined with the results of the ICON viable cell count assay to generate a specific productivity value (Qp).

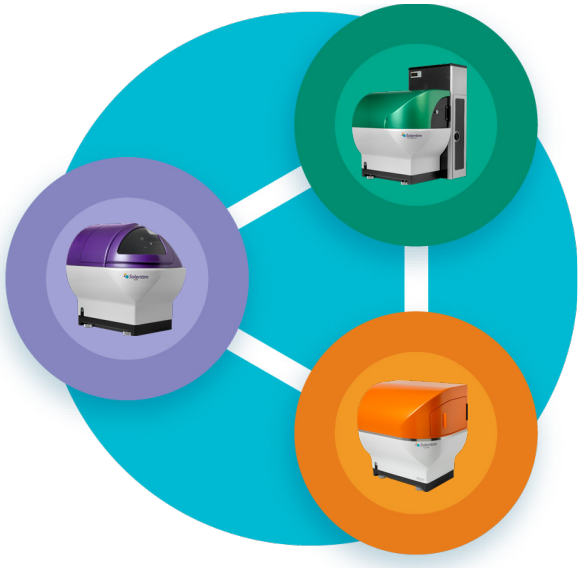


STUDIUS can perform calculations and hence transform results from the IgG Titer assay in the cloning plates by normalizing against Cell Metric confluency data or generating a specific cell productivity value using titer in the suspension culture plates and the ICON viable cell counting results.

Easily Satisfy Regulators

As the pressures for regulatory compliance grow, STUDIUS features such as a common database across CLD, audit trails and multi-level password protected user log-ins and access provide a toolkit to ensure compliance with 21 CFR part 11, Annex 11 and other guidelines are easier and less time-consuming.

Reporting is easy with automatically created reports for example, the Clonality Report is now created within STUDIUS.



STUDIUS is a single point for oversight of the entire cell line development process from single cell cloning to scale-down mini-bioreactor studies using user defined levels of clonality, outgrowth and productivity as selection criteria to rank the best performing clones in a fast, secure and consistent workflow.

The other components of the STUDIUS powered ecosystem complementing ICON include:

Cell Metric

A high contrast imager designed for single cell imaging, identification and clonal outgrowth characterization. Cell Metric captures and records crucial evidence of the whole well image of the single cell at day 0 and daily imaging after, all wrapped up in a clonality report which is the industry gold standard for documenting Master Cell Bank creation.

Available as a stand-alone single plate system or with automated plate handling within a temperature-controlled environment as the Cell Metric CLD, or downstream third-party robotic integration.

Cell Metric also integrates with your VIPS system via the Data Sync system for enhanced laboratory workflows.

Verified In-Situ Plate Seeding (VIPS)

Takes single cell cloning and image based clonality assurance to a whole new level of quality. The multi-tasking, compact instrument delivers a rock solid, 'double-lock' solution for regulatory submission.

VIPS accelerates projects. High seeding efficiency for both 96 and 384 well plates, single cloning round workflows for massively enhanced productivity and reduced timelines.

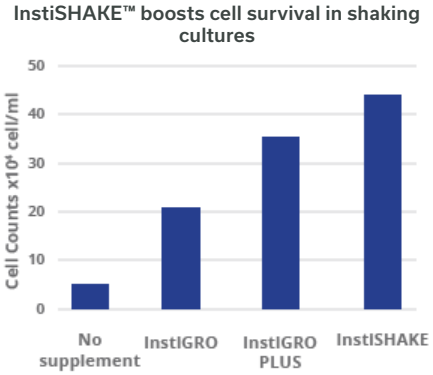
With VIPS, you get healthier cells, more confirmed single cells per plate and better outgrowth.

ICON

Uniquely combines titer, viable cell count and accurate productivity data using low volume assays on a single reader, with the clonality and confluence data from Cell Metric and/or VIPS to track and rank clones automatically, rapidly and consistently from the cloning plate, through fed-batch suspension shaking cultures to shake flask and multi-parallel mini bio-reactors such as Ambr, regardless of the different formats used and without the risk of error.

Growth Supplements

Solentim offers a range of advanced cell growth supplements for use with CHO cells. The Insti range of supplements is designed to enhance growth at different stages of cell line development for accelerated workflows: InstiGRO™ to assist with early cell growth and single cell survival in the cloning plates, InstiSHAKE™ to boost cell survival in shaking culture and InstiTHAW™ to protect cells during freezing and thawing for cell banking.



Impact of supplements when moving from 96 to 24 static wells at the day 15 cell count

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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Two Technology Way/ Norwood, Massachusetts 02062, USA

800-225-4034 | 781-320-9000 | www.aicompanies.com

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