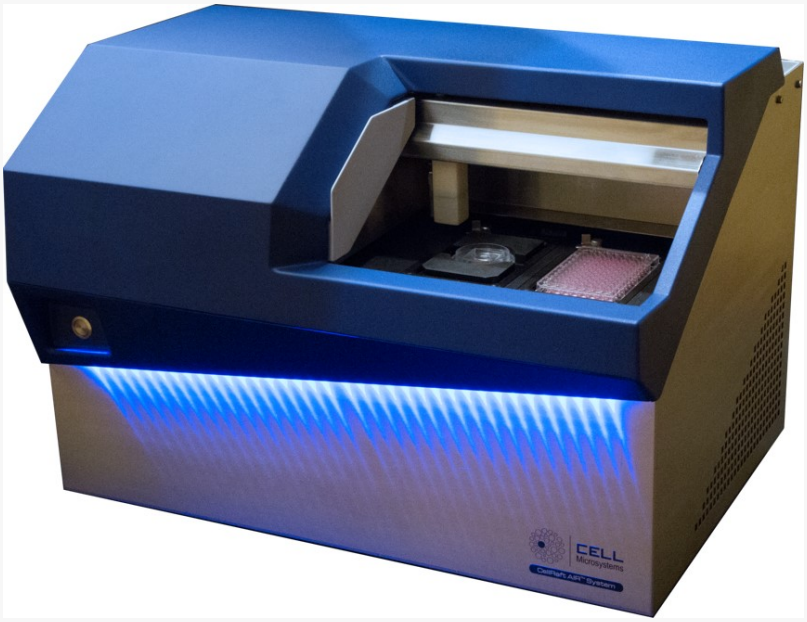
Cell Microsystems Launches Software Supporting 21 CFR Part 11 Compliance, Expanding CellRaft AIR to Regulated Workflows

Strengthens the CellRaft AIR with secure, traceable workflows and compliance-focused controls to help bridge discovery and regulated cell line development.



CellRaft AIR System

DURHAM, NC, UNITED STATES, July 15, 2026 /EINPresswire.com/ -- Cell Microsystems, a leader in cell line development instrumentation, today announced the launch of new software for the CellRaft® AIR System designed to support 21 CFR Part 11 compliance. The addition expands the platform from a powerful solution for discovery and cell line development into one capable of supporting regulated cell-based workflows.

As biopharmaceutical, cell therapy, and gene editing programs advance toward clinical and commercial milestones, development teams face rigorous demands for data integrity, traceability, and documentation. The new software provides current and future customers with compliance-focused workflow controls that support secure electronic records, audit trails, user accountability, and process transparency throughout cell line development.
Designed specifically for CellRaft AIR workflows, the software supports traceability from single-cell identification to clone selection, helping laboratories generate documentation to support quality and regulatory review while extending CellRaft AIR's proven cell isolation workflow into regulated development environments.

CellRaft AIR enables researchers to image, track, and isolate single cells and monoclonal colonies through a gentle, fluidics-free workflow. Unlike traditional approaches such as limiting dilution, FACS, or automated dispensing systems, CellRaft technology allows cells to remain in a shared-media culture environment during colony formation, reducing cellular stress and dramatically improving the success rate of monoclonal cell line development.

> Regulated cell line development workflows require more than high cloning efficiency—they demand trust in every data point and every decision"
>
> *Scott McGinnis, President*

The new software extends these core capabilities by providing a validation-ready framework for managing electronic records and workflow approval processes in regulated laboratories.

Key features include:

- Secure user authentication and role-based access controls
- Electronic signatures for workflow approvals and audit readiness
- Automated audit trails with time-stamped event logging
- Protected electronic records with controlled data access
- Improved traceability of clone selection and monoclonality documentation
- Data retention and reporting tools for quality and regulatory review

"Regulated cell line development workflows require more than high cloning efficiency—they demand trust in every data point and every decision," said Scott McGinnis, President of Cell Microsystems. "Our new compliance-focused software gives customers the ability to combine the biological advantages of CellRaft AIR with the compliance infrastructure needed for therapeutic development and manufacturing workflows."

The addition of compliance-focused software expands the role of CellRaft AIR in organizations developing:

- Monoclonal production cell lines
- Gene-edited therapeutic cell lines
- Cell therapy and CAR-T workflows
- iPSC-derived cellular products
- Rare or difficult-to-clone cell populations

By combining automated imaging, AI-assisted isolation verification, and secure, traceable workflow controls in a single platform, Cell Microsystems enables customers to move more seamlessly from research and discovery into regulated development environments. This release expands CellRaft AIR from a discovery and cell line development platform into a solution capable of supporting regulated cell-based workflows, helping organizations maintain confidence in clonality, cell health, and data integrity as programs advance toward therapeutic and commercial applications.

About Cell Microsystems

Cell Microsystems' transformative platforms for cell engineering, culture, and analysis empower research laboratories worldwide to unlock the full potential of their cells, making what was once impossible possible. Fueling progress in research and discovery, Cell Microsystems' product

range includes the CellRaft AIR System, which fosters the growth and verified isolation of healthy monoclonal colonies; the BioFlux Shear Flow Systems, which replicate in vivo conditions using physiological shear flow; the CERO 3D Cell Culture & Bioreactor for long-term organoid growth and 3D culture expansion; as well as comprehensive lab services and other innovative offerings.

For more information, visit cellmicrosystems.com/cellraft-air-systems/.

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