



Sterile Express Media Service

STERILE MEDIA MANUFACTURED IN AN ISO 5 ENVIRONMENT

The First Service of Its Kind for Tested *Sterile*, Non-GMP Media

Testing the feasibility of your cell culture media is crucial before scale-up. Express Media Service (EMS) from FUJIFILM Irvine Scientific meets this need by delivering small-scale, rapid production of non-GMP media in as little as 10 days. Now, take your test media a step further and ensure its sterility with **Sterile Express Media Service (SEMS)**, the first service of its kind for tested **sterile**, non-GMP media. Up to 100 L, flexibly and rapidly manufactured in a Grade A/ISO 5 environment, your media is shipped in as little as 15 business days.*

SEMS relies on isolator technology, paired with hydrogen peroxide vapor decontamination, to provide an aseptic manufacturing environment. Sterility testing, according to USP71 and ISO 13408 requirements, confirms sterility of the media for your pilot-scale applications.

Sterile non-GMP media provides an extra measure of control and security for valuable cells and helps streamline the successful development of cell and gene therapies and clinical drugs.

Our cell and gene therapy and biopharmaceutical customers prefer to use sterile media, rapidly formulated, to protect their valuable cells. Sterile Express Media Service makes this possible.

Kevin Kolell
Director of Global Marketing,
FUJIFILM Irvine Scientific

EMS Express Media Service	SEMS Sterile Express Media Service
<ul style="list-style-type: none">• Non-GMP• Small-scale• Production using GMP-qualified RMs• Sterile-filtered • 10-day turnaround	<ul style="list-style-type: none">• Non-GMP• Small-scale• Production using GMP-qualified RMs• Sterile-filtered • 15-day turnaround*• Sterility tested according to USP71 and ISO 13408



Sterile Express Media Service Features & Benefits

Feature	Benefits
Small-scale liquid formulations:	<ul style="list-style-type: none">• Sterile small lots and pilot-scale lots to test the feasibility of media during scale-up in applications that do not require GMP-grade media• Non-GMP, small-scale liquid formulations, manufactured using the same qualified raw materials used for GMP manufacturing• Batch size up to 100 L; standard as well as custom media packaging available to accommodate specific process requirements
Confirmed sterility:	<ul style="list-style-type: none">• Isolator technology provides an aseptic environment for media manufacturing• Media remains in a Grade A/ISO 5 environment throughout the manufacturing process, reducing risk for contamination of media for critical applications• Trial small volumes of sterile, non-GMP media for scale-up process, before progressing to higher volume requirements of GMP manufacturing• Media are released for rapid shipping pending sterility confirmation
Broad range of media support:	<ul style="list-style-type: none">• Manufacturing of customers' proprietary formulas, modified FUJIFILM Irvine Scientific formulas, and classical formulas with or without modifications
Extensive technical support from Manufacturing Support and Services:	<ul style="list-style-type: none">• Dedicated scientists provide formulation support based on 50 years of media experience• Access to experienced support team for formula review, optimization, and consultation ensures a smooth transfer to GMP manufacturing
Quality raw materials and technology:	<ul style="list-style-type: none">• Utilization of the same tested and qualified raw materials and milling technology used in our GMP manufacturing environment supports your small-scale media needs• Raw materials are monitored in accordance with ISO 13485:2016 standards and meet manufacturing Quality Assurance measures• Extra security during manufacturing through Environmental monitoring and 21 CFR-Part 11 compliant data logging
Quality Control testing:	<ul style="list-style-type: none">• Testing appearance, pH, and osmolality of products free of charge• Each lot of media is confirmed sterile according to USP71 and ISO 13408 requirements
Fast turnaround time:	<ul style="list-style-type: none">• Sterile media prototype can be manufactured and shipped in as little as 15 business days*

*Pending sterility confirmation.

Additional Services for Custom Media

Express Media Service

Rapid media solutions for every cell culture

Express Media Service (EMS) provides rapid, non-GMP media production to expedite time-to-market needs during scale-up. Media are manufactured using the same tested and qualified raw materials used in our GMP manufacturing, in as little as 10 business days.

Media Development and Optimization Services

Making media your own

When our dedicated scientific team develops custom media for your particular cell culture process, the result is a significant difference between “a medium” and “*your* medium.” Start with our Media Survey Panel and then customize your top performers, if desired, with one of our Media Development and Optimization options.

- **Media Survey Panel**

Working with our R&D scientists, you will screen a curated selection of growth and feed media in your lab. Promising media can be ordered through EMS or GMP for larger-scale cell culture, or they can be further optimized in a Media Optimization Panel or Complete Service MDO option.

- **Media Optimization Panel**

Media are developed in the FUJIFILM Irvine Scientific laboratory and then tested in your lab, with all the protocols, instructions, and consecutive new media iterations necessary to perform the cell culture experiments provided to you.

- **Complete Service**

Your cells and protocols are used in the FUJIFILM Irvine Scientific laboratory to develop and deliver a complete cell culture media solution that meets your specific process requirements, such as improved cell growth, maximal titer, or enhanced product quality.



Life.Support.

With over 50 years of industry experience, FUJIFILM Irvine Scientific is focused on providing the highest quality cell culture media. We are dedicated to bringing life to products, and ultimately, to the patients who benefit from the resulting therapeutic advances. World-renowned for our unwavering commitment to full-spectrum partnership, FUJIFILM Irvine Scientific has defined the industry standard in support, innovation, and best-in-class turnaround time.

Contact a Media Specialist today at getinfo@irvinesci.com to learn more about Sterile Express Media Service and our other cell culture media services.

FUJIFILM
Value from Innovation

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