



Make it *Your* Media

Media Development and Optimization

SOLUTIONS FOR BIOMANUFACTURING

Developing Custom Media Solutions for Biomanufacturing

Biotherapeutics change lives, and FUJIFILM Irvine Scientific helps make this possible by supporting countless innovators in the biopharmaceutical, vaccine, and gene therapy industries with the development and optimization of cell culture media solutions. We work collaboratively with you to discover, develop, and perfect media that maximize the potential of your cell line and protein/product performance, while delivering the service and support you expect from a leader in cell culture media.

Life-changing therapies are based upon the foundation of optimal cell culture media, and finding the right media solution starts with support from the R&D experts at FUJIFILM Irvine Scientific. As a leader in cell culture media manufacturing since 1970, we understand how to help you create a custom media solution and bring it full-scale for commercialization. Off-the-shelf products serve as an excellent starting point. However, optimized custom formulations can further elevate your specific cell line and process by achieving higher titers and improved product quality.



Support at Every Step

FUJIFILM Irvine Scientific is ready to partner with you every step of the way, from the moment that you request a Media Survey Panel, through development, and into bioproduction. Our experts personally select your Media Survey Panel, so that the development process starts with a refined, more focused level and achieves the results you need sooner. Our partnership with you is based on support from our sales team, assistance from our field application scientists, and collaboration with the scientists in R&D.

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

Media Survey Panel

Maximize Cell Line Potential

Discovering the optimal cell culture solution begins with evaluating a curated Media Survey Panel from FUJIFILM Irvine Scientific. Each Media Survey Panel features a diverse selection of off-the-shelf, made-to-order, and cGMP-ready media samples, customized for your cell line and application, as well as the protocols necessary to maximize performance. All of our media are formulated for scalability, quality, and process consistency—this is where the development of custom media begins.

- **Unparalleled support.** Partner with your dedicated FUJIFILM Irvine Scientific team to access unrivaled cell culture expertise and an extensive media library based on more than 45 years of research and development.
- **Clear, concise plan of action.** Customized, comprehensive protocols to evaluate your custom media panel for improved growth, productivity, and quality.
- **Spectrum of quality, proven media.** Selection of different media formulations developed for a wide range of cell lines, based on your capacity and application.
- **Rapid turnaround time.** Panels shipped to you in as little as 10 business days—one of the fastest turnaround times in the industry.



Custom Media Development

Making Media Your Own

Custom media development services start with a promising formulation, for example from your Media Survey Panel or based on a catalog medium, and modify it for your particular needs. Support from our highly qualified technical team within R&D makes all the difference between “a medium” and “your medium.”

Media Development Services

Once you have identified a promising medium, we develop it further via our Media Development and Optimization (MDO) Services. Depending on your available time, instrumentation, and personnel, you may proceed with either a Media Optimization Panel or Complete Service MDO option to develop your new media.

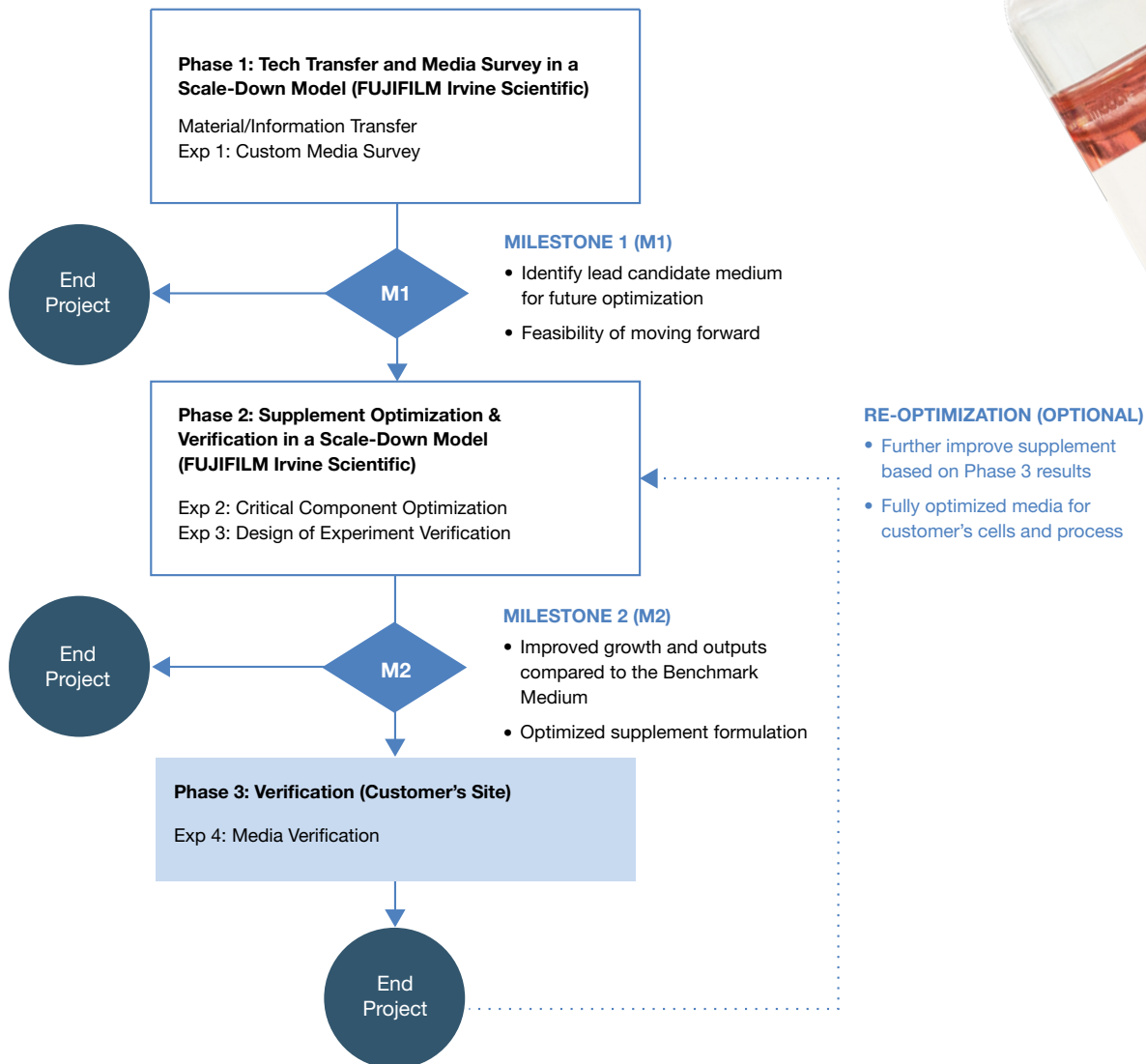
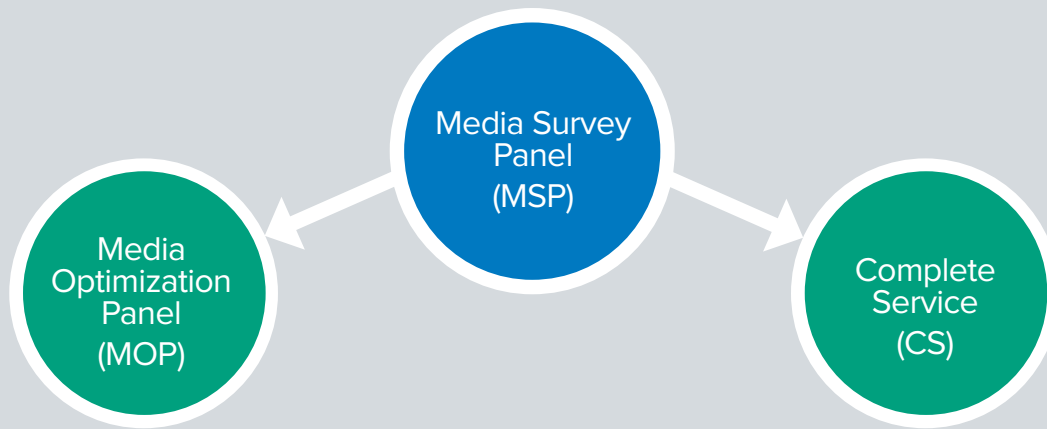


Figure 1. Example of a project flow chart.



Media Optimization Panel (MOP)

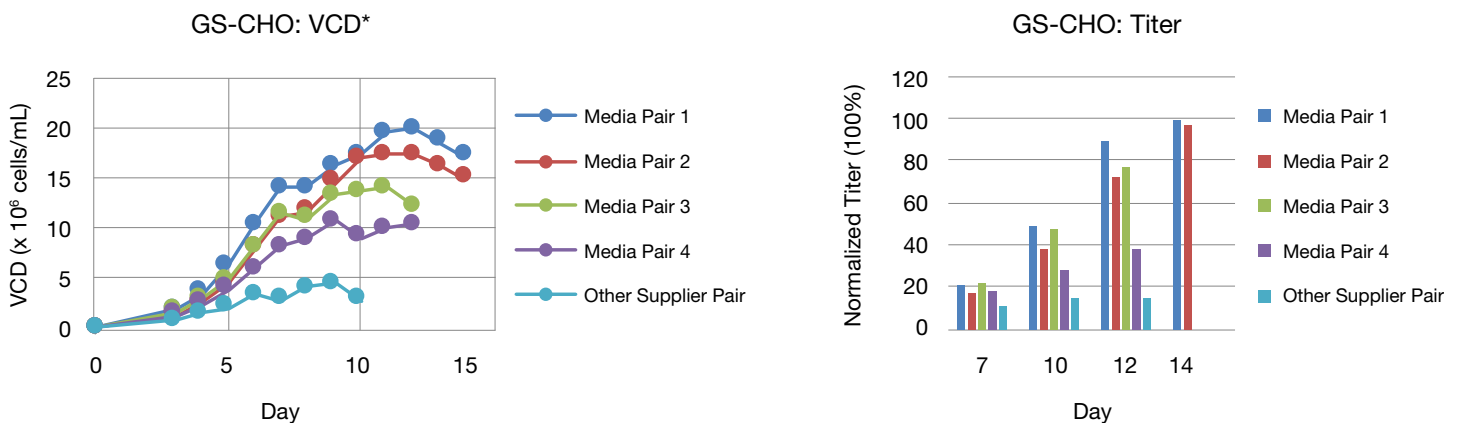
Your project is conducted within your laboratory, with protocols, instructions, and the custom media necessary to perform the cell culture experiments provided by FUJIFILM Irvine Scientific. With each MOP, we design the experiments, send the custom media panel, analyze the results, and manage the timeline while you control the speed of development.

Complete Service (CS)

Your project is conducted within FUJIFILM Irvine Scientific's laboratories to develop and deliver a cell culture media solution that meets your specific process requirements, such as improved cell growth, maximal titer, and desired product quality.

With a Complete Service MDO, we are able to deliver the most improvement in a shorter amount of time than with MOP, since all of the work is performed in-house at FUJIFILM Irvine Scientific. You may halt the optimization process at any time that satisfactory results are achieved.

Custom Media: One Size Does *Not* Fit All



*Cultures were terminated when viability reached below 75%

Figure 2. A Media Survey Panel consisting of 4 FUJIFILM Irvine Scientific media pairs (growth and feed media) and one commercial supplier pair were assayed with GS-CHO cells expressing a monoclonal antibody. Viable cell density (VCD) was compared. GS-CHO cells were seeded at 0.3×10^6 cells/mL and cultured for up to 14 days.

Cells were fed 4% of the total working volume per day on days 3-7 for a total of 20%. Commercially available growth and feed media (Other Supplier Pair) were obtained and fed at the supplier's recommended concentration and method.

Custom Media Developed to Meet Every Need

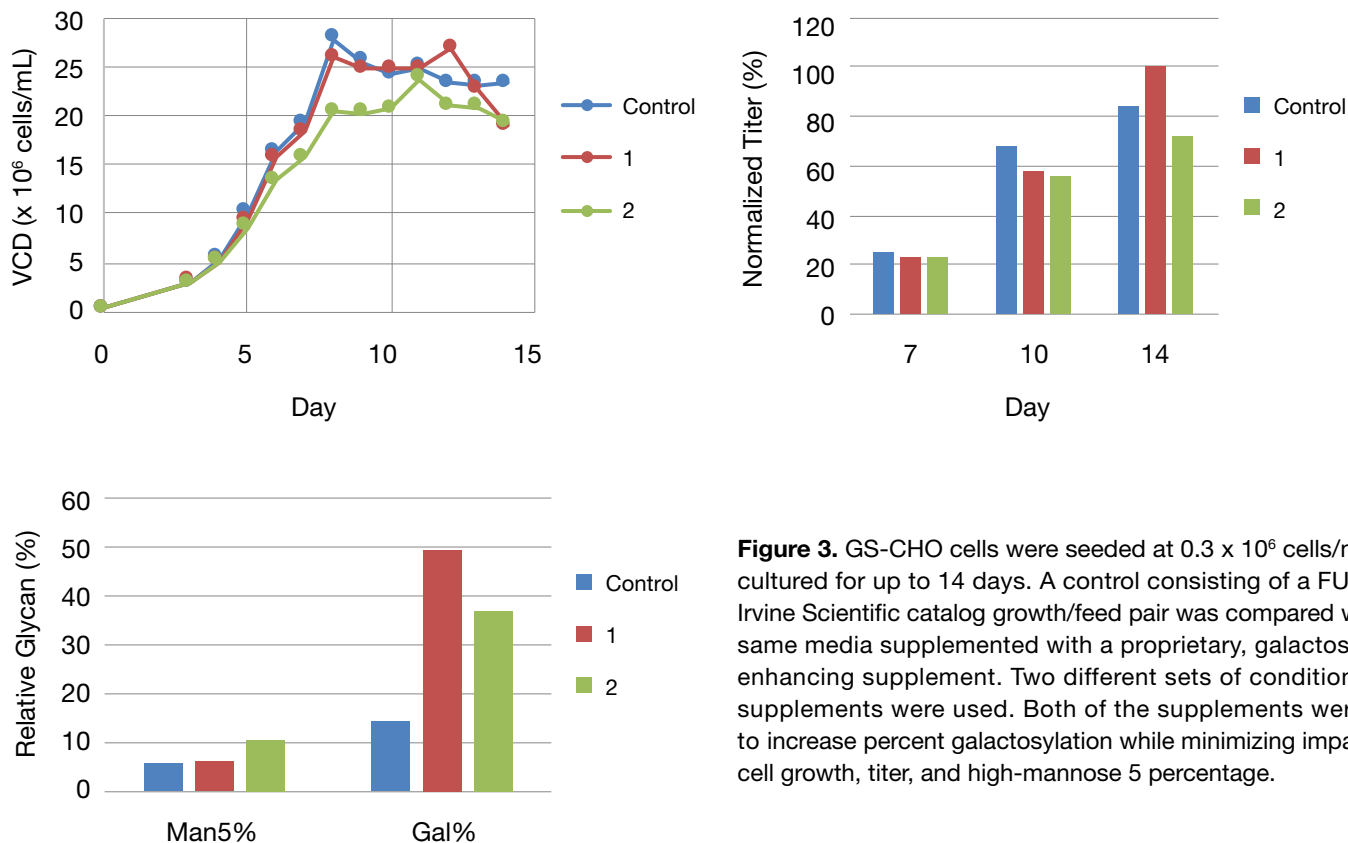


Figure 3. GS-CHO cells were seeded at 0.3×10^6 cells/mL and cultured for up to 14 days. A control consisting of a FUJIFILM Irvine Scientific catalog growth/feed pair was compared with the same media supplemented with a proprietary, galactosylation-enhancing supplement. Two different sets of conditions and supplements were used. Both of the supplements were able to increase percent galactosylation while minimizing impacts on cell growth, titer, and high-mannose 5 percentage.

Analysis Options to Enhance Media Development

FUJIFILM Irvine Scientific offers a full complement of analysis options. Data generated by our R&D and Quality Control (QC) departments optimize your cell culture process in order to achieve the best quality and quantity for your biologics.

Spent Media Analysis (SMA)

In-house testing of nutrients/metabolites, amino acids, and water-soluble vitamins. Qualified partner labs for testing of lipids and metals. Optimization of media development based on data from SMA.

Stability Studies

Expiration dates, in-use stability, and freeze/thaw studies performed in-house with customized protocols, for a range of testing requirements and time points. Media quality can be assessed with higher accuracy when based upon stability studies.

Setting Specifications

QC studies to analyze pH and osmolality ranges as well as other parameters upon which to base release criteria during GMP production.

Pilot Lots

Non-GMP manufacturing of test and pilot lots of custom media to provide insight and assurance before scale-up.

Express Media Service

Advanced Media Solutions for Every Cell Line

Our Express Media Service (EMS) provides rapid, flexible, small-scale media production to expedite time-to-market needs. Customer-developed formulas and modified classical formulas are manufactured in a non-GMP environment using cGMP-grade raw materials, in as little as 10 business days. Express Media Service can also serve to manufacture small lots and pilot scale lots of media to test the feasibility of scale-up.

Distinctive and Diverse EMS Benefits

Small-scale liquid and powder formulations

Simplification of scale-down modeling and small-scale process development with small lot sizes (10 L to 200 L for liquids, 1 kg to 18 kg for powders) and small pack sizes prior to scale-up.

Broad range of media support

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

Access to our experienced Manufacturing Support and Services team for formula review, optimization, and consultation simplifies the technology transition from research to commercialization.

Quality raw materials and technology

Utilization of cGMP-quality raw materials and the same milling technology used in our cGMP manufacturing environment supports your small-scale media needs.

Quality-control testing

Testing appearance, pH, and osmolality of products by request, free of charge.

One of the fastest turnaround times in the industry

Feasible media prototype can be manufactured and shipped in as little as 10 business days of customer approval and receipt of PO.



Flexible Solutions to Suit All Applications

FUJIFILM Irvine Scientific offers an array of solutions to help you achieve the best media for your application. From custom powders and liquids, to buffers and water-for-injection (WFI), we provide what you need to accomplish your goals.

Custom cGMP Liquids and Powders

Our world-class cGMP facilities offer flexible production capacity to provide you with a rapid, uninterrupted supply of custom liquid and powder media within a six- to eight-week timeframe.*

- Liquid media—100 L to 10,000 L production capacity
- Powder media—10 kg to 7,000 kg production capacity

Custom Buffers

Designated animal component-free (ACF) cGMP buffer manufacturing.

- Liquid batch sizes from 50 L to 10,000 L (standard buffers)
- Customized fill volumes and bioprocess container (BPC) options to meet your process requirements
- Industry-leading turnaround times

*Time frames may vary depending on individual customer requirements.

Water for Injection (WFI) Quality Water

- Meets or exceeds testing requirements for Sterile Water-for-injection stated in current USP, PhEur, and JP guidelines
- Pretreatment system, vapor compression still, and WFI distribution loop
- Tested for toxicity and cytopathic effects on cell growth, and includes CoA
- Off-the-shelf sizes range from 1 L to 200 L, or custom BPCs up to 500 L

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Life.Support.

With over 45 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.

FUJIFILM
Value from Innovation

 IrvineScientific