

INTERVIEW

Finding a happy medium: meeting the rising demand for bioproduction media



MARLIN FRECHETTE has over 30 years of experience in the medical device industry, servicing pharmaceutical and biopharmaceutical customers. As Chief Quality and Compliance Officer at FUJIFILM Irvine Scientific, she holds global responsibility for all FUJIFILM Irvine Scientific sites and affiliates for Compliance, Quality Systems, Global Regulatory, and EHS. She holds a Bachelor's of Science with a major in Business Administration and Personnel Management.

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Recent years have seen shortages of raw materials across the biopharmaceutical industry, including critical components of cell culture media. Here, Marlin Frechette, Chief Quality and Compliance Officer and ISO Management Representative, FUJIFILM Irvine Scientific, shares how the global supplier is adapting to meet the needs of its customers.

Q How is the demand for media for bioproduction evolving worldwide and how are you meeting the needs of this global sector?

MF: With the high rate of growth in the biopharmaceutical market, and pharmaceutical drugs and vaccines moving into clinical trials and commercialization at a fast pace, our customers require full support as their products advance through

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regulatory approvals. To address these needs, FUJIFILM Irvine Scientific utilizes a global forecasting strategy that incorporates flexibility and consistency while keeping apprised of trends in supply interruptions or bottlenecks to support growth. We also hold Drug Master Files (DMF) for our media products in many parts of the world, stay apprised of global regulations for raw materials and components in each country, and communicate directly with authorities during

customer file reviews to answer questions regarding media or raw materials.

To meet the increasing customer production and reliable, regional supply needs, we have built a world-class cGMP manufacturing facility in Europe. The facility encompasses 245,428 square feet of space and increases production capacity by 320,000 kg/year of powder and 470,000 L/year of liquids. The new European site will follow the same certified Quality System as our locations in the US and Japan and includes sustainable initiatives important to FUJIFILM Irvine Scientific and our customers, such as reducing manufacturing water usage, using a membrane bioreactor for wastewater purification, and windmill-powered electricity.

Q What are FUJIFILM Irvine Scientific's procedures for the qualification of raw materials for media?

MF: To guarantee ultimate safety, consistency, and effectiveness of the cell culture media, FUJIFILM Irvine Scientific has a robust and stringent supplier and raw material qualification and maintenance program. A risk-based approach is used during the qualification process to remove and minimize the potential risks associated with materials used. Once a supplier is qualified, the raw material documentation such as Certificate of Analysis, TSE/BSE statements (to confirm components are free from human- or animal-derived materials), and other relevant documentation are evaluated. We then audit the manufacturing site, production history, and the supplier quality system. Once we receive a new raw material, samples are evaluated and tested in three separate manufacturing lots and processed through our Quality System. The decision to qualify a material for use or not takes all of these actions into account.

Q What is your approach to ensuring continuity of supply?

MF: To secure our supply chain, FUJIFILM Irvine Scientific utilizes multiple risk mitigation strategies, continuous improvement, and custom management as fundamental principles of excellence. We strive to ensure continuity of supply through robust supply agreements with terms and conditions that protect us, as the customer, should a

supplier divest or close their business. These contracts also provide us with the right to procure materials up to a certain point in time – typically nine months to a year – until we find an alternative source.

The facility in Tilburg, Netherlands, further solidifies continuity of supply for our European manufacturers. Providing customers with our products from a local source enables FUJIFILM Irvine Scientific to reduce time-to-market and helps to lower drug manufacturing costs. The new facility will use the same raw materials, equipment, and certified Quality System as our locations in the US and Japan, with the consistency of finished goods assured by our standardized raw materials program, equipment validation, adherence to SOPs, and environmental monitoring.

AFFILIATION

Marlin Frechette

Chief Quality & Compliance Officer (CQO), FUJIFILM Irvine Scientific

AUTHORSHIP & CONFLICT OF INTEREST

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Local Supply.
Global Partnership.

Timelines Change. Flexibility is a Must. Local Supply Chain Access is Critical.

Solid, local manufacturing delivers uninterrupted supply

The new FUJIFILM Irvine Scientific facility in Tilburg, Netherlands, is your local supply chain solution for cell culture media. Now our expertise, flexibility, industry-leading turnaround times, robust raw materials program, and best-in-class Quality System are coming to Europe in 2021.

Collaborative partnership for best-in-class manufacturing

We become an extension of your supply chain to provide you with advanced cell culture solutions including media products, services, and technologies for bioprocessing and cell and gene therapy. Our capabilities, expertise, and support help your life-saving medicines and therapies get to market.

Exceptional customer service and faster response times

FUJIFILM Irvine Scientific is your trusted and responsive local advisor. We are here when you need us with a dedicated team of media manufacturing experts ready to support you.